

practice medicine in Texas, the state in which he is registered with DEA.³

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 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. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (“The Attorney General can register a physician to dispense controlled substances ‘if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.’ . . . The very definition of a ‘practitioner’ eligible to prescribe includes physicians ‘licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices’ to dispense controlled substances. § 802(21).”). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.*, 76 FR 71371, 71372 (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 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.” The material fact here is that Registrant, as of the date of this decision, is not licensed to practice medicine in Texas. Accordingly, Respondent 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.

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(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

According to Texas statute, “dispense” means “the delivery of a controlled substance in the course of professional practice or research, by a practitioner or person acting under the lawful order of a practitioner, to an ultimate user or research subject. The term includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.” Tex. Health & Safety Code Ann. section 481.002(12) (2024). Further, a “practitioner” includes “a physician . . . or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state.” *Id.* section 481.002(39)(A).

Here, the undisputed evidence in the record is that Respondent lacks authority to practice medicine in Texas. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in Texas. Thus, because Respondent lacks authority to practice medicine in Texas and, therefore, is not authorized to handle controlled substances in Texas, Respondent is not eligible to maintain a DEA registration. RD, at 6. Accordingly, the Agency will order that Respondent’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. BD9134254 issued to Willard J. Davis, D.O. 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 Willard J. Davis, D.O., to renew or modify this registration, as well as any other pending application of Willard J. Davis, D.O., for additional registration in Texas. This Order is effective April 28, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 20, 2025, by Acting Administrator Derek Maltz. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in

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 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, M.D.*, 43 FR 27617.

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.

[FR Doc. 2025–05166 Filed 3–26–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 25–9]

Joely Keen, A.P.R.N.; Decision and Order

On September 24, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Joely Keen, A.P.R.N., of The Woodlands, Texas (Respondent). OSC, at 1, 4. The OSC proposed the revocation of Respondent’s DEA Certificate of Registration No. MK4402210, alleging that Respondent’s DEA registration should be revoked because Respondent is “without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Texas, the state in which [she is] registered with DEA.” *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

On October 22, 2024, Respondent requested a hearing,¹ and on October 23, 2024, Respondent filed an Answer to the allegations in the OSC. *See* Order For Respondent To File Answer. On November 1, 2024, the Government filed a Motion for Summary Disposition, to which Respondent did not respond. On November 19, 2024, Administrative Law Judge Paul E. Soeffing (the ALJ) granted the Government’s Motion for Summary Disposition and recommended the revocation of Respondent’s registration, finding that because Respondent lacks state authority to handle controlled substances in Texas, the state in which

¹ Respondent initially responded to the OSC via email on October 18, 2024, but her email did not include a hearing request. *See* Respondent’s Request for Hearing (October 18, 2024). On October 21, 2024, the Administrative Law Judge (ALJ) directed Respondent to file a request for a hearing if she desired one, along with an answer to the allegations in the OSC. Order for Respondent to File Request for Hearing and Answer and for Government to File Evidence of Lack of State Authority.

she is registered with DEA, “there is no other fact of consequence for th[e] tribunal to decide.” 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 (RD), at 5–6. Respondent did not file exceptions to the RD.

Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ’s rulings, findings of fact, conclusions of law, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

Findings of Fact

According to Texas online records, of which the Agency takes official notice, Respondent’s Texas APRN license and Texas registered nurse license are revoked.² Texas Board of Nursing License Verification Portal, <https://txbn.boardsofnursing.org/licenselookup> (last visited date of signature of this Order). Accordingly, the Agency finds that Respondent is not currently licensed to practice as an APRN or registered nurse in Texas, the state in which she is registered with DEA.³

Additionally, as of March 27, 2024, Respondent has not had an active prescriptive authority agreement with a supervisory physician, which is required for an advanced practice registered nurse (APRN) in Texas to handle controlled substances. RD, at 4; 22 Tex. Admin. Code sections 193.7(a), 222.4(a)(1)(A), 222.5(a).⁴

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 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. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (“The Attorney General can register a physician to dispense controlled substances ‘if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.’ . . . The very definition of a ‘practitioner’ eligible to prescribe includes physicians ‘licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices’ to dispense controlled substances. § 802(21).”). The Agency has applied these principles consistently. See, e.g., *James L. Hooper, M.D.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App’x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27616, 27617 (1978).⁵

According to Texas statute, “dispense” means “the delivery of a controlled substance in the course of professional practice or research, by a practitioner or person acting under the lawful order of a practitioner, to an ultimate user or research subject. The term includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.” Tex. Health & Safety Code Ann. section 481.002(12)

⁵ 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). 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, M.D.*, 76 FR 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, M.D.*, 43 FR 27617.

(2024). Further, a “practitioner” includes “an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order a drug or device” *Id.* section 481.002(39)(D). Texas statute provides that “[a] physician may delegate to an advanced practice registered nurse or physician assistant, acting under adequate physician supervision, the act of prescribing or ordering a drug or device as authorized through a prescriptive authority agreement between the physician and the advanced practice registered nurse or physician assistant, as applicable.” Tex. Occ. Code Ann. section 157.0512(a) (2024).

Here, the undisputed evidence in the record is that Respondent lacks authority to handle controlled substances in Texas because her Texas APRN license and Texas registered nurse license have both been revoked. Respondent also lacks authority to handle controlled substances in Texas because she has not had an active prescriptive authority agreement with a supervisory physician since March 27, 2024. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in Texas, and for an advanced practice registered nurse to meet the definition of a practitioner, he or she must be delegated the authority to handle controlled substances via a prescriptive authority agreement with a supervisory physician.

Thus, because Respondent lacks authority to practice as an advanced practice registered nurse in Texas, Respondent is not authorized to handle controlled substances in Texas and is therefore not eligible to maintain a DEA registration. RD, at 5–6.

Accordingly, the Agency will order that Respondent’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. MK4402210 issued to Joely Keen, A.P.R.N. 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 Joely Keen, A.P.R.N., to renew or modify this registration, as well as any other pending application of Joely Keen, A.P.R.N., for additional registration in Texas. This Order is effective April 28, 2025.

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).

³ 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.” The material fact here is that Registrant, as of the date of this decision, is not licensed to practice medicine in Texas. Respondent may dispute this fact 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.

⁴ See also Government’s Notice of Filing of Evidence and Motion for Summary Disposition, Exhibit 1.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 18, 2025, by Acting Administrator Derek Maltz. 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.

[FR Doc. 2025-05164 Filed 3-26-25; 8:45 am]

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No.1519]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Baxter Research Lab

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 27, 2025.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instruction at that site for

submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulation. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as bulk manufacturer of marihuana the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on August 20, 2024, Baxter Research Lab, 5200 North Lake Road, Merced, California 95343-5001, applied to be registered as bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

Matthew Strait,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No. DEA-1522]

Importer of Controlled Substances Application: Patheon API Services, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Services, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 28, 2025. Such persons may also file a written request for a hearing on the application on or before April 28, 2025.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement