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Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Richard Washinsky, M.D.; Decision and Order

On August 11, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC/ISO) to Richard Washinsky, M.D., (hereinafter, Registrant) of Las Vegas, Nevada. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2, at 1. The OSC/ISO informed Registrant of the immediate suspension of his DEA Certificate of Registration, Control No. BW3227318, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes "an imminent danger to the public health or safety." *Id.* The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant has "committed such acts as would render [his] registration inconsistent with the public interest" and that Registrant is "without authority to handle controlled substances in the State of Nevada, the state in which [he is] registered with DEA." ¹ *Id.* at 1, 3 (citing 21 U.S.C. 824(a)(4), 823(g)(1),² 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated February 6, 2023.³

¹ The registered address of Registrant's DEA Certificate of Registration, Control No. BW3227318, is 9010 West Cheyenne Avenue, Las Vegas, Nevada 89129. *Id.* at 2.

² Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117-215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

³ Based on the Declarations from two DEA Group Supervisors, the Agency finds that the Government's service of the OSC/ISO on Registrant was adequate. RFAAX 3, at 2-3; RFAAX 4, at 1-2. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC/ISO and Registrant has neither requested

I. Findings of Fact

On March 2, 2022, the Nevada State Board of Pharmacy issued an Order on Show Cause Hearing that immediately suspended Registrant's Nevada controlled substance license. RFAAX 3, Attachment C, at 1-2. On September 7, 2022, the Nevada State Board of Pharmacy issued a Stipulation and Order on Second Order to Show Cause that revoked Registrant's Nevada controlled substance license.⁴ RFAAX 3, Attachment F, at 1-2. According to Nevada's online records, of which the Agency takes official notice, Registrant's Nevada controlled substance license is still revoked.⁵ Nevada State Board of Pharmacy License Verification, https://bop.nv.gov/resources/ALL/License_Verification (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to handle controlled substances in Nevada, the state in which he is registered with the DEA.

The Agency further finds that the Government's evidence shows that Registrant continued to prescribe controlled substances after his Nevada controlled substance license was suspended, with Registrant issuing at least three prescriptions for controlled substances from at least March 4, 2022, through at least July 15, 2022. RFAAX 5, at 3-6, 9-12.

II. Discussion

A. 21 U.S.C. 824(a)(3): Loss of State Authority

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

a hearing nor submitted a corrective action plan and therefore has waived any such rights. RFAA, at 3; see also 21 CFR 1301.43 and 21 U.S.C. 824(c)(2).

⁴ The September 7, 2022 Stipulation Order further states "[Registrant] may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until . . . the Board reinstates his certificate of registration." *Id.*, at 2-3.

⁵ 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 Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

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 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).⁶

According to Nevada statute, "[e]very practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State shall obtain biennially a registration issued by the [State Board of Pharmacy] in accordance with its regulations." Nev. Rev. Stat. § 453.226(1) (2022). Further, Nevada statute defines a "practitioner" as a "physician . . . who holds a license to practice his or her profession in this State and is registered pursuant to [the Uniform Controlled Substances Act]." *Id.* at § 453.123(1). Finally, under Nevada statute, "dispense" means "to deliver a controlled substance to an ultimate user, patient 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." *Id.* at § 453.056(1).

Here, the undisputed evidence in the record is that Registrant's Nevada

⁶ 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(g)(1). 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.

controlled substance license is revoked. As discussed above, a physician must hold a controlled substance registration to dispense a controlled substance in Nevada. Accordingly, the Agency finds that Registrant is unauthorized to handle controlled substances in Nevada, the state in which he is registered with the DEA, and is therefore not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's registration be revoked.

B. 21 U.S.C. 823(g)(1): The Five Public Interest Factors

Section 304(a) of the CSA provides that "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37,507, 37,508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),⁷ the Government's evidence

in support of its *prima facie* case for revocation of Registrant's registration is confined to Factors A, B, and D. See RFAA, at 9–11. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Registrant's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a). The Agency further finds that Registrant failed to provide sufficient evidence to rebut the Government's *prima facie* case.

