

denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .” *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.*, 80 FR 28643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51592, 51601 (1998)). In fact, the Agency has found in favor of revocation in cases where registrants have failed to document their prescribing decisions—a violation which has been clearly established in this case. The Agency has repeatedly emphasized that “[c]onscientious documentation is . . . not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician’s prescribing practices are within the usual course of professional practice.” *Cynthia M. Cadet, M.D.*, 76 FR 19,450, 19,464 (2011) (internal citation and quotation omitted); *see also Kaniz F. Khan-Jaffery, M.D.*, 85 FR 45,667, 45,686 (2020) (“DEA’s ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.”).

The case at hand demonstrates prescribing beneath the applicable standard of care and outside the usual course of professional practice in California to multiple patients over the course of many years. I agree with the Chief ALJ that this conduct was egregious and I agree with his rationale for sanction. As stated above, for many reasons, I cannot find that I can entrust Respondent with a registration.

Accordingly, I reject Respondent’s Exceptions and affirm the RD’s conclusion that Respondent’s registration should be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. BC1317165 issued to Bradley H. Chesler, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending application of Bradley H. Chesler, M.D., to renew or modify this registration, as well as any other pending application of Bradley H. Chesler, M.D. for registration

in California. This Order is effective March 2, 2022.

Anne Milgram,
Administrator.

[FR Doc. 2022–01838 Filed 1–28–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–947]

Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Siegfried USA, LLC. has applied to be registered as a bulk manufacturer 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 file written comments on or objections to the issuance of the proposed registration on or before April 1, 2022 Such persons may also file a written request for a hearing on the application on or before April 1, 2022.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 8, 2021, Siegfried USA, LLC., 33 Industrial Park Road, Pennsville, New Jersey 08070–3244, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid ..	2010	I
Dihydromorphine	9145	I
Hydromorphanol	9301	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Oripavine	9330	II

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Opium tincture	9630	II
Oxymorphone	9652	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substance in bulk for development of a new active pharmaceutical ingredient (API) and validation for a Drug Master File submission to the Food and Drug Administration. No other activity for this drug code is authorized for this registration.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2022–01816 Filed 1–28–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–4]

Austin J. Kosier, M.D.; Decision and Order

On September 30, 2021, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Austin J. Kosier, M.D. (hereinafter, Respondent) of Zanesville, Ohio. OSC, at 1 and 3. The OSC proposed the revocation of Respondent’s Certificate of Registration No. FK6714504. It alleged that Respondent “[does] not have authority to dispense or prescribe controlled substances in the [s]tate of Ohio, the state in which [Respondent is] registered with DEA.” *Id.* at 1 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about May 12, 2021, the State Medical Board of Ohio issued an Order suspending Respondent’s state license to practice medicine and surgery. *Id.* at 2. The Order was effective immediately and ordered that Respondent “immediately cease the practice of medicine and surgery in Ohio.” *Id.*

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 (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)).

On October 25, 2021, Respondent timely requested a hearing by email.¹ Administrative Law Judge Exhibit (hereinafter, ALJX) 4 (Request for Hearing). Respondent's Request for Hearing also indicated that Respondent was "considering the submission of a corrective action plan." *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ). On October 25, 2021, the ALJ issued a Briefing Schedule. *See* ALJX 5. The Government timely complied with the Briefing Schedule by filing a Notice of Filing of Evidence and Motion for Summary Disposition (hereinafter, Motion for Summary Disposition) on November 10, 2021. 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 2; *see also* ALJX 6. In its Motion for Summary Disposition, the Government requested summary disposition and recommended that Respondent's DEA registration be revoked based on Respondent's lack of authority to handle controlled substances in Ohio, the state in which he is registered with the DEA. Motion for Summary Disposition, at 5. On November 30, 2021, Respondent untimely filed a Memorandum in Opposition of Respondent [sic] to Government's Motion for Summary Disposition (hereinafter, Respondent's Opposition). RD, at 2; *see also* ALJX 7.² Respondent's Opposition argued that there "does not exist and [sic] mandate under the [Controlled Substances Act] whereas [the] tribunal shall or must revoke or suspend the [DEA registration] of a physician under a state summary suspension." Respondent's Opposition, at 1. Respondent's Opposition also noted that Respondent's state medical license, though suspended, was still

¹ Though the Request for Hearing itself is undated, the record indicates that the Request for Hearing was filed on October 25, 2021. *See* Order Directing the Government to File Evidence Regarding its Lack of State Authority Allegation and Briefing Schedule (hereinafter, Briefing Schedule), at 1. I find that the Government's service of the OSC was adequate and that the Request for Hearing was timely filed on October 25, 2021.

² As a result of Respondent's untimely filing, on November 30, 2021, the ALJ issued an Order to Show Good Cause Regarding Respondent's Late Filing (hereinafter, Order to Show Good Cause). *See* ALJX 8. On November 30, 2021, Respondent timely filed a Response to Order to Show Good Cause stating that the untimely filing was due to a death in Respondent's counsel's family. RD, at 2; *see also* ALJX 9. The ALJ found that "the delay was minimal and caused no prejudice to the Government" and thus accepted Respondent's Opposition. RD, at 2.

intact;³ that "[t]he issue that led to his current case [was] unrelated to the practice of medicine and was in no way arose [sic] in the course and scope of practice";⁴ and that "[Respondent] has had no previous issues in any way with his medical license in the past." *Id.* Moreover, Respondent's Opposition highlighted "the unbelievable work [Respondent] has done and is continuing to do within the medical community and specifically an online training and tutorial platform for health care practitioners and medical students around the world." *Id.* at 2–3. Finally, Respondent's Opposition highlighted that Respondent "has also taken [the] opportunity to maintain and enhance his own medical education" with CME courses. *Id.* at 3. Respondent's Opposition sought the denial of the Government's Motion for Summary Disposition and for the Tribunal to either grant Respondent's request for a hearing or to stay the matter pending the outcome of the Ohio Medical Board hearing. *Id.*

