

Controlled substance	Schedule
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
1-Piperidinocyclohexanecarbonitrile (8603)	II
Alphaprodine (9010)	II
Anileridine (9020)	II
Etorphine HCl (9059)	II
Dihydrocodeine (9120)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Ethylmorphine (9190)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Metazocine (9240)	II
Metopon (9260)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Dihydroetorphine (9334)	II
Levo-alphaacetylmethadol (9648)	II
Noroxymorphone (9668)	II
Phenazocine (9715)	II
Piminodine (9730)	II
Racemethorphan (9732)	II
Racemorphan (9733)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Tapentadol (9780)	II
Bezitramide (9800)	II
Moramide-intermediate (9802)	II

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: November 19, 2015.

Louis J. Milione,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

William Mikaitis, M.D.; Decision and Order

On July 23, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to William Mikaitis, M.D. (Registrant), of Lockport, Illinois. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration AM1585770, and the denial of any applications to renew or modify the registration as well as any other applications for a DEA registration, on the ground that he "do[es] not have authority to practice medicine or handle controlled substances in Illinois, the [S]tate in which [he] is registered with the DEA." Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

The Show Cause Order alleged that Registrant is registered with the DEA as a practitioner authorized to handle controlled substances in Schedules II through V at the registered address of 1206 E. 9th St., Suite 210, Lockport,

Illinois. *Id.* The Order alleged that Registrant's registration expires by its terms on January 31, 2018. *Id.*

The Order further alleged that "[e]ffective March 5, 2015, the State of Illinois, Department of Financial and Professional Regulation (IDFPR), Division of Professional Regulation, issued an Order in which the IDFPR temporarily suspended [his] Illinois [P]hysician and [S]urgeon [L]icense and [his] controlled substance licenses" and that "[t]his Order remains in effect." *Id.* The Show Cause Order thus asserted that "DEA must revoke [his] registration based upon [his] lack of authority to handle controlled substances in the State of Illinois." *Id.* (citing 21 U.S.C. 802(21), 823(f) and 824(a)(3)).

The Show Cause Order also notified Registrant of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43).

On July 30, 2015, a Diversion Investigator met Registrant at the office of his attorney and personally served the Show Cause Order on him. *See* GX 5 (Affidavit of DI). The Government

represents that since the date of service, neither Registrant, nor any person purporting to represent him, has requested a hearing or submitted a written statement while waiving his right to a hearing. See Govt. Req. for Final Agency Action, at 3–4. Because more than thirty (30) days have now passed since the date of service of the Show Cause Order and Registrant has neither requested a hearing nor submitted a written statement in lieu of a hearing, I find that he has waived his right to either request a hearing or to submit a written statement. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on the record submitted by the Government. *Id.* § 1301.43(e). I make the following findings.

Findings

Registrant is the holder of DEA Certificate of Registration AM1585770, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a practitioner, at the registered address of 1206 E. 9th St., Suite 210, Lockport, Illinois. GX 2. His registration does not expire until January 31, 2018. *Id.*

On March 5, 2015, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation, ordered the suspension of Respondent's Illinois Physician and Surgeon License, as well as his state Controlled Substance Licenses, pending proceedings before the Department of Financial and Professional Regulation and the Medical Disciplinary Board of the State. GX 4 at 1. I take official notice that as of this date, the public Web site maintained by the Illinois Department of Financial and Professional Regulation shows that Registrant's Physician and Surgeon License as well as his Illinois Controlled Substance Licenses remain suspended based on the State's allegations that he engaged in “unprofessional conduct, aid[ed] and abet[ed] [the] unlicensed practice of medicine and [committed] multiple violations of the Controlled Substance Act.”¹ See <https://ilesonline.idfpr.illinois.gov/DPR/Lookup/LicenseLookup.aspx>.

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, “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.” Moreover, DEA has repeatedly 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 *James L. Hooper*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. App'x 826 (4th Cir. 2012).

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 . . . to dispense . . . controlled substances . . . 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 Act, DEA has long held that the 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 medicine. See, e.g., *Calvin Ramsey*, 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988).

This is so even where a state board has suspended a practitioner's authority prior to providing the practitioner with a hearing to contest the board's allegations. See *Gary Alfred Shearer*, 78 FR 19009 (2013) (holding that revocation is warranted even where a state order has summarily suspended a practitioner's controlled substances authority and the state agency's order remains subject to challenge in either administrative or judicial proceedings); see also *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007); *Winfield Drugs, Inc.*, 52 FR 27070 (1987). Accordingly, consistent with agency precedent, the revocation of Registrant's registration is warranted.

Because Registrant currently lacks authority to dispense controlled substances in Illinois, the State in which he holds his DEA registration, I will order that his registration be revoked and that any pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b), I order that DEA Certificate of Registration AM1585770, issued to William Mikaitis, M.D., be, and it hereby is, revoked. I further order that any pending application of William Mikaitis, M.D., to renew or modify his registration, as well as any other pending application of William Mikaitis, M.D., for a DEA Certificate of Registration, be, and it hereby is, denied. This Order is effective immediately.²

Dated: November 17, 2015

Chuck Rosenberg,
Acting Administrator.

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DEPARTMENT OF JUSTICE

[OMB Number 1117–0034]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Collection of Laboratory Analysis Data on Drug Samples Tested by Non-Federal (State and Local Government) Crime Laboratories

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: 60-day Notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. **DATES:** Comments are encouraged and will be accepted for 60 days until January 25, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection

¹ Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

² Based on the State's finding “that Respondent's actions constitute an immediate danger to the public,” I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.