1. Factor A

In determining the public interest under Factor A, the Agency considers the recommendation of the appropriate state licensing board. Here, the state licensing board has taken disciplinary actions resulting in a loss of state authority, and one of those actions involved a matter that is a bases for the DEA OSC. See *Kenneth Harold Bull, M.D.*, 78 FR 62,666, 62,672 (2013); see also *George M. Douglass, M.D.*, 87 FR 67,497, 67,498 (2022); *John O. Dimowo*, 85 FR 15,800, 15,809 (2020). Specifically, the record shows that the Nevada State Board of Pharmacy revoked Registrant's state controlled substance license following a June 14, 2022 Second Order to Show Cause, which alleged that on March 4, 2022, Registrant prescribed a controlled substance even though his controlled substance license had been immediately suspended two days prior. RFAAX 3, Attachment F, at 2, 21.

In this matter, the Government has presented evidence establishing that Registrant issued three controlled substances prescriptions after his state controlled substance license was suspended: the March 4, 2022, prescription that resulted in the revocation of Registrant's state controlled substance license, and two others issued after the date of the Second Order to Show Cause. RFAAX 5, at 3–6, 9–12. The Nevada State Board of Pharmacy revoked Registrant's Nevada controlled substance license with less record evidence than is available here, and Registrant's Nevada controlled substance license has not since been restored. As such, the Agency finds that Factor A weighs against Registrant's continued registration.

within the parameters of Factors A, B, and D and does not raise "other conduct which may threaten the public health and safety." 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

2. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. See *Kareem Hubbard, M.D.*, 87 FR 21,156, 21,162 (2022). In the current matter, the Government has alleged that Registrant has violated both federal and Nevada state law regulating controlled substances. RFAAX 2 (OSC/ISO), at 3. According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). Further, Nevada law prohibits the dispensing of controlled substances without a Nevada controlled substance license. Nev. Rev. Stat. § 453.226(1) (2022).

Here, the record demonstrates that Registrant issued at least three controlled substance prescriptions after his Nevada controlled substance license was suspended, conduct in clear violation of Nevada law, which renders Registrant's prescribing outside the usual course of professional practice. As such, the Agency sustains the Government's allegations that Registrant violated 21 CFR 1306.04(a) and Nev. Rev. Stat. § 453.226(1).

In sum, the Agency finds that Factors A, B, and D weigh in favor of revocation of Registrant's registration and thus finds Registrant's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1).

III. Sanction

Where, as here, the Government has established grounds to revoke Registrant's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct

⁷ As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law "relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010). Agency cases have therefore found that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.* As to Factor E, the Government's evidence fits squarely

that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33,738, 33,746 (2021).

Here, Registrant did not request a hearing, submit a corrective action plan, respond to the OSC/ISO, or otherwise avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA nor demonstrated that he can be entrusted with registration. Moreover, the evidence presented by the Government clearly shows that Registrant violated the CSA and the Agency has found that Registrant is ineligible to maintain a DEA registration. *See supra* at II.A. Accordingly, the Agency will order the revocation of Registrant's registration.

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. BW3227318 issued to Richard Washinsky, 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 Richard Washinsky, M.D., to renew or modify this registration, as well as any other pending application of Richard Washinsky, M.D., for additional registration in Nevada. This Order is effective May 11, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 4, 2023, by Administrator Anne 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

Emed Medical Company LLC and Med Assist Pharmacy; Decision and Order

On September 15, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) proposing to revoke the registrations of and deny any pending applications of Emed Medical Company LLC and Med Assist Pharmacy (collectively Registrants).¹ Request for Final Agency Action (RFAA), Exhibit (RFAAX) 38 (OSC), at 1, 2, 3, 7. The OSC alleged that Registrants materially falsified multiple applications for registration and renewal. *Id.* at 2–6 (citing 21 U.S.C. 824(a)(1)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated February 10, 2023.²

