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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jeffrey Stein, M.D.; Decision and Order

On February 26, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Jeffrey Stein, M.D. (hereinafter, Respondent) of New York, NY. OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. FS6587868 on the ground that Respondent was "mandatorily excluded . . . from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of ten years pursuant to 42 U.S.C. 1320a-7(a)"; and that such exclusion "warrants revocation of [Respondent's] registration pursuant to 21 U.S.C. 824(a)(5)." *Id.* at 2.

Specifically, the OSC alleged that, on July 31, 2015, the United States District Court for the Southern District of New York (hereinafter, SDNY) issued a judgment against Respondent "based on [Respondent's] guilty plea to 'Corruptly Endeavoring to Obstruct and Impede the Due Administration of the Internal Revenue Laws' in violation of 26 U.S.C. 7212(a) and 'Tax Evasion' in violation of 26 U.S.C. 7201. *U.S. v. Jeffrey S. Stein*, No. 1:15CR00195-01(DLC) (S.D.N.Y. filed July 31, 2015)." OSC, at 2. The OSC further alleged that "based on [such] conviction, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS/OIG"), by letter dated December 29, 2017, mandatorily excluded [Respondent] from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of ten years pursuant to 42 U.S.C. 1320a-7(a), effective January 18, 2018." *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

The record includes a Form DEA-12 (8-02) "Receipt for Cash or Other Items," dated February 28, 2019, which indicates that the OSC was provided to Respondent and the form is signed by "Jeffrey Stein." Request for Final Agency Action (hereinafter, RFAA) Ex. 6.

By letter dated March 21, 2019, Respondent submitted a written statement (hereinafter, Respondent Statement) in response to the OSC, in which he "waive[d] a hearing and submit[ted a] written statement regarding [his] position on the matters of fact and law involved in this matter." RFAA Ex. 7 (Respondent Statement), at 1.

On May 31, 2019, the Government submitted an RFAA, in which it argued, among other things, that "Section 824(a)(5) should be read as requiring revocation of a respondent's DEA certificate of registration, upon an adequate showing of the factual predicate, at least for the duration of the mandatory exclusion." RFAA, at 4.

I issue this Decision and Order based on the record and brief submitted by the Government in the RFAA and the Respondent Statement, which constitute the entire record before me. 21 CFR 1301.43(e).

FINDINGS OF FACT

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. FS6587868 at the registered address of 1385 York Avenue, Suite 3B, New York, NY 10021-3911. RFAA Ex.1

(Certificate of Registration History), at 1. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Respondent's registration expires on February 29, 2020, and currently is "in an active pending status." *Id.*

Respondent's Exclusion

The evidence in the record demonstrates that judgment was entered following a guilty plea on July 31, 2015, in the SDNY by Respondent for "'Corruptly Endeavoring to Obstruct and Impede the Due Administration of the Internal Revenue Laws' in violation of 26 U.S.C. 7212(a) and 'Tax Evasion' in violation of 26 U.S.C. 7210. *U.S. v. Jeffrey Stein*, No. 1:15CR00195-01(DLC) (S.D.N.Y. filed July 31, 2015)." RFAA, at 3; *see also* RFAA Ex. 4 (Judgment). Respondent pled guilty to both counts of criminal violations of the Internal Revenue Code listed in the Information. RFAA Ex. 4, at 1. The first count alleged that Respondent and his wife "provided various false and fictitious information to [his] Accountant in order to fraudulently reduce the amount of taxes they would have to pay to the IRS." RFAA Ex. 3 (Information), at 4. Further, after notification by the Internal Revenue Service (hereinafter, IRS) of an audit, Respondent and his wife, "created and provided to the Accountant various fabricated and fictitious documents and information as part of a corrupt effort to convince the IRS Auditor that the expenses claimed . . . were legitimate." *Id.* at 7. The Information additionally alleged that Respondent, "[u]sing the names of four disabled military veterans (including two former patients) whose identities he obtained as a result of his work for the V.A., . . . created bogus invoices in the names of those veterans." *Id.*

By letter dated December 29, 2017, the HHS OIG notified Respondent of his exclusion from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a-7(a) for a minimum period of ten years based on Respondent's felony convictions in SDNY. RFAA Ex. 5

(hereinafter, Exclusion Letter), at 1. The Exclusion Letter stated that the exclusion would become effective twenty days from the date of the letter, or January 18, 2018,[1] and notified Respondent of his appeal rights. *Id.* at 1-2.

