

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Irene G. Gurvits, M.D.; Decision and Order

On August 19, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Irene G. Gurvits, M.D. (hereinafter, Registrant). OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BG6075875. *Id.* It alleged that Registrant is without "authority to handle controlled substances in the State of New York, the state in which [Registrant is] registered with the DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on May 26, 2020, "the New York State Board for Professional Medical Conduct issued a Determination and Order revoking [Registrant's] license to practice medicine in the State of New York." *Id.* The OSC further alleged that because Registrant's medical license was revoked, Registrant lacks the authority to handle controlled substances in the State of New York. *Id.*

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising 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 Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

A DEA Diversion Investigator (hereinafter, DI) personally served Registrant with the OSC on August 31, 2020, at her home address, which is also the mail address on her registration. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 4, at 1–2 (Declaration of DI). The DI stated that after the DI explained the purpose of the Order, Registrant "refused to accept the Order and slammed the door shut." *Id.* The DI slipped the envelope with the Order under Registrant's door and "Registrant then opened the door and [the DI] again explained the purpose of the Order. Registrant took the envelope containing the signed Order from underneath the door and immediately closed the door." *Id.*

I find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's

written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing "or otherwise corresponded or communicated with DEA regarding the Order served on her." RFAA, at 1. 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 1301.46.

I. Findings of Fact

a. Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BG6075875 at the registered address of 102 West 75 St., Suite 107, New York, NY 10023. RFAAX 1 (Certification of Registration Status). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner-DW/30. *Id.* Registrant's registration expires on September 30, 2022, and "is in an active pending status until the resolution of administrative proceedings." *Id.*

b. The Status of Registrant's State License

The State of New York Department of Health State Board for Professional Conduct (hereinafter, the Board) entered a Determination and Order on May 26, 2020, revoking Registrant's medical license effective upon service on Registrant. RFAAX 3 (Board Order), at 8. The State of New York's online records, of which I take official notice, document Registrant's license status as "license revoked." ¹ New York Office of the Professions, Verification Searches,

¹ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov).

<http://www.op.nysed.gov/opsearches.htm#> (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in New York, the state in which Registrant is registered with the DEA.

II. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

According to the New York Controlled Substances Act (hereinafter, the Act), “[i]t shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.” N.Y. Pub. Health Law § 3304 (West 2020). The Act defines “practitioner,” as “a physician . . . or other person licensed, or otherwise permitted to dispense, administer, or conduct research with respect to a controlled substance in the course of a licensed professional practice. . . .” *Id.* at § 3302(29). Finally, New York regulations state that “[a] prescription for a controlled substance may be issued only by a practitioner who is . . . authorized to prescribe controlled substances pursuant to his licensed professional practice . . .” N.Y. Comp. Codes R. & Regs. Tit. 10, § 80.64 (West 2020).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in New York. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in New York. Thus, because Registrant lacks authority to practice medicine in New York and, therefore, is not authorized to handle controlled substances in New York, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant’s DEA registration be revoked.

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. BG6075875 issued to Irene G. Gurvits, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Irene G. Gurvits, M.D. to renew or modify this registration or for any other registrations in the State of New York. This Order is effective January 28, 2021.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–33]

Steven M. Kotsonis, M.D.; Order

On May 3, 2018, the Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Steven M. Kotsonis, M.D. (hereinafter, Respondent), which sought to revoke Respondent’s DEA Certificate of Registration FK1584336 and to deny any pending applications for renewals or modifications of such registration, based on its contention that his continued registration is inconsistent with the public interest. Administrative Law Judge Exhibit (ALJX) 1 (OSC). In response to the OSC, Respondent submitted a timely request for a hearing, which was held from August 14–17, 2018. On October 23, 2018, Chief Administrative Law Judge John J. Mulrooney, II issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision), which recommended that I revoke Respondent’s registration and that I deny any pending application for renewal. Respondent filed Exceptions to the Recommended Decision, and the record was forwarded to me for final Agency action on November 26, 2018.

After reviewing the record, I learned that Respondent had surrendered his DEA registration on December 23, 2019. I issued an Order on September 25, 2020, requiring the Government to produce documentation of Respondent’s surrender of his registration. The Order further instructed the parties to file a Request for Dismissal “if it is the intent of [the] party to rely on Respondent’s voluntary surrender of his registration to terminate this proceeding” or a brief on the issue “if [the] party opposes the dismissal of this proceeding prior to the issuance of my Decision on the Government’s allegation in the OSC.” Both parties filed timely responses.

Respondent filed a Request for Dismissal on October 15, 2020. As grounds for the dismissal, Respondent stated that, “upon DEA request, he voluntarily surrendered his DEA registration on December 23, 2019.” Respondent Request for Dismissal.

The Government submitted a response to my September 25 Order on October 23, 2020 (hereinafter, the Government Response). As required by my September 25 Order, the

Government submitted a copy of the Voluntary Surrender of Controlled Substances Privileges form, DEA–104, signed by Respondent surrendering DEA Registration No. FK1584336. The Government stated that Respondent voluntarily surrendered his DEA registration following a guilty plea to felony criminal drug charges in a criminal matter concurrent to the instant matter. Government Response at 2. The Government Response neither requested that I dismiss this matter nor that I file a final Decision on the allegations it made in the OSC. Rather, the Government provided legal arguments regarding why Respondent’s voluntary surrender of his registration did not preclude me from issuing a final Decision. *Id.* at 2–3. The Government then concluded its Response stating that I “should issue whatever order is appropriate in light of the administrative record presented.” *Id.* at 3.

Based upon my review of the parties’ submissions, the record, and public documents from Respondent’s criminal case, I am granting Respondent’s Request for Dismissal.

Facts

Respondent was registered with DEA as a practitioner in schedules II through V under Certificate of Registration No. FK1584336, at the registered address of 347 Park Ave., Pewaukee, Wisconsin 53702. OSC at 1. In its OSC, the Government contended that Respondent’s registration was inconsistent with the public interest and should be revoked because Respondent failed to comply with applicable federal law relating to controlled substances. *Id.* at 1–2. Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, in violation of 21 CFR 1306.04(a). *Id.* at 2.

On December 23, 2019, Respondent voluntarily surrendered his DEA registration. Government Response, Attachment 1 (DEA Form 104 signed by Respondent). In his surrender form, Respondent affirmed that he was voluntarily surrendering his registration for cause “[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.” *Id.* Respondent also acknowledged that submitting the form to DEA would result in the immediate termination of his registration. *Id.*

The Government stated in its Response that Respondent surrendered his DEA registration “following a guilty plea to felony criminal drug charges in [a] concurrent criminal matter.”