On December 2, 2021, the ALJ granted the Government's Motion for Summary Disposition, finding that "[t]here is no genuine issue of material fact in this case" because "[t]he Government has established that Respondent currently lacks a medical license." RD, at 7–8. The ALJ recommended that Respondent's DEA registration be revoked and that any application to renew or modify his DEA registration be denied "because Respondent lacks state authority to handle controlled substances in Ohio." *Id.* at 8. By letter dated December 27, 2021, the ALJ certified and transmitted the record to me for final Agency action. Transmittal Letter, at 1. The ALJ also advised that neither party filed exceptions. *Id.*

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

According to Agency records, Respondent is the holder of DEA Certificate of Registration No. FK6714504 at the registered address of

³ According to Respondent's Opposition, the Ohio Medical Board "issued a summary suspension pending the outcome of a Medical Board Hearing in January of 2022." *Id.* at 2. Further, according to Respondent's Opposition, the suspension "was based on a provision in the Ohio Administrative Code that allows the Ohio Medical Board to summarily suspend a license of a physician based on [the] physician's entry into an intervention program to address a mental health matter" and "[t]he matter at hand with [Respondent] is his ongoing struggle with his homosexuality." *Id.*

⁴ *See supra* n.3.

2916 Vangader Dr., Zanesville, OH 43701. Pursuant to this registration, Respondent is authorized to dispense controlled substances in Schedules II through V as a practitioner. Respondent's registration expires on December 31, 2022.

The Status of Respondent's State License

On May 12, 2021, the State Medical Board of Ohio (hereinafter, the Board) issued a Notice of Summary Suspension and Opportunity for Hearing (hereinafter, Summary Suspension) and an Entry of Order. Government Exhibit (hereinafter, GX) A, at 3 and 5. According to the Summary Suspension, on or about December 16, 2019, "the Franklin County Court of Common Pleas filed an indictment alleging [Respondent] had committed attempted unlawful sexual contact with a minor" on or about September 10, 2019. *Id.* Further, according to the Summary Suspension, "[o]n or about November 13, 2020, [Respondent] appeared before the Court for a hearing on [his] application for intervention in lieu of conviction for these offenses" and "[t]he Court granted [Respondent's] application." *Id.* The Summary Suspension states that "[Respondent] pleaded guilty to [the] felony offenses at a subsequent hearing held on or about December 9, 2020" and "[t]he Court ordered further proceedings be stayed while [Respondent was] under community control." *Id.* In its Entry of Order on May 12, 2021, the Board found that "[Respondent's] continued practice presents a danger of immediate and serious harm to the public" and ordered, effective immediately, that Respondent's license to practice medicine and surgery in the state of Ohio be summarily suspended, that Respondent "immediately cease the practice of medicine and surgery in Ohio," and that Respondent "immediately refer all active patients to other appropriate physicians." *Id.* at 3.

According to Ohio's online records, of which I take official notice, Respondent's medical license is still suspended and inactive.⁵ Ohio License

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, Respondent may dispute my finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the

Look Up, https://elicense.ohio.gov/oh_verifylicense (last visited date of signature of this Order). Accordingly, I find that Respondent is not currently licensed to practice medicine in Ohio, 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 71,371 (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 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 27617.

Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner’s registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the final outcome of the underlying action may still be pending. What is consequential is my finding that Respondent is not currently authorized to dispense controlled substances in Ohio, the state in which he is registered with the DEA.

Under Ohio law, “[n]o person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog,” except⁶ pursuant to a “prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical purpose.” Ohio Rev. Code Ann. § 2925.11(A), (B)(1)(d) (West 2021). Ohio law further states that a “[l]icensed health professional authorized to prescribe drugs’ or ‘prescriber’ means an individual who is authorized by law to prescribe drugs or dangerous drugs . . . in the course of the individual’s professional practice.” *Id.* at § 4729.01(I). The definition further provides a limited list of authorized prescribers, the relevant provision of which is “[a] physician authorized under Chapter 4731 of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.” *Id.* at § 4729.01(I)(5). In addition, the Ohio Uniform Controlled Substances Act permits “[a] licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional’s practice” to prescribe or administer schedule II, III, IV, and V controlled substances to patients. *Id.* at § 3719.06(A)(1)(a)–(b).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to practice medicine in Ohio. As already discussed, a physician is authorized by law to prescribe or administer drugs in Ohio only when authorized to practice medicine and

surgery under Ohio law. Thus, because Respondent lacks authority to practice medicine in Ohio and, therefore, is not authorized to handle controlled substances in Ohio, Respondent is not eligible to maintain a DEA registration. Accordingly, I 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. FK6714504 issued to Austin J. Kosier, 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 application of Austin J. Kosier, M.D. to renew or modify this registration, as well as any other pending application of Austin J. Kosier, M.D., for additional registration in Ohio. This Order is effective March 2, 2022.

Anne Milgram,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–946]

Importer of Controlled Substances Application: Mylan Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Mylan Pharmaceuticals 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 file written comments on or objections to the issuance of the proposed registration on or before March 2, 2022. Such persons may also file a written request for a hearing on the application on or before March 2, 2022.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield,

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.

⁶Other irrelevant exceptions omitted.