Respondent admits to the guilty plea and to the HHS exclusion; however, he asserts that he appealed and that an HHS Administrative Law Judge sustained the exclusion, but reduced the period of exclusion to eight years "based on the I.G. having issued an amended exclusion letter removing 42 CFR 1001.102(b)(9) as an aggravating factor and adjusting the term of exclusion from ten to eight years." Respondent Statement, at 2.

Respondent included the HHS Administrative Law Judge's decision citation in his written statement. *Id.* at 2. The ALJ issued an opinion on August 3, 2018, upholding Respondent's exclusion and reducing it.[2] In particular, she found that his crimes were committed in connection with the delivery of a health care item or service to warrant mandatory exclusion because:

> Petitioner abused his position by appropriating the personal information of four veterans (including two individuals to whom he had provided health care services) to further his tax evasion scheme. Petitioner would not have been in a position to misuse the veterans' personal information had he not been part of the chain of delivery of V.A. health care benefits.

Jeffrey S. Stein, M.D., Department Appeals Board No. CR5153, at 5 (2018) (*available at*: https://www.hhs.gov/about/agencies/dab/decisions/alj-decisions/2018/alj-cr5153/index.html) (hereinafter HHS Appeals Board). The ALJ further found that:

[1] The date of exclusion is 20 days from the date of the letter. RFAA Ex. 5, at 1.

[2] I believe that it is appropriate to take note of the full contents of this decision, as it was referenced on page 2 of Respondent's Statement. *See, e.g.*, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 568 n.13 (2007) (stating that courts may "take notice of the full contents" of published documents "referenced in the complaint" (citing Fed. R. Evid. 201)).

> Petitioner used patient information, to which he had access based on his position of trust as a V.A. physician, to create fraudulent invoices in an attempt to cover up his income tax evasion . . . . These factors underscore the seriousness of his dishonest scheme. It is not unreasonable to infer . . . that he may pose a risk to the integrity of patient data systems.

Id. at 6.

Respondent asserts that "the two counts to which [he] pled guilty . . . pertained solely to [his] personal income tax statements" and that "[t]here were never any allegations of impropriety with respect to my medical practice or the furnishing of or billing for medical care, services or supplies." Respondent Statement, at 2. Additionally, Respondent states that "full restitution of all taxes owed to the Federal government was made before the date of [his] sentencing"[3] and he has "completed serving [his] sentence of 18 months and [he is] now once again a law-abiding person who continues to contribute to the well being of [his] community." *Id.*

Respondent submitted evidence related to the temporary suspension of his medical license in New York and subsequent censure, reprimand, and reinstatement by the Department of Health State Board for Professional Medical Conduct (hereinafter, BPMC) through a Hearing Committee (hereinafter, Committee) Determination and Order, dated December 15, 2016. Respondent Statement Ex. 2; *see also* Respondent Statement, at 3.

The BPMC Committee based its decision on several factors. "Importantly, Respondent's crimes did not affect his clinical competence or quality of patient care. The Committee did not feel that [he] was a threat to the public. Moreover, the Committee acknowledged an exemplary surgical career and stable family life." Respondent Statement Ex. 2 (BPMC Hearing Committee Determination and Order), at 3. The Committee further cited to seventeen letters, which "described Respondent as a talented, compassionate physician and trustworthy person." *Id.*

[3] Respondent appended to his Respondent Statement a Satisfaction of Judgment demonstrating that his restitution was satisfied. Respondent Statement Ex. 1 (Satisfaction of Judgment), at 1.

Respondent additionally testified in front of the Committee, during which "the Committee learned of [his] genuine connection to his patients" and noted that it "appreciated [his] sincere sense of remorse and repentance for his actions. Respondent accepted full responsibility for his conduct and the Committee felt that he has learned from his mistakes." *Id*.

In sum, based on all of the evidence in the record, I find that the HHS OIG excluded Respondent from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a-7(a) for eight years effective January 18, 2018, based on Respondent's conviction of two federal income tax-related felonies in the SDNY.

DISCUSSION

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration "may be suspended or revoked" upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant "has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42." *Id.* 42 U.S.C. 1320a-7(a) provides a list of four predicate offenses for which exclusion from Medicare, Medicaid and federal health care programs is mandatory and sets out mandatory timeframes for such exclusion. *Id.* Respondent admits that the HHS OIG mandatorily excluded him and, as such, there is no dispute in the record about this fact. Respondent Statement, at 2; *see also* RFAA, at Ex. 5.

