

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–29]

Lisa Hofschulz, N.P.; Decision and Order

On June 21, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Lisa Hofschulz, N.P. (hereinafter, Respondent) of Wauwatosa, Wisconsin. OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. MH1088182. *Id.* It alleged that Respondent is without "authority to handle controlled substances in Wisconsin, the state in which [Respondent is] registered with DEA." *Id.*

Specifically, the OSC alleged that Respondent's Wisconsin "Advance Practice Nursing Prescriber [hereinafter, APNP] license expired on September 30, 2018, and has not been renewed. As a result of the expiration of [her] APNP license, [Respondent] currently lack[s] the authority to handle controlled substances in Wisconsin." *Id.* at 1–2 (citing 21 U.S.C 802(21), 823(f), and 824(a)(3)).

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.* at 2–3 (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)).

By letter dated July 17, 2019, Respondent timely requested a hearing.¹ Hearing Request, at 1. In the Hearing Request, Respondent stated that "[o]n May 17, 2019, Respondent applied to transfer her DEA registration from the State of Wisconsin to the State of Florida" and that "Respondent has a current and active Nurse Practitioner license . . . in the State of Florida." *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). The ALJ issued an Order for Prehearing Statements, dated July 18, 2019. The Government timely complied with the Briefing Schedule by filing a Motion for

Summary Disposition on July 25, 2019 (hereinafter, Government Motion or Govt Motion). In its Motion, the Government submitted evidence that the Wisconsin Board of Nursing (hereinafter, Board) entered a Final Decision and Order with an attached Stipulation on April 12, 2018, which suspended Respondent's APNP following an investigation into unlawful prescribing practices, and Respondent therefore lacked authority to handle controlled substances in Wisconsin, the state in which she is registered with DEA. Govt Motion, at 1. The Government acknowledged that Respondent had requested a modification of her registration to Florida, but stated that the "Government's allegations in support of revocation of Respondent's [registration] pertain solely to Respondent's current authorization to handle controlled substances in Wisconsin [] and . . . do not address any denial of Respondent's pending application for modification of that [registration]." *Id.* at 4. In light of these facts, the Government argued that DEA must revoke her registration. Govt Motion, at 6.

On July 31, 2019, Respondent requested an extension of time to file her Prehearing Statement and Response to Government's Motion for Summary Disposition, which the ALJ granted that same day. *See* Respondent's Unopposed Motion for Extension and ALJ's Order Granting Respondent's Unopposed Motion for Extension. On August 5, 2019,² Respondent filed a Response in Opposition to Government's Motion for Summary Disposition (hereinafter, Resp Opposition). Respondent argued that "Under the Administrative Procedure[] Act ("APA"), "[w]hen the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.'" Resp Opposition, at 1 (quoting 5 U.S.C. 558). Respondent, therefore, argued that the Agency is obligated to act on Respondent's application for a registration in Florida. In the alternative, Respondent argued that even if the Agency decided that it must revoke Respondent's application, then it "should determine that the application for modification is not affected." *Id.* at 4.

On August 8, 2019, the ALJ issued an Order Granting the Government's Motion for Summary Disposition, and

Recommended Rulings, Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge (hereinafter, Summary Disposition or SD). The ALJ granted the Government Motion for Summary Disposition—finding that the only subject of the underlying action was Respondent's Wisconsin registration, Respondent had conceded that she had no authority in Wisconsin, and therefore, "summary disposition of an administrative case is warranted where, as here, 'there is no factual dispute of substance.'" SD, at 7 (citing *Veg-Mix, Inc. v. U.S. Dep't of Agric.*, 832 F.2d 601, 607 (D.C. Cir. 1987) ("[A]n agency may ordinarily dispense with a hearing when no genuine dispute exists." (citations omitted))). By letter dated September 4, 2019, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions. I find that the time period to file exceptions has expired. *See* 21 CFR 1316.66.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact*Respondent's DEA Registration*

Respondent is the holder of DEA Certificate of Registration No. MH1088182 at the registered address of 6163 Washington Circle, Wauwatosa, Wisconsin 53213. Govt Motion Exhibit (hereinafter, GX) 2, 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 October 31, 2021, and is currently in "active pending status." *Id.*

The Status of Respondent's State License

On April 12, 2018, the Wisconsin Board of Nursing issued a Final Decision and Order (hereinafter, Board Order), in which Respondent stipulated to facts and conclusions of law related to her prescribing practices. Respondent Exhibit (hereinafter, RX) C (Board Order). The Board Order was "effective on the date of its signing." *Id.* at 29. According to the Board Order, Respondent "engaged in unprofessional conduct . . . by departing from or failing to conform to the minimal standards of acceptable nursing practice that may create unnecessary risk or danger to a patient's life, health, or safety." *Id.* at 27. The Board suspended Respondent's professional nursing

¹ The Hearing Request was deemed filed on July 17, 2019. Order for Prehearing Statements, at 1. I find that the Government's service of the OSC was adequate and that the Hearing Request was timely filed on July 17, 2019.

