

Manufacturer of Marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a) as described in 84 FR 44920, published on August 27, 2019.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on October 25, 2019, Spocannabis LLC, 1321 North Stanley Road, Suite B, Spokane Valley, Washington 99212 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols.	7370	I

The applicant noticed above applied to become registered with DEA to grow marihuana as a bulk manufacturer subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Before DEA completes the evaluation and registration process for applicants to grow marihuana, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law, as described in 84 FR 44920.

Dated: January 7, 2020.

William T. McDermott,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Theresa L. Wendt, N.P.; Decision and Order

On January 24, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause to Theresa L. Wendt, N.P., (hereinafter, Registrant), of Milwaukee, Wisconsin. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. MW2120006. It alleged that Registrant is "without authority to handle controlled substances in the State of Wisconsin, the state in which . . . [she is]

registered with the DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that the Wisconsin Board of Nursing (hereinafter, BON) issued an Order on January 19, 2018, suspending Registrant's professional nursing (hereinafter, RN) license and her advanced practice nurse prescriber (hereinafter, APNP) certificate. OSC, at 1. The OSC further alleged that Registrant's RN license expired on February 28, 2018, and her APNP certificate expired on September 30, 2018. *Id.* at 1-2.

The Show Cause Order notified Registrant of the right to request a hearing on its 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 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 1, 2-3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated April 2, 2019, a Diversion Investigator (hereinafter, DI) assigned to the Milwaukee District Office, Chicago Field Division, stated that she and a Special Agent (hereinafter, SA) travelled to Registrant's home address on February 6, 2019, to personally serve Registrant with the OSC. RFAA, Exhibit (EX) 4 (DI Declaration), at 1. The DI stated she "knew this was Registrant's home address because it was the address listed on her Wisconsin d[r]iver's license" and, upon arriving at the residence, the DI "recognized Registrant because [she] had previously met with her." *Id.* The DI further stated that she "personally served the [OSC] on Registrant by handing it to her" and "Registrant signed a DEA-12, Receipt for Cash or Other Items, acknowledging her receipt" of the OSC. *Id.*, *see also* RFAA, EX 4B (executed DEA-12).

The Government forwarded its RFAA, along with the evidentiary record, for adjudication on April 3, 2019. The Government represents that "at least thirty days have passed since the time the [OSC] was served on Registrant" and she "has not requested a hearing and has not otherwise corresponded or communicated with DEA." RFAA, at 2. The Government requests that "Registrant's DEA registration be revoked based on 21 U.S.C. 824(a)(3) because Registrant has no valid nursing license in Wisconsin." *Id.* at 3.

Based on the DI'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 February 6, 2019. 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 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

On February 17, 2010, DEA Certificate of Registration No. MW2120006 was assigned to Registrant at the registered address of 6001 W North Ave., Milwaukee, Wisconsin. RFAA, EX 5 (Certification of Registration History), at 1. This registration authorized Registrant to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expired on May 31, 2019. *Id.* According to Agency records, Registrant did not submit a renewal application and her registration was retired on July 1, 2019.¹

The Status of Registrant's State Licensure

On May 11, 2017, the Wisconsin BON issued a Final Decision and Order (hereinafter, collectively, Final Decision) restricting Registrant's RN license and APNP certificate.² RFAA, EX 3, at 3-5. On January 19, 2018, the BON determined that Registrant failed to comply with the Final Decision's restrictions and issued an Order, effective immediately, suspending both Registrant's RN license and her APNP certificate. RFAA, EX 3, at 9 (Order Suspending License).

¹ The fact that a Registrant allows her registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68474 (2019).

² In its Final Decision, the BON found that Registrant issued a controlled substance prescription to an individual who was not a patient at the pain clinic where Registrant was employed, substituted her cell number for the clinic's phone number, and did not maintain a treatment record at the clinic for that individual.

According to the website of the Wisconsin Department of Safety and Professional Services, of which I take official notice, Registrant's RN license and her APNP certificate remain suspended.³ Wisconsin Credential/License Search, <https://licensesearch.wi.gov/> (last visited January 3, 2020). The website also states that Registrant's RN license expired on February 28, 2018 and that her APNP certificate expired on September 30, 2018. Thus, neither Registrant's Wisconsin RN license nor her APNP certificate was current on the date the Assistant Administrator issued the OSC, and neither is current today.

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 27616, 27617 (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

³ 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) or by mail to Office of the Administrator, Attn: ADDO, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.

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.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton*, 43 FR at 27617.

In Wisconsin, an "advanced practice nurse" is a registered nurse who "has a current license to practice professional nursing" in Wisconsin. Wis. Admin. Code N § 8.02(1) (West, Westlaw current through Wisconsin Register 767B, published November 25, 2019). An "advanced practice nurse prescriber" is "an advanced practice nurse who has been granted a certificate to issue prescription orders" under Wis. Stat § 441.16(2). Wis. Admin. Code N § 8.02(2) (West, Westlaw current through Wisconsin Register 767B, published November 25, 2019).⁴

Under the Wisconsin Uniform Controlled Substances Act (hereinafter, Act), a person must have a federal controlled substances registration in order to lawfully dispense controlled substances in Wisconsin.⁵ Wis. Stat. § 961.32(1m)(a) (West, Westlaw current through 2019 Act 21, published November 14, 2019). The Act further provides that a "practitioner" includes an "advanced practice nurse . . . licensed, registered, certified or otherwise permitted to . . . dispense

⁴ An advanced practice nurse (hereinafter, APN) who meets the requisite education, training and examination requirements, and who pays the required fee, "shall [be] grant[ed] a certificate to issue prescription orders." Wis. Stat. § 441.16(2) (West, Westlaw current through 2019 Act 21, published November 14, 2019).

⁵ Under Wisconsin law, "dispensing" a controlled substance includes "prescribing" a controlled substance. Wis. Stat. § 961.01(7) (West, Westlaw current through 2019 Act 21, published November 14, 2019).

. . . a controlled substance in the course of professional practice." Wis. Stat. § 961.01(19)(a) (West, Westlaw current through 2019 Act 21, published November 14, 2019).

Here, the undisputed evidence in the record is that Registrant is not currently licensed as a RN or an APN, prerequisites for her to be licensed as an APNP. As such, she is not authorized to dispense controlled substances in Wisconsin, the state in which she is registered with the DEA. Since Registrant lacks authority to dispense controlled substances in Wisconsin, she is not eligible to hold a DEA registration. 21 U.S.C. 823(f). 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 MW2120006 issued to Theresa L. Wendt, N.P. I further hereby deny any pending application of Theresa L. Wendt, N.P. to renew or modify this registration, as well as any other applications of Theresa L. Wendt, N.P. for an additional registration in Wisconsin. 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

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