

barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country*, and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry*; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: January 29, 2020.

Lisa Barton,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Shelton W. Barnes, M.D.; Decision and Order

On June 28, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Shelton W. Barnes, M.D., (hereinafter, Registrant), of New Orleans, Louisiana. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BB1040269, because the United States Department of Health and Human Services, Office of Inspector General (hereinafter, HHS OIG) "mandatorily excluded [Registrant] from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of twenty-five years pursuant to 42 U.S.C. 1320a-7(a)"; and such exclusion "warrants revocation of [Registrant's] registration pursuant to 21 U.S.C. 824(a)(5)." *Id.* at 2.

Specifically, the OSC alleged that, on September 25, 2018, Judgment was entered against Registrant in the United States District Court for the Eastern District of Louisiana (hereinafter, E.D. La.) "based on [Registrant's] conviction on one count of 'Conspiracy to Commit

Health Care Fraud,' in violation of 18 U.S.C. 1349, one count of 'Conspiracy to Pay and Receive Illegal Health Care Kickbacks,' in violation of 18 U.S.C. 371, fifteen counts of 'Health Care Fraud,' in violation of 18 U.S.C. 1347 and 2,¹ and one count of 'Obstruction of a Federal Audit,' in violation of 18 U.S.C. 1516 and 2."² *Id.* at 2 (citing *United States v. Barnes*, No. 2:15-cr-0061-SM-JCW (E.D. La. 2018)). The OSC further alleged that "based on [such] conviction, HHS OIG, by letter dated March 29, 2019, mandatorily excluded [Registrant] from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of twenty-five years pursuant to 42 U.S.C. 1320a-7(a), effective April 18, 2019." *Id.*

The Show Cause Order notified Registrant 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.* at 2-3 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3-4 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration, dated October 24, 2019, a Diversion Investigator (hereinafter, DI) assigned to the New Orleans Field Division stated that she and another DI traveled to the Federal Prison Camp Pensacola, 110 Raby Ave., Pensacola, Florida 32509, where Registrant was incarcerated, on July 10, 2019. Request for Final Agency Action (hereinafter, RFAA), EX 6 (Declaration of Service). The DI stated that they were taken to a room where correctional officers brought in Registrant, who "was wearing an inmate nametag with his name on it," and she further "recognized him based on his driver's license photo." *Id.* The DI then "handed the [OSC] to [Registrant] and explained it to him, including his options to request a hearing or surrender his registration." *Id.*

The Government submitted its RFAA, along with the evidentiary record, for adjudication on December 4, 2019. In its RFAA, the Government represented that "at least thirty days have passed since the . . . [OSC] was served on Registrant. Registrant has not requested a hearing and has not otherwise corresponded or communicated with DEA regarding the Order served on him, including the

filing of any written statement in lieu of a hearing." RFAA, at 2. The Government requested that Registrant's Certificate of Registration be revoked and his pending application for renewal be denied "because Registrant lacks state authority and because Registrant has been excluded from Medicare, Medicaid and all Federal health care programs, either of which alone is a sufficient basis to revoke Registrant's registration . . ." ³ *Id.* at 7.

Based on the Government's representations and my review of the record, I find that the Government served the OSC on Registrant on July 10, 2019. I also find that more than thirty days have now passed since the date of service. Further, based on the Government's representations, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR § 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BB1040269 at the registered address of 3600 Prytania, Suite 50, New Orleans, LA 70115. RFAA, EX 1 (Certificate of Registration History), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration was set to expire on July 31, 2018, but on that date, Registrant submitted an online renewal application for 10555 Lake Forest Blvd., Ste. 5J, New Orleans, LA 70127-5208,

³ In the RFAA, the Government argued for revocation based on a ground that does not appear in the OSC—that the Registrant currently lacks authority to practice medicine in Louisiana, the state in which he is registered with the DEA, and his registration is thus also subject to revocation pursuant to 21 U.S.C. 824(a)(3). Although state authority is a prerequisite to holding (or having) a DEA registration, *see* 21 U.S.C. 823, I see no evidence in the record that Registrant was notified of this additional charge. As such, he has had no opportunity to determine whether to address the status of his state authority. *See Hatem M. Ataya, M.D.*, 81 FR 8221, 8245 (2016) (permitting the consideration of 21 U.S.C. 824(a)(3), because the respondent had a "meaningful opportunity to show that he retains his state authority."). In this case, I decline to allow the Government to add the lack of state authority charge.

¹ The Court's notation of 18 U.S.C. 2 appears in this format, which was replicated in the OSC.

² *See* n.1.

and his registration is currently “in a renewal pending status.” *Id.*

Registrant's Exclusion

The evidence in the record demonstrates that, on September 25, 2018, Judgment was entered against Registrant in E.D. La. “based on [Registrant's] conviction on one count of ‘Conspiracy to Commit Health Care Fraud,’ in violation of 18 U.S.C. 1349, one count of ‘Conspiracy to Pay and Receive Illegal Health Care Kickbacks,’ in violation of 18 U.S.C. 371, fifteen counts of ‘Health Care Fraud,’ in violation of 18 U.S.C. 1347 and 2, and one count of ‘Obstruction of a Federal Audit,’ in violation of 18 U.S.C. 1516 and 2.” RFAA EX 3 (Judgment in a Criminal Case at 1, *United States v. Barnes*, No. 2:15-cr-61-SM-JCW (E.D. La. September 28, 2018)).

