

Dated: March 13, 2019.

Melody Braswell,

*Department Clearance Officer for PRA, U.S.
Department of Justice.*

[FR Doc. 2019-04968 Filed 3-15-19; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joel A. Smithers, D.O.; Decision and Order

On November 15, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Joel A. Smithers, D.O. (Registrant), of Martinsville, Virginia. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration No. FS4850459 on the ground that he "has no state authority to handle controlled substances." Government Exhibit (GX) 2 (Order to Show Cause) to Government's Request for Final Agency Action (RFAA), at 1 (citing 21 U.S.C. 824(a)(3)). For the same reason, the Order also proposed the denial of "any applications for renewal or modification of such registration and any applications for any other DEA registrations." *Id.*

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Registrant is the holder of Certificate of Registration No. FS4850459, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 445 Commonwealth Blvd. East, Suite A, Martinsville, Virginia. *Id.* The Order