In pursuing revocation or suspension of Respondent's registration, the Government makes no argument on the merits of Respondent's mitigating evidence, but elects to make a legal argument that, instead of reviewing Respondent's individual circumstances, the Agency should read 21 U.S.C. 824(a)(5) to *require* revocation as long as the basis for revocation—here,

exclusion from federal health care programs—is adequately shown. RFAA, at 4. In making this argument, the Government seems to be relying on two notions:

1. That "the best reading of the statutory language in 21 U.S.C. 824(a)(5) and 42 U.S.C. 1320a-7(a) recognizes that Congress intended to carve out a specific set of circumstances (*i.e.*, a criminal conviction for a specific set of crimes) that it found particularly serious. Therefore, . . . Section 824(a)(5) should be read as requiring revocation." *Id*.

2. That, due to what the Government perceives as the Agency's inconsistency in evaluating revocations under Section 824(a)(5), particularly where the predicate crime has no nexus to controlled substances, the Agency should instead summarily revoke or suspend all registrants who have been excluded from federal health care programs for, at least, the duration of the exclusion. *Id.* at 6-9.

I will address each of these issues separately prior to addressing the facts I found.

1. The Government Has Not Provided a Reasonable Interpretation of the CSA as Mandating Suspension or Revocation Under Section 824(a)(5).

The Government's argument in proffering what it deems the "best reading" of the CSA is that in mandating exclusion from federal health care programs for certain predicate crimes in Section 1320a-7(a) of Title 42, Congress intended to carve out a particular set of crimes that it found particularly serious. RFAA, at 4. However, no further support for this reading of the statute is offered.

Such a reading would be a significant departure from past Agency decisions. Notably, in *Dinorah Drug Store, Inc.*, 61 Fed. Reg. 15,972, 15,974 (1996), "the Deputy Administrator agree[d] with Judge Tenney's conclusion that the denial of registration under Section 824(a)(5) is discretionary." Furthermore, the Government has not cited to, nor has there been, another

mandatory exclusion case that has held that I must revoke or suspend on the basis of the mere finding of a mandatory exclusion under 42 U.S.C. 1320a-7(a), as is demonstrated by the fact that cases on this section have carefully considered mitigating evidence provided by the respondent. *See, e.g.*, *Mohammad Asgar, M.D.*, 83 Fed. Reg. 29,569 (2018); *George D. Osafo, M.D.*, 58 Fed. Reg. 37,508 (1993).

The Government correctly notes, however, that under the third of the five grounds for revocation or suspension in Section 824(a), the Agency interprets the statute to require revocation or suspension once there is a conclusive finding that the registrant lacks authority to practice medicine and dispense controlled substances in the state of registration. 21 U.S.C. 824(a)(3). This procedure is unique amongst the five grounds listed in Section 824(a) and is rooted in two provisions of the CSA. The two provisions, when read together, lead to the ineluctable conclusion that the CSA leaves the decision maker no discretion as to sanction when such lack of authority is established. 21 U.S.C. 802(21) (defining "practitioner" to require a license to dispense controlled substances in the state of registration) and 21 U.S.C. 823(f) (establishing authorization to dispense controlled substances as a prerequisite for the issuance of a registration); *see, e.g.*, *James L. Hooper, M.D.*, 76 Fed. Reg. 71,371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 Fed. Reg. 27,616 (1978).

Unlike Section 824(a)(3), the Government has proffered no reasonable statutory basis in the CSA, or otherwise, to read 824(a)(5) to require automatic revocation if a practitioner has been mandatorily excluded from Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a-7(a). The Government implies that the mandatory nature of the statute that controls the HHS Secretary in excluding an individual from participation in any

federal health care program also negates the discretion of the Attorney General in applying the CSA. RFAA, at 10. However, in arguing this interpretation of the CSA, the Government would have to demonstrate that the interpretation is not "in excess of statutory jurisdiction, authority, or limitations or short of statutory right." 5 U.S.C. 706(2)(C). In order for the Agency to support such a reading, the Government would at the very least have to demonstrate that the statute is ambiguous and that the interpretation "is based on a permissible construction of the statute." *Chevron U.S.A. v. Nat. Resources Def. Council*, 467 U.S. 837, 843 (1984).

