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Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Donna Winingham, MD; Decision and Order

On July 19, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Donna Winingham, M.D. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. AW1730729 in Templeton, CA 93465. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of California, the state in which [she is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of her right to file with DEA a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.¹ "A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

¹ Based on the Government's submissions in its RFAA dated September 26, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Government's included Notice of Service of Order to Show Cause indicates that Registrant was served with the OSC by certified mail on August 9, 2023. RFAAX 1, at 1; *see also id.* at 6.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective July 30, 2021, the Medical Board of California revoked Registrant's California medical license. RFAAX 2, at 2. According to California's online records, of which the Agency takes official notice, Registrant's California medical license remains revoked.² California DCA License Search, <https://search.dca.ca.gov/> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in California, the state in which she is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "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, 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, D.O.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, D.O.*, 43 FR 27616, 27617 (1978).³

² 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 the Agency's 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 and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

³ This rule derives from the text of two provisions of the Controlled Substances Act (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

According to California statute, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery." Cal. Health & Safety Code section 11010 (West 2024). Further, a "practitioner" means a person "licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in [the] state." *Id.* section 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant currently lacks authority to practice medicine in California and, therefore, is not currently authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency 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. AW1730729 issued to Donna Winingham, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Donna Winingham, M.D., to renew or modify this registration, as well as any other pending application of Donna Winingham, M.D., for additional registration in California. This Order is effective August 23, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 15, 2024, by Administrator Anne

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(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, 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 71371–72; *Sheran Arden Yeates, D.O.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, D.O.*, 58 FR 51104, 51105 (1993); *Bobby Watts, D.O.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton*, 43 FR 27617.

Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Carrie L. Madej, DO; Decision and Order

On May 15, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Carrie L. Madej, D.O. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. FM6088997 at the registered address of 527 Luther Bailey Road, Senoia, Georgia 30276. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the state of Georgia," the state in which Registrant is registered with DEA. *Id.* at 1-2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of her right to file with DEA a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.¹ "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

¹ Based on the Government's submissions in its RFAA dated October 12, 2023, the Agency finds that service of the OSC on the Registrant was adequate. Specifically, the submitted Declaration from a DEA Diversion Investigator indicates that Registrant was personally served with the OSC on May 25, 2023. RFAAX 2, at 1.

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, on January 4, 2023, Registrant surrendered her Georgia medical license, with the surrender made effective on January 6, 2023. RFAAX 1, at 1. According to Georgia online records, of which the Agency takes official notice, Registrant's Georgia medical license remains "Voluntarily Surrendered."² Georgia Composite Medical Board License Search, <https://gcmb.mylicense.com/verification> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Georgia, the state in which she is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "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, 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

² 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 the Agency's 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 and response shall be filed and served by email to the other party and to DEA Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, D.O.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, D.O.*, 43 FR 27616, 27617 (1978).³

According to Georgia statute, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery." Ga. Code Ann. section 16-13-21(9) (2023). Further, a "practitioner" means a "physician . . . or other person licensed, registered, or otherwise authorized under the laws of [Georgia] to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in [Georgia]." *Id.* section 16-13-21(23)(A).

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

³ This rule derives from the text of two provisions of the Controlled Substances Act (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(g)(1) (this section, formerly sec. 823(f), was redesignated as part of the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117-215, 136 Stat. 2257 (2022)). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, 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 71371-72; *Sheran Arden Yeates, D.O.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, D.O.*, 58 FR 51104, 51105 (1993); *Bobby Watts, D.O.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton*, 43 FR 27617.