I. Findings of Fact

a. Relationship Between Registrants

The OSC was addressed to both Emed Medical Company LLC and Med Assist Pharmacy. RFAAX 38, at 1. The Agency finds that for the purposes of this matter, Registrants are one and the same. The Missouri "Registration of Fictitious Name" documentation provides that Emed Medical Company LLC is the sole owner of Med Assist Pharmacy and identifies Eric Bailey, who is the sole owner and operator of Emed Medical Company LLC, as the point of contact. RFAAX 2; RFAAX 7, at 2. Further, both Agency records and publicly available Missouri records show that Registrants share a registered address and share a President/contact, Eric Bailey. RFAAX 1, at 2–3; RFAAX 3; RFAAX 4; RFAAX 5, at 1–2; RFAAX 6; RFAAX 34, at 1–2.

b. Registrants' Falsified Applications

At all times relevant to this matter (July 2007 through August 2022), the

¹ The OSC proposed to revoke Emed Medical Company LLC's Certificate of Registration No. RE0357271 at the registered address of 11551 Adie Road, Maryland Heights, Missouri 63043, and Med Assist Pharmacy's Certificate of Registration No. FM2022008 at the registered address of 11551 Adie Road, Maryland Heights, Missouri 63043.

² Based on a Declaration from a DEA Diversion Investigator, the Agency finds that the Government's service of the OSC on Registrants was adequate. RFAAX 39, at 2. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrants were served with the OSC and Registrants have neither requested a hearing nor submitted a corrective action plan and therefore have waived any such rights. RFAA, at 10; *see also* 21 U.S.C. 824(c)(2); 21 CFR 1301.43.

DEA "Application for Registration Under Controlled Substances Act of 1970" (Application) asked as a question regarding liability information: "3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" RFAAX 18, at 1; *see also* RFAAX 19–33, 37.

As part of a settlement agreement with the Missouri State Board of Pharmacy, Eric Bailey, signing on behalf of Emed Medical Products,³ agreed that Emed's license as a wholesale distributor would be placed on probation for two years beginning on or about January 17, 2003. RFAAX 7, at 1, 6, 9.⁴ Despite clear evidence of having had their wholesale distributor license placed on probation, Registrants answered "No" to liability question 3 for their initial application with DEA on July 7, 2007, and on each of the sixteen subsequent applications submitted by Registrants annually between 2008 and 2022. RFAAX 18–33, 37.

Moreover, the following events occurred but were never disclosed by Registrants in response to liability question 3 on any of their applications.⁵ *See* RFAAX 18–33, 37. On January 28, 2013, the State Board of Pharmacy of South Carolina temporarily suspended Emed Medical Company's pharmacy permit. RFAAX 10, at 1. Further, on January 22, 2019, the State Board of Pharmacy of South Carolina permanently revoked Emed Medical Company's pharmacy permit as a result of, among other things, a criminal

³ The record shows that in Missouri, Emed Medical Company does business as Emed Medical Products. RFAAX 16, at 1; (*compare* the registration numbers in RFAAX 7, at 2 with RFAAX 16, at 2).

⁴ The agreement settled an allegation that Mr. Bailey purchased medication through Emed for his personal use rather than for distribution. *Id.* at 2–3.

⁵ On September 14, 2012, Eric Bailey, on behalf of Emed Medical Company, entered into a Consent Agreement with the Maine Board of Pharmacy. RFAAX 9, at 1, 3. The Consent Agreement stated that "Emed Medical Company admit[ed] to failing to disclose disciplinary action to the Board for [its] initial Wholesaler application," and that based on that information, "the Board voted to preliminarily deny Emed Medical Company's application for licensure as a Wholesaler." *Id.* at 1, 2. However, the Consent Agreement also stated that because Emed Medical Company executed the Consent Agreement, "the Board [would] not deny Emed Medical Company's application . . . and [would] approve the application." *Id.* at 2. In the current matter, because there are various other grounds for revocation, the Agency does not have to determine whether the Maine Board of Pharmacy's vote to preliminarily deny was required to be disclosed on Registrants' DEA applications under the circumstances. This information is included here as background information.