By letter dated March 29, 2019, HHS OIG notified Registrant 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 twenty-five years based on Registrant's felony convictions in E.D. La. RFAA, EX 4 (hereinafter, Exclusion Letter), at 1. The Exclusion Letter stated that the period of exclusion was greater than the minimum of five years, because the acts resulting in conviction “caused a financial loss to a government agency or program or to one or more entities of \$50,000 or more,” and specifically, the court ordered Registrant “to pay approximately \$10,850,200 in restitution.” *Id.* at 2. Further, the HHS OIG reasoned that “the acts were committed over a period of one year or more,” and specifically, that “the acts occurred from November 2008 to about May 2014.” *Id.* Finally, the HHS OIG considered whether the Registrant was incarcerated and found that the “court sentenced [Registrant] to 60 months of incarceration.” *Id.* Per the Exclusion Letter, the exclusion became effective twenty days from the date of the letter, or April 18, 2019. *Id.* at 1. The Exclusion Letter notified Registrant of his appeal rights. *Id.* at 2-4.

Accordingly, I find that the HHS OIG excluded Registrant from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a-7(a) for twenty-five years, effective April 18, 2019, based on Registrant's convictions in the E.D. La.

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. Each subsection of Section 824(a) provides an independent

ground to impose a sanction on a registrant. *Arnold E. Feldman, M.D.*, 82 FR 39614, 39617 (2017); *see also Gilbert L. Franklin, D.D.S.*, 57 FR 3441 (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).”). 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.” 42 U.S.C. 1320a-7(a) provides a list of four predicate offenses for which exclusion from Medicare, Medicaid, and other federal health care programs is mandatory and sets out mandatory timeframes for such exclusion. *Id.*

When a registrant facing a sanction under 21 U.S.C. 824(a)(5) offers no mitigating evidence for the Administrator to consider, “it is reasonable that the Administrator might revoke or suspend.” *Jeffrey Stein, M.D.*, 84 FR 46968, 46971 (2019); *see, e.g., Narciso A. Reyes, M.D.*, 83 FR 61678, 61681 (2018); *Richard Hauser, M.D.*, 83 FR 26308, 26310 (2018). Further, “[t]here 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.” *Jeffrey Stein, M.D.*, 84 FR at 46972; *Narciso Reyes, M.D.*, 83 FR at 61681; *KKK Pharmacy*, 64 FR 49507, 49510 (1999) (collecting cases); *Melvin N. Seglin, M.D.*, 63 Red. Reg. 70431, 70433 (1998); *Stanley Dubin, D.D.S.*, 61 FR 60727, 60728 (1996).

Here, there is no dispute in the record that Registrant is mandatorily excluded pursuant to Section 1320a-7(a) of Title 42 and, therefore, that a ground for the revocation or suspension of Registrant's registration exists. 21 U.S.C. 824(a)(5). Indeed, Registrant was convicted of multiple counts involving fraud, kickbacks, and obstruction of a federal audit. The HHS OIG estimated that Registrant's criminality spanned six years and resulted in a financial loss of approximately \$10,850,200. RFAA, EX 4, at 2.

Where, as here, the Government has met its *prima facie* burden of showing that a ground for revocation exists, the burden shifts to the Registrant to show why he can be entrusted with a registration. *See Jeffrey Stein, M.D.*, 84 FR at 46972. Registrant, as already discussed, failed to respond in any way to the OSC. *See RFAA*, at 6. Therefore, among other things, Registrant has not accepted responsibility for his criminality, shown any remorse for it, or provided any assurance that he would

not repeat it. *See Jeffrey Stein, M.D.*, 84 FR at 46972-74. Such silence weighs against the Registrant's continued registration. *Zvi H. Perper, M.D.*, 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough*, 73 FR 264, 387 (2008); *Samuel S. Jackson*, 72 FR 23848, 23853 (2007)); *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 831 (11th Cir. 2018) (“‘An agency rationally may conclude that past performance is the best predictor of future performance.’” (quoting *Alra Laboratories, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995))).

Based on the record before me, I conclude that Registrant's founded criminality involving dishonesty and obstruction, resulting in his exclusion from Medicare, Medicaid, and all federal health care programs, makes him ineligible for a DEA registration at this time. Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BB1040269 issued to Shelton W. Barnes, M.D. Further, I hereby deny any pending application of Shelton W. Barnes, M.D., to renew or modify this registration, as well as any pending application of Shelton W. Barnes, M.D., for registration in Louisiana. This Order is effective March 4, 2020.

Dated: January 3, 2020.

Uttam Dhillon,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-576]

Bulk Manufacturer of Controlled Substances Application: Noramco Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 3, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701