The Medicare and Medicaid Patient and Program Protection Act of 1987 (hereinafter, Medicare Protection Act) enacted the mandatory and permissive exclusions in question and also simultaneously added Section 824(a)(5) into the CSA. Medicare Protection Act, Public Law 100-93, § 8(j), 101 Stat. 680, 695 (1987). Notably, and as mentioned previously, Section 824(a) of the CSA uses the term "may" when prefacing the five grounds, including the ground in question, upon which "a registration … *may* be suspended or revoked." 21 U.S.C. 824(a) (emphasis added). "Interpretation of a statute must begin with the statute's language." *Mallard v. U.S. Dist. Court*, 490 U.S. 296, 300-301 (1989) *(*citing *e.g.*, *United States v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241 (1989); *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 685 (1985)). Further, the "cardinal principle of statutory construction [is] that courts must give effect, if possible, to every clause and word of a statute." *Williams v. Taylor*, 533 U.S. 167, 174; *see also Duncan v. Walker*, 533 U.S. 167, 173 (2001). In general, "the word 'may,' when used in a statute, usually implies some degree of discretion." *United States v. Rodgers*, 461 U.S. 677, 706 (1983). Although, it should be observed that that longstanding canon of statutory construction "can be defeated by indications of legislative intent to the contrary or by obvious inferences from the structure and purpose of the statute." *Id.* (citing *Mason v. Fearson*, 50 U.S.

248 (1850); *see generally United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359–360 (1895)). Unlike the Agency's interpretation of Section 824(a)(3), here the Government has not offered any other statutory indication or legislative intent that the term "may" should be read differently under the provision in question.

Furthermore, in passing the Medicare Protection Act, Congress clearly demonstrated that it knew how to differentiate between mandatory and permissive exclusions, because it did so unequivocally in the context of federal health care programs. In lieu of using the same clear language for the provision regarding controlled substance registrations, Congress chose to place this ground for revocation or suspension under the "may" provisions in Section 824. *See Duncan v. Walker*, 533 U.S. 167, 173 (2001) (holding that "it is well settled that "'[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'"" (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)); *see also Bates v. United States*, 522 U.S. 23, 29–30 (1997).

Additionally, there is no further indication from legislative history that Congress intended to require automatic revocation or suspension in the context of the CSA on the grounds of exclusion. Congress amended Section 304 of the CSA to "add exclusion from Medicare or a State health care program as a basis for denial, revocation, or suspension of registration to manufacture, distribute or dispense a controlled substance." S. REP. NO. 100-109, at 22 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 682, 702; *see also* H.R. REP. NO. 100-85, pt. 1, at 21 (1987). Although the phrase "as a basis for" could be read to be mandatory or permissive, there is no clear indication of a mandate, and throughout the Senate Report, lengthy explanation was provided to justify the reasoning behind each of the mandatory provisions of the Medicare

Protection Act. *See* S. REP. at 23-26. Furthermore, given the lack of conflicting statutory language and the statute's "straightforward statutory command, there is no reason to resort to legislative history." *United States v. Gonzales*, 520 U.S. 1 (1997).

The Government has offered no evidence to demonstrate that Congress intended to remove the discretion of the Attorney General in revoking a registration in the context of the CSA, nor has the Government proven that an interpretation other than the plain meaning of this provision of the CSA is reasonable. In light of the lack of support for the proffered interpretation of the controlling provision of the CSA, I must review the evidence provided by Respondent to determine whether revocation or suspension is appropriate given the particular facts. *See* 5 U.S.C. 556(d) ("A party is entitled to present his case or defense by oral or documentary evidence."); 21 CFR 1301.43(c) (permitting a Respondent to file "a waiver of an opportunity for a hearing . . . together with a written statement regarding such person's position on the matters of fact and law involved in such hearing."); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 829 (11th Cir. 2018) ("[W]e may set aside a decision as 'arbitrary and capricious when, among other flaws, the agency has . . . entirely failed to consider an important aspect of the problem.'"); *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("To uphold DEA's decision, . . . we must satisfy ourselves 'that the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made."'"); *Kirk v. Mullen*, 749 F.2d 297, 299 (6th Cir. 1984) (Respondent "was given an opportunity to present his case before his registration was revoked. This satisfied due process.").

2. Agency Caselaw Revoking or Suspending a Registration on the Ground of Mandatory Exclusion Consistently Provides Respondent an Opportunity to Present Mitigating Evidence and Does Not Require a Nexus to Controlled Substances as a Prerequisite to Sanction.

In reviewing the Agency decisions on Section 824(a)(5), several of the existing cases involve additional grounds under 824(a), do not rely heavily on the (a)(5) exclusion, and thus do not always offer useful guidance in how the Agency has evaluated this ground in the past. *See, e.g.*, *John P. Moore, III, M.D.*, 82 Fed. Reg. 10,398 (2017) (revocation based on (a)(2) controlled substances felony, (a)(3) loss of state authority and (a)(5) mandatory exclusion not related to controlled substances). I agree with the Government that "each subsection [of Section 824(a)] provides 'an independent and adequate ground to impose a sanction on a registrant.'" RFAA, at 4 (citing *Arnold E. Feldman, M.D.*, 82 Fed. Reg. 39,614, 39,617 (2017)); *see also Gilbert L. Franklin, D.D.S.*, 57 Fed. Reg. 3,441 (1992) ("[M]andatory exclusion from participation in the Medicare program constitutes an independent ground for revocation pursuant to 21 U.S.C. [§] 824(a)(5).").

