

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–37]

Nicky Shah, M.D.; Decision and Order

On June 29, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) filed an Order to Show Cause (hereinafter, OSC) issued to Nicky Shah, M.D. (hereinafter, Respondent). OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BS6061345 at the registered address of 293 Corbett Ave., San Francisco, CA 94114. *Id.* The OSC alleged that Respondent's registration should be revoked because Respondent is “without authority to handle controlled substances in the State of California, the state in which [he is] registered with DEA.” *Id.* at 1–2 (citing 21 U.S.C. 824(a)(3)).¹

By email dated August 3, 2022, Respondent requested a hearing.² On August 23, 2022, the Government filed a Motion for Summary Disposition, which Respondent opposed. On September 13, 2022, the ALJ granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's registration and the denial of Respondent's request to renew his registration, finding that because Respondent lacks state authority to handle controlled substances in California, the state in which he is registered with DEA, there is no genuine issue of material fact. Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD), at 5–6.

The Agency issues this Decision and Order based on the entire record before it, 21 CFR 1301.43(e), and makes the following findings of fact.

Findings of Fact

On April 2, 2020, an Administrative Law Judge from the State of California, Office of Administrative Hearings, issued a Proposed Decision revoking Respondent's California medical license. Government Exhibit (hereinafter, GX) B, at 2, 12. On May 13,

2020, the Medical Board of California issued a Decision adopting the Administrative Law Judge's Proposed Decision, effective June 12, 2020. *Id.* at 1.

According to California's online records, of which the Agency takes official notice, Respondent's state medical license is revoked.³ Medical Board of California License Verification, <https://www.mbc.ca.gov/License-Verification> (last visited date of signature of this Order). Accordingly, the Agency finds that Respondent is not licensed to engage in the practice of medicine in California, the state in which he is registered with the DEA.

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 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).⁴

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 the Agency's finding by filing a properly supported motion for reconsideration of finding 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.usdoj.gov.

⁴ 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

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 2022). 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 this state.” *Id.* at section 11026(c).

Here, the undisputed evidence in the record is that Respondent 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 Respondent lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Respondent is not eligible to maintain a DEA registration based in California. Accordingly, the Agency will order that Respondent's DEA registration be revoked and that Respondent's request for renewal of his registration be denied.⁵

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

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 71371–72; *Sheran Arden Yeates, 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.

⁵ Respondent argued that his registration should be renewed because prior to the issuance of the OSC, he had requested to renew his registration with a change of registered address to Iowa, where he maintains an unrestricted, active medical license and an Iowa controlled substance registration. Resp Opposition, at 4–6; *see also* RX B–D. As the ALJ stated “[a]n attempt to modify the registered location of a [registration] is deemed an application for a new [registration].” RD, at 5 (citing 21 CFR 1301.51(c); *Gazelle A. Craig, D.O.*, 83 FR 27628, 27631 (2018)). Here, the subject of the current proceeding is Respondent's Certificate of Registration No. BS6061345, not Respondent's eligibility for a new registration based in Iowa. As such, it is only of consequence whether Respondent has state authority to handle controlled substances in California, the state in which Certificate of Registration No. BS6061345 is based.

¹ According to Agency records, Respondent's Certificate of Registration No. BS6061345 expired on February 28, 2022, and Respondent's request for renewal of his registration was received on April 1, 2022.

² On August 8, 2022, Respondent filed an additional hearing request document that included a more detailed response to the OSC.

of Registration No. BS6061345 issued to Nicky Shah, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Nicky Shah, M.D., to renew or modify this registration, as well as any other pending application of Nicky Shah, M.D., for additional registration in California. This Order is effective December 8, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, 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

George M. Douglass, M.D.; Decision and Order

On June 28, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC/ISO) to George M. Douglass, Jr., M.D., (hereinafter, Registrant) of Lake Oswego, Oregon. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2 (OSC/ISO), at 1. The OSC/ISO informed Registrant of the immediate suspension of his DEA Certificate of Registration, Control No. BD5898575, 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 Oregon, the state in which [he is] registered with DEA.”¹ *Id.* at 1, 3 (citing 21 U.S.C. 824(a)(4), 823(f), 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated September 20, 2022.²

I. Findings of Fact

On June 2, 2022, the Oregon Medical Board issued a Final Order Upon Default revoking Registrant's Oregon medical license. RFAAX 3, at 4, 7. According to Oregon's online records, of which the Agency takes official notice, Registrant's license is still revoked.³ Oregon Medical Board Licensee Search, <https://omb.oregon.gov/search> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not currently licensed to engage in the practice of medicine in Oregon, 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 Oregon medical license was revoked; he issued at least six controlled substance prescriptions from June 9–21, 2022. RFAAX 4.

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

¹ The registered address of Registrant's DEA Certificate of Registration, Control No. BD5898575, is 17355 Boones Ferry Road, Suite C, Lake Oswego, Oregon 97035. *Id.* at 2.

² Based on a Declaration from a DEA Diversion Investigator, the Agency finds that the Government's service of the OSC/ISO on Registrant was adequate. RFAAX 3, at 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 a hearing nor submitted a written statement or corrective action plan and therefore has waived any such rights. RFAA, at 2; *see also* 21 CFR 1301.43 and 21 U.S.C. 824(c)(2).

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 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.usdoj.gov.

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 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).⁴

According to Oregon 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, and includes the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.” Or. Rev. Stat. § 475.005(10) (2022). Further, a “practitioner” means a person “licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in [the] state.” *Id.* at § 475.005(17).

Here, the undisputed evidence in the record is that Registrant has had his Oregon medical license revoked and thus lacks authority to practice medicine in Oregon. As discussed above, an individual must be a licensed practitioner to dispense a controlled

⁴ 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 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.