² Respondent filed a Prehearing Statement on the same day.

license and advanced practice nurse prescriber certificate in Wisconsin for twenty-one (21) days, and further limited her license requiring that she “not practice pain management” and “not return to practice in the State of Wisconsin unless she provides written notification to the Board, or its designee, of intent to return to Wisconsin at least fifteen (15) days prior to return” at which time the Board “may impose additional limitations upon Respondent’s license.” *Id.* at 27–28.

According to Wisconsin’s online records, of which I take official notice, Respondent’s Advance Practice Nurse Prescriber license status is listed as “license is not current (Expired)” and further states “Not Eligible to Practice (See board order).”³ Wisconsin Department of Safety and Professional Services Credential/Licensing Search, <https://licensesearch.wi.gov> (last visited on date of this Order).

Based on the entire record before me, I find that Respondent currently is not licensed as an Advance Practice Nurse Prescriber in Wisconsin, the state in which Respondent is registered with DEA.

I further find, as recommended by the ALJ, that Respondent’s application for modification is not the subject of this proceeding, and agree that the Government did not challenge that application modification in its OSC. *See* OSC, at 1; *see also* SD, at 7–8.

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 (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[⁴] 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 in that state. *See, e.g., James L. Hooper, M.D.*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 F. App’x 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 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.

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, Current through Wisconsin Register 776B, published August 31, 2020). 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). *Id.* § 8.02(2).⁵

⁴ “[D]ispense[] means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance” 21 CFR 802(10).

⁵ An advanced practice nurse (hereinafter, APN) who meets the requisite education, training and examination requirements, and who pays the

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.⁶ Wis. Stat. § 961.32(1m)(a) (West, Current through 2019 Act 186, published April 18, 2020). The Act further provides that a “practitioner” includes an “advanced practice nurse . . . licensed, registered, certified or otherwise permitted to . . . dispense . . . a controlled substance in the course of professional practice.” *Id.* § 961.01(19)(a).

Here, the undisputed evidence in the record is that Respondent is not currently licensed as an APNP in Wisconsin. As such, she is not authorized to dispense controlled substances in Wisconsin, the state in which she is registered with the DEA. Because Respondent lacks authority to dispense controlled substances in Wisconsin, she is not eligible to hold a DEA registration in Wisconsin. 21 U.S.C. 823(f).

I agree with the ALJ’s finding that “[t]he subject of the instant litigation is not whether the Respondent has requested to modify her [registration] to reflect an address in Florida, but whether she has state authority to dispense controlled substances in the state in which her [registration] is currently registered, Wisconsin, which she concedes, she does not.” SD, at 7. The current issue before me is whether Respondent has state authority in Wisconsin, and I find that she does not. *See Parth S. Bharill*, 84 FR 39014 (2019).

Although she admitted that her Wisconsin APRN license expired about forty days before she asked DEA to change the address of her registration from Wisconsin to Florida, Respondent opposed the Government’s Motion for Summary Disposition and argued for my focus first to be on her request for a change of address. *Resp Opposition*, at 1. In doing so, as already discussed, Respondent suggested that I ignore the fact that the Show Cause Order I am adjudicating is based on Respondent’s lack of authority to dispense controlled substances in Wisconsin. 21 U.S.C. 823(f) (stating that a prerequisite to receiving a registration is having authorization to dispense controlled substances in the state of requested

required fee, “shall [be] grant[ed] a certificate to issue prescription orders.” Wis. Stat. § 441.16(2) (West, Current through 2019 Act 186, published April 18, 2020).

⁶ Under Wisconsin law, “dispensing” a controlled substance includes “prescribing” a controlled substance. Wis. Stat. § 961.01(7) (West, Current through 2019 Act 186, published April 18, 2020).

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, Respondent may dispute my finding by filing a properly supported motion for reconsideration of findings of fact 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 Respondent files a motion, the Government shall have fifteen calendar days to file a response. Any motion and response shall be filed and served by email to the other party and to the Office of the Administrator at dea.addo.attorneys@dea.usdoj.gov.

registration). Respondent made no argument that convinces me to ignore the statutorily mandated show cause order process or to limit the Agency's enforcement discretion and prerogatives by addressing her modification request based merely on a chronological sequence of events. 21 U.S.C. 823(c). The *Wedgewood Village Pharmacy* case Respondent cited explicitly articulates this process and DEA's enforcement discretion and prerogatives when it states that, "[w]hen an application for modification of an existing practitioner's registration is received by DEA, and before an approval may be given, DEA must determine whether there is any need to conduct a further investigative inquiry." *Wedgewood Village Pharmacy, Inc. v. Ashcroft*, 293 F. Supp. 2d, 462, 467 (D.N.J. 2003). Here, Respondent's loss of APRN authority in Wisconsin was reason "to conduct a further investigative inquiry." *Id.* Similarly, I reject Respondent's alternative argument that, even if I revoke her registration, "then the application for modification should continue and be granted." Resp Opposition, at 4.