Additionally, in many of the previous Section 824(a)(5) cases, the registrant offered no mitigating evidence upon which the Administrator could analyze the facts. *See, e.g.*, *Sassan Bassiri, D.D.S.*, 82 Fed. Reg. 32,200, 32,201 (2017). In particular, the Government highlights *Richard Hauser, M.D.*, 83 Fed. Reg. 26,308 (2018), where revocation was sought under Section 824(a)(5) of the CSA and the registrant "did not respond." RFAA, at 6 (citing to *Hauser*, at 26,310). Therefore, the registrant's certificate of registration was revoked "'based on the unchallenged basis for his mandatory exclusion.'" *Id.* (quoting *Hauser* at 26,310). When the basis for revocation or suspension is clear and the registrant has had notice and the opportunity to present evidence, whether in a hearing or a written statement in accordance with 21 CFR

1301.43, but has chosen not to present any such evidence that could inform the Administrator's decision, it is reasonable that the Administrator might revoke or suspend. *See KK Pharmacy*, 64 Fed. Reg. 49,507, 49,510 (1999); *Orlando Ortega-Ortiz, M.D.* 70 Fed. Reg. 15,122 (2005); *Lazaro Guerra*, 68 Fed. Reg. 15,266 (2003) (basis for revocation was both (a)(3) and (a)(5)).

In contrast, as I have explained above, when a respondent *does* present evidence either in a written statement or in the context of a hearing, then I must review the relevant data and adequately articulate the rationale for my decision. *See Morall v. Drug Enf't Admin.*, 412 F.3d 165, 177 (D.C. Cir. 2005). With respect to the ground for revocation or suspension in Section 824(a)(5), Congress has given little indication of how the Agency should weigh mitigating evidence in revocations or suspensions, and to what extent the underlying crime that forms the basis for the mandatory exclusion should have a nexus to controlled substances. *See generally* S. REP. 100-109, at 22 (1987).

This Agency has concluded repeatedly that the underlying crime requiring exclusion from federal health care programs under Section 1320a-7(a) of Title 42 does *not* require a nexus to controlled substances in order to be used as a ground for revocation or suspension of a registration. *See Narciso Reyes, M.D.*, 83 Fed. Reg. 61,678, 61,681 (2018); *KK Pharmacy*, 64 Fed. Reg. at 49,510 (collecting cases); *Melvin N. Seglin, M.D.*, 63 Red. Reg. 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.*, 61 Fed. Reg. 60,727, 60,728 (1996). I believe that this conclusion is well founded in the CSA for several reasons. First, only one of the four mandatory exclusion categories is related to controlled substances. 42 U.S.C. 1320a-7(a)(4) ("Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, 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."). However,

Congress specifically cited to the entirety of 1320a-7(a) of Title 42 in 21 U.S.C. 824(a)(5), rather than only including Section 1320a-7(a)(4). The legislative history further supports the notion that Congress intended to add exclusion from federal health care programs as a basis for revocation or suspension under the CSA, not just the particular section related to controlled substances. *See* S. REP. 100-109, at 22 (1987). Moreover, to require such crimes to be related to controlled substances would be largely duplicative of Section 824(a)(2), which provides as a basis for revocation or suspension, a registrant's conviction "of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical." 21 U.S.C. 824(a)(2). To limit the application of Section 824(a)(5) to crimes involving controlled substances would be an impermissible statutory construction, because it would render Congress's amendment superfluous. *See Dept. of Def., Army Air Force Exchange Serv. v. Fed. Labor Relations Auth.*, 659 F.2d 1140, 1160 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 945 (1982) (A statute should be read in a "manner which effectuates rather than frustrates the major purpose of the legislative draftsmen.").

The Government raises concerns that the *Reyes* decision creates confusion about whether the Government is required to demonstrate a controlled substance nexus in order to revoke or suspend a registration under Section 824(a)(5). *See* RFAA, at 8. *Reyes* is factually distinct from the present case, because the respondent in *Reyes* provided no substantive mitigating evidence. *Reyes*, 83 Fed. Reg. at 61,680. As discussed herein, I believe that in such cases, where the ground for exclusion has been proven, and there is nothing for me to weigh, revocation or suspension is appropriate. *See, e.g.*, *KK Pharmacy*, 64 Fed. Reg. at 49,510. Despite the lack of substantive mitigating evidence in *Reyes*, my predecessor took the opportunity to agree with and

quote the ALJ stating, "'this type of fraudulent behavior does not inspire confidence that . . . [Respondent] can be trusted with a prescription pad bearing a DEA registration number.'" *Reyes*, 83 Fed. Reg. at 61,681. The decision goes on to state, "After all, if Respondent signed blank certificates of medical necessity for durable medical equipment that was not medically necessary, 'it is doubtful that DEA can expect . . . [Respondent] to honestly prescribe controlled substances for only legitimate medical purposes.'" *Id.* Where the underlying crimes have a nexus to the practice of medicine, and in particular, as in *Reyes*, where the crime demonstrates activity that is similar to activity that is frequently used to divert controlled substances, such activity logically should explicitly be factored into my determination of whether the practitioner can be entrusted with a DEA registration. As demonstrated in *Reyes*, there does not need to be a nexus to controlled substances to make a connection between the activity that caused the mandatory exclusion and the potential for abuse of a DEA registration. In Respondent's case, the crimes related to tax fraud clearly have no nexus to controlled substances, but as explained below, in particular, the crime related to obstructing justice could be relevant to Respondent's compliance with the CSA and its implementing regulations.

SANCTION

Here, there is no dispute in the record that Respondent is mandatorily excluded pursuant to Section 1320a-7(a) of Title 42 and, therefore, that a ground for the revocation or suspension of Respondent's registration exists. RFAA, at 4; Respondent Statement, at 1. Additionally, I have explained that there is no requirement for the mandatory exclusion to have a nexus to controlled substances in order to revoke or suspend a registration under Section 824(a)(5) of the CSA.

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient

execution of his functions under this subchapter." 21 U.S.C. 871(b). This authority specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." *Gonzales v. Oregon*, 546 U.S. 243, 259 (2006). A clear purpose of this authority is to "bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking." *Id*. at 270. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondent submitted to determine whether or not he has presented "sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). "'Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 463 (2009) (quoting *Medicine Shoppe*, 73 Fed. Reg. 364, 387 (2008)); *see also Jackson*, 72 Fed. Reg. at 23,853; *John H. Kennnedy, M.D.*, 71 Fed. Reg. 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (1995).[4] The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while

[4] In future 824(a)(5) cases, I hope to additionally have the benefit of the Government's analysis of Respondent's mitigating evidence.

also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016).

In evaluating the degree required of a Respondent's acceptance of responsibility to entrust him with a registration, in *Mohammed Asgar, M.D.*, 83 Fed. Reg. 29,569, 29,572 (2018), the Agency looked for "unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct." *Id.* (citing *Lon F. Alexander, M.D.*, 82 Fed. Reg. 49,704, 49,728). In this case, I believe the charge to which Respondent pled guilty of "Corruptly Endeavoring to Obstruct and Impede the Due Administration of the Internal Revenue Laws," where Respondent falsified documents in order to conceal his tax fraud from IRS officials, sufficiently demonstrates knowing and intentional misconduct to require clear acceptance of responsibility. *See* RFAA, at 3 and Ex 4.

Respondent indisputably states, "I accept and acknowledge complete personal responsibility for the actions that I have pled guilty to and remain sincerely remorseful for my actions." Respondent Statement, at 3. There was no DEA hearing in which to judge Respondent's credibility in making this statement, or the other evidence he offered on his own behalf, thus under the CSA regulations, I must "consider . . .[the statement] in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein." 21 CFR 1301.43(c). Respondent did attach to his statement the results of his testimony in front of the BPMC Hearing Committee, and during which the Committee noted in restoring his license that it "appreciated [his] sincere sense of remorse and repentance for his actions. [Respondent] accepted full responsibility for his conduct and the Committee felt that he has learned from his mistakes." Respondent Statement Ex. 2, at 3. Respondent's direct

statement and the Hearing Committee's finding weigh heavily in favor of Respondent's acceptance of responsibility, and the Government offers no contradictory evidence.

However, Respondent also asserts that his crimes "pertained solely to [his] personal income tax statements" and "[t]here were never any allegations of impropriety with respect to [his] medical practice or the furnishing of or billing for medical care services or supplies." Respondent Statement, at 2. Contrary to this assertion, in his HHS exclusion proceeding, the HHS ALJ particularly found that Respondent's crime was committed in connection with the delivery of a health care item or service because:

> Petitioner abused his position by appropriating the personal information of four veterans (including two individuals to whom he had provided health care services) to further his tax evasion scheme. [Respondent] would not have been in a position to misuse the veterans' personal information had he not been part of the chain of delivery of V.A. health care benefits.

