



BILLING CODE: 4410-09-P

**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**Andrzej Kazimierz Zielke, M.D.
Decision and Order**

On December 1, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Andrzej Kazimierz Zielke, M.D. (hereinafter, Registrant), of North Huntingdon, Pennsylvania. OSC, at 1. The OSC proposed the revocation of Registrant's DEA Certificate of Registration No. BZ6248199 on the ground that Registrant does not have authority to handle controlled substances in the Commonwealth of Pennsylvania, the state in which Registrant is registered with the DEA. *Id.* (citing 21 U.S.C. §§ 823(f) and 824(a)(3)).

Specifically, the OSC alleged that on October 11, 2017, the Pennsylvania State Board of Medicine issued an "Order of Temporary Suspension and Notice of Hearing in which it suspended [Registrant's] license to practice medicine and surgery," and that Registrant is "without authority to practice medicine or handle controlled substances in the Commonwealth of Pennsylvania, the state in which [he is] registered with DEA." *Id.* at 1-2. The OSC asserts that "[c]onsequently, DEA must revoke [his] DEA registration based on [his] lack of authority to handle controlled substances in the Commonwealth of Pennsylvania." *Id.* at 2 (citing 21 U.S.C. § 824(a)(3); 21 CFR § 1301.37(b)).

The OSC 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. OSC, at 2 (citing 21 CFR §

1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 2-3 (citing 21 U.S.C. § 824(c)(2)(C)).

Adequacy of Service

The Government submitted its Request for Final Agency Action (hereinafter, RFAA) in this matter to my office on February 6, 2018, representing that since the service of the Order to Show Cause, Registrant “has not requested a hearing and has not otherwise corresponded or communicated with DEA.” RFAA, at 1. The Government’s initial RFAA included only a Form DEA-12 Receipt as evidence of service of the Show Cause Order on Registrant. A former Acting Administrator issued an Order directing the Government to provide a declaration setting forth the circumstances regarding how it accomplished service. May 17, 2018, Order of the Acting Administrator. On February 26, 2019, the Government filed its Response to my office, including therein the Declaration of the Special Agent detailing how service was effectuated. Government’s Response to Acting Administrator’s Order (hereinafter, Government’s Response).

On December 6, 2017, a DEA Special Agent (hereinafter, SA) and a Diversion Investigator (hereinafter, DI) with the DEA Pittsburgh District Office, Philadelphia Field Division, personally served Registrant with the OSC at his residence. Government’s Response, Declaration of Service of Order to Show Cause (hereinafter, SA’s Declaration). The SA stated that upon arrival at the registered address, Registrant identified himself as Dr. Zielke. *Id.* The SA then “personally served the [OSC] on Registrant.” *Id.* Registrant signed a DEA Form 12, Receipt for Cash or Other Items, to acknowledge his receipt of the Show Cause Order. *Id.*; *see also* Government’s Response, EX B.

Based on the SA’s Declaration, the Government’s written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on

December 6, 2017. I also 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 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. BZ6248199 at the registered address of 8775 Norwin Avenue, Suite 114, North Huntingdon, Pennsylvania. OSC, 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 expires on May 31, 2020, and is "in an active pending status." *Id.*

On October 11, 2017, the State Board of Medicine for the Commonwealth of Pennsylvania (hereinafter, the Board), issued Registrant an Order of Temporary Suspension and Notice of Hearing (hereinafter, Suspension Order), suspending his state license to practice medicine and surgery. RFAA, EX 3, at 2.

The Government contends that Registrant currently lacks state authority to practice medicine and surgery on the basis of the Suspension Order issued by Board. RFAA, at 3. Upon review of the Petition for Temporary Suspension of Registrant's license (hereinafter, Petition), filed by the Prosecuting Attorney for the Commonwealth of Pennsylvania's Department of State,

the Board found that the “alleged facts...if taken as true,” establish that “[Registrant’s] continued practice of medicine and surgery...makes [Registrant] an immediate and clear danger to the public health and safety.” EX 3, at 1 (Suspension Order). According to the Petition, on October 4, 2017, a criminal complaint and arrest warrant were filed in the U.S. District Court for the Western District of Pennsylvania, charging Respondent with: illegal distribution of Schedule II prescription narcotics and conspiracy to illegally distribute schedule II prescription narcotics in violation of 21 U.S.C §§ 841(a)(1) and 846, mail fraud in violation of 18 U.S.C. § 1341, and health care fraud, in violation of 18 U.S.C. § 1347. EX 3, at 9 (Petition). Therefore, the Board ordered that the “license to practice medicine and surgery issued to the Respondent . . . along with any other authorizations to practice the profession issued by the Board to Respondent, are temporarily suspended upon service of [the] Order.” *Id.* at 1-2 (Suspension Order) (emphasis omitted).

According to Pennsylvania’s online records, of which I take official notice, Registrant’s license is still suspended.¹ Pennsylvania Department of State, Bureau of Professional and Occupational Affairs, <https://www.pals.pa.gov/> (last visited January 3, 2020).

Therefore, I find that Registrant currently is not licensed to engage in the practice of medicine in the Commonwealth of Pennsylvania, the state in which Registrant is registered with the DEA.

¹ Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding – even in the final decision.” U.S. Dept. of Justice, *Attorney General’s Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA’s regulations, Respondent is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. § 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

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 Controlled Substances Act (hereinafter, 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 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, 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, M.D.*, 76 Fed. Reg. at 71,371-72; *Sheran Arden Yeates*,

M.D., 71 Fed. Reg. 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 Fed. Reg. 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 Fed. Reg. 11,919, 11,920 (1988); *Frederick Marsh Blanton, M.D.*, 43 Fed. Reg. at 27,617.

Pennsylvania law defines a “practitioner” as a “(i) a physician . . . licensed, registered or otherwise permitted to distribute, dispense . . . or to administer a controlled substance . . . in the course of professional practice or research in the Commonwealth of Pennsylvania.” 35 PA. STAT. AND CONS. STAT. ANN. § 780-102 (West 2019). Pennsylvania law further defines a “physician,” as a “medical doctor,” and a “medical doctor,” as an “individual who has acquired” a license “to practice medicine and surgery issued by the board.” 63 PA. STAT. AND CONS. STAT. ANN. § 422.2 (West 2019). State law prohibits “[t]he administration, dispensing, delivery, gift or prescription of any controlled substance by any practitioner . . . unless done (i) in good faith in the course of his professional practice; (ii) within the scope of the patient relationship; (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession.” 35 PA. STAT. AND CONS. STAT. ANN. § 780-113(14). Additionally, the statute prohibits “knowingly or intentionally possessing a controlled . . . substance by a . . . practitioner not registered or licensed by the appropriate state board.” *Id.* at § 780-113(15). Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine and surgery in Pennsylvania. A practitioner, who is a physician and a medical doctor, must be licensed and cannot prescribe controlled substances in his professional practice or possess controlled substances without a license to practice medicine and surgery. *Id.* at § 780-113(14), (15). Because Registrant lacks authority to practice medicine in Pennsylvania and, therefore, is not authorized to possess or prescribe controlled substances in Pennsylvania, 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. BZ6248199, issued to Andrzej Kazimierz Zielke, M.D. Further, I hereby deny any pending application of Andrzej Kazimierz Zielke, M.D. to renew or modify this registration, as well as any pending application of Andrzej Kazimierz Zielke, M.D., for registration in the Commonwealth of Pennsylvania. This Order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: January 3, 2020.

Uttam Dhillon,
Acting Administrator.

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