Respondent suggested that, even if I revoke her registration, her requested modification should continue and either be granted or be the subject of an order to show cause and a demonstration that "granting the application is not in the public interest." *Id.* She did not, however, address how to implement the regulatory requirement of maintaining the modification with the "old certificate" until its expiration when the old certificate already expired due to revocation. 21 CFR 1301.51(c).

Respondent argued that the statement in 21 CFR 1301.51(c), that a "request for modification shall be handled in the same manner as an application for registration," means that the Agency is "required to register an applicant, unless it determines that the applicant's registration would be inconsistent with the public interest." Resp Opposition, at 2 (citing 21 U.S.C. 823). The further support Respondent provided for her argument is the *Wedgewood Village Pharmacy* federal district court decision. *Id.* (citing *Wedgewood Village Pharmacy, Inc. v. Ashcroft*, 293 F. Supp. 2d at 469).

Respondent's arguments ignore the entirety of 21 U.S.C. 823. That statutory provision premises a public interest analysis, in the first instance, on an applicant's existing authorization "to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Respondent admitted that she lacks authority to dispense controlled substances in

Wisconsin. Accordingly, if she were to apply for a registration in Wisconsin, the public interest portion of section 823 would not be reached due to her failure to meet the threshold eligibility requirements for a registration. Thus, Respondent's reliance on the district court's decision in *Wedgewood Village Pharmacy* is unavailing. Although *Wedgewood Village Pharmacy* retained its state authorization to dispense controlled substances during its litigation and, as such, its eligibility for a registration, Respondent has not.

Respondent did not address past Agency decisions concerning the precise portion of 21 CFR 1301.51(c) that she cited. Those decisions starkly show the weakness of Respondent's position. Most recently, my predecessor noted that this portion of the regulation "does not mean that a modification request is the same as an application for a new registration in every respect." *Parth S. Bharill, M.D.*, 84 FR 39014 n.2 (2019) (citing *Craig S. Morris, D.D.S.*, 83 FR 36966, 36967 (2018)). In *Craig S. Morris, D.D.S.*, my predecessor had noted that "[u]nlike a timely renewal application, a request to modify the registration address of an existing registration . . . does not remain pending after the registration expires, nor does it operate to extend when that registration expires." 83 FR at 36967.

Respondent also cited the Administrative Procedure Act (hereinafter, APA) as "clearly indicat[ing] a governmental policy, by which agencies must consider a timely application before terminating a current registration," and 21 CFR 1301.36(i) for the proposition that "as long as a current DEA registrant submits his renewal application in a timely manner, an Order to Show Cause in administrative revocation proceedings will not void the registration." Resp Opposition, at 2 (citing 5 U.S.C. 558 and *Wedgewood Village Pharmacy*, 293 F. Supp. 2d at 467). Both of these arguments fail because both section 558 of the APA and section 1301.36(i) of DEA's regulations concern applications for reregistration (renewal) or for a new registration. 5 U.S.C. 558 ("When the licensee has made timely and sufficient application for a renewal or a new license . . ."); 21 CFR 1301.36(i) ("In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration . . .").

Respondent's request under 21 CFR 1301.51(c) was not to renew or obtain a new registration. Her request was "for modification of her DEA registration, to change the address of her registration"

from Wisconsin to Florida. Resp Opposition, at 1. As discussed above, the regulations are clear that the request to modify is not an extension of an existing registration, but shall be handled in the same manner as an application. See *Cleveland J. Enmon, Jr. M.D.*, 77 FR 57,116, 57,125 (2012) ("[W]hile the address change request is pending with the DEA, the registrant is not authorized to handle controlled substances at the new location until the DEA approves the modification.").

Accordingly, I will order that Respondent's DEA registration in Wisconsin 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. MH1088182 issued to Lisa Hofschulz, N.P. This Order is effective January 11, 2021.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18-13]

George Pursley, M.D.; Denial of Application

I. Introduction

On December 1, 2017, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to George Pursley, M.D. (hereinafter, Applicant), of Augusta, Georgia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the denial of Applicant's application for a DEA certificate of registration on the ground that his registration "would be inconsistent with the public interest," citing 21 U.S.C. 823(f). *Id.*

The substantive grounds for the proceeding, as more specifically alleged in the OSC, are that Applicant unlawfully pre-signed and pre-printed prescriptions, committed violations of applicable federal and state recordkeeping requirements, unlawfully prescribed controlled substances, and, citing 21 U.S.C. 823(f)(5), did not exhibit candor during DEA's investigation. *Id.* at 2-8.

The OSC notified Applicant of his right to request a hearing on the