HHS Appeals Board, at 5. Although the HHS ALJ was reviewing the connection between Respondent's criminal misconduct and "health services" under HHS legal precedent, and therefore the HHS ALJ's finding is contextually distinct from Respondent's statement, I believe that Respondent goes too far in claiming that there was no impropriety related to his medical practice. *See* Respondent Statement, at 2. Respondent had reason to know that this statement was inaccurate, because the HHS ALJ had explicitly rejected his argument. HHS Appeals Board, at 5.

Had there been a hearing on the OSC, it is possible that the HHS ALJ's finding would have come to light on cross-examination and that Respondent could have clarified his statement that his crimes were not related to impropriety related to his medical practice in the sense that they were not related to patient care, but without a hearing and a DEA ALJ's assessment of credibility in this case, I must weigh this statement against Respondent's overall credibility in

accepting responsibility. There were no allegations with respect to Respondent's care of his patients, which was clearly one of the reasons that New York reinstated his state license to practice, but I cannot find that his crimes were unrelated to his medical practice. *See* Respondent Statement Ex.3, at 2. With such limited information from Respondent, this statement appears to be aimed at minimizing the egregiousness of his conduct, which the Agency has previously weighed against a finding of acceptance of full responsibility. *See Ronald Lynch, M.D.*, 75 Fed. Reg. 78,745, 78,754 (2010) (Respondent did not accept responsibility noting that he "repeatedly attempted to minimize his [egregious] misconduct"; *see also Michael White, M.D.*, 79 Fed. Reg. 62,957, 62,967 (2014) (finding that Respondent's "acceptance of responsibility was tenuous at best" and that he "minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict."). In light of Respondent's minimization of his crimes' connection to his medical practice, and the lack of a hearing to determine whether his remorse is credible, Respondent's acceptance of responsibility cannot be characterized as unequivocal. As this situation highlights, the degree of acceptance of responsibility that is required does not hinge on the respondent uttering "magic words" of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.

The Agency also looks to the nature of the crime in determining the likelihood of recidivism and the need for deterrence. In this case, Respondent's actions can be characterized as egregious. He clearly acted out of greed in defrauding the government of taxes and he further misused the trust of his positions in stealing the identities of veterans in order to hide his criminal activity. *See Nelson Ramirez-Gonzales, M.D.*, 58 Fed. Reg. 52,787, 52,788 (1993) ("fraud perpetrated by the respondent casts doubt upon his integrity, and as such supports an action

against his registration"); *George D. Osafo, M.D.* 58 Fed. Reg. 37,508, 37,509 (1993) ("Respondent's submission of fraudulent medical claims and subsequent convictions of larceny indicated that Respondent placed monetary gain above the welfare of his patients, and in so doing, endangered the public health and safety."). In addition, Respondent callously endangered the livelihood of his unwitting accountant in the cover-up by submitting the fraudulent invoices to the accountant to then provide to the IRS. RFAA Ex. 3, at 7.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,095 (2009); *Singh*, 81 Fed. Reg. at 8248. Where the respondent has committed a crime with no nexus to controlled substances, and that is only partially related to his medical practice, it is much more difficult to demonstrate that sanction will be useful to generally deter the community of registrants. The underlying crimes in this case relate to tax fraud, and although I believe that deterring the registrant community from committing tax fraud is certainly in the best interest of the United States, it is not arguably within the purview of the CSA. In the context of general deterrence as it relates to the CSA, what is concerning is Respondent's misappropriation of his patients' identities to cover up his criminal activity. RFAA Ex. 3, at 7. If practitioners used their patients' identities to hide their illicit activities in violation of the CSA, such activity would be very challenging to detect.

Respondent has asserted that he has served his sentence of 18 months, paid his restitution in full, and that "the goals of justice, deterrence and punishment have already been fully realized." Respondent Statement, at 2. *See Asgar*, 83 Fed. Reg. at 29,573 (suspending registration until "Respondent[] provid[es] evidence that he has satisfied the judgment of the District Court"); *but see Singh*, 81 Fed. Reg. at 8248-49 (denying Respondent's application even

though underlying crime was 15 years prior and debt to society had been paid because it was overwhelmingly clear that Respondent did not believe he was mistaken in any way). Here, it is undisputed that Respondent complied with the criminal judgment, but it remains unclear whether he can be entrusted with a CSA registration and whether sanction is appropriate to protect the public from a recurrence of his fraudulent actions. *See Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988) (describing revocation as a remedial measure "based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.").

Despite the fact that Respondent did not violate the CSA in committing the underlying crimes, I believe that Respondent's particular criminal activity and egregious behavior in impeding the IRS investigation into his tax fraud is relevant to his particular future compliance with the CSA and its implementing regulations. Stealing the identities of patients to create fraudulent receipts is a clear indication that Respondent lacks respect for the investigatory process and will take extreme measures to hide his illegal activity. RFAA Ex. 3, at 6. As the HHS ALJ summarized, Respondent "used patient information, to which he had access based on his position of trust as a V.A. physician, to create fraudulent invoices in an attempt to cover up his income tax evasion . . . . These factors underscore the seriousness of his dishonest scheme." *Jeffrey S. Stein, M.D.*, HHS Appeals Board, at 6. It is this activity, which demonstrates a lack of integrity, coupled with Respondent's statement attempting to minimize the connection of his crimes to his medical practice that give me the most pause in determining the nature or appropriateness of a sanction in this case. *See Dubin,* 61 Fed. Reg. at 60,728 (revoking based on

respondent's "continual use of the Medical Assistance claims, the names and provider numbers of his employee dentists without their permission" and finding that "'these actions cast substantial doubt on Respondent's integrity.'").

Respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not recur. In some circumstances, the Agency has found that repentance and honesty weigh in favor of continuing to entrust the respondent with a registration. *See, e.g.*, *Melvin N. Seglin, M.D.*, 63 Fed. Reg. 70,431, 70,433 (1998) (The ALJ was "'persuaded that Respondent has accepted responsibility for his misconduct and that is not likely to recur.' The Deputy Administrator agree[d] with [the ALJ], finding it significant that Respondent did not attempt to conceal his misconduct and in fact was quite straightforward with the investigator."). Here, Respondent pled guilty and stated remorse and seemingly accepted responsibility, but the crime itself demonstrates a complex scheme in which he misused patients' personal information to conceal his original crime of tax fraud. *See* RFAA Ex. 3, at 7.

If Respondent were to repeat such dishonest interference in the context of a DEA investigation, it could impact the Agency's mission in preventing the diversion and misuse of controlled substances. DEA budgets for approximately 1,625 Diversion positions involved in regulating more than 1.8 million registrants overall.[5] Ensuring that a registrant is honest and does not avoid detection through fraudulent documentation is crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population.

"While mandatory exclusion can provide an independent basis for revocation, DEA has often reserved that sanction to cases where 'there were serious questions as to the integrity of the

[5] *See* DEA FY2020 Budget Request *available at* https://www.justice.gov/jmd/page/file/1142431/download.

registrant.'" *Kwan Bo Jin, M.D.*, 77 Fed. Reg. 35,021, 35,026 (2012) (quoting *Anibal P. Herrera, M.D.*, 61 Fed. Reg. 65,075, 65,078 (1996) (permitting the continuation of registration with restriction where respondent fully accepts responsibility and has paid restitution)). I will refrain from revocation in this case because of the conflicting information in the record with regard to Respondent's integrity and because I appreciate the forthright nature of his statements regarding acceptance of responsibility. However, in light of his diminishment of the full extent of his crimes, and without having the benefit of a hearing to weigh the credibility of such statements, I believe that the record presents a legitimate concern that Respondent might impede a DEA investigation in the same manner as he obstructed his IRS investigation. Even though he has accepted responsibility and demonstrated remorse, he also glossed over the misuse of patient information, which seems consistent with his prior behavior of concealing his crimes. I am concerned that, although Respondent may not be likely to commit tax fraud again, he may be dishonest in dealing with Diversion Investigators or DEA Special Agents in the future. I believe that some degree of sanction is appropriate to prevent Respondent from circumventing the CSA requirements to the detriment of its effective implementation in order to protect the public. Therefore, I will suspend Respondent's registration for a period of two years. The suspension is significantly less than his eight-year federal health care program exclusion, because the CSA is not bound by the same minimal suspension standards as HHS. Respondent has paid his restitution, he has completed his incarceration and is fulfilling his probation, but I must ensure that he is fully candid and cooperative and his fraudulent behavior is not likely to recur in order to entrust him with a CSA registration.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby suspend DEA Certificate of Registration No. FS6587868 issued to Jeffrey Stein, M.D. for a period of two years starting from the effective date of this Order. This Order is effective **[INSERT DATE THIRTY DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

Dated: August 23, 2019.

Uttam Dhillon,

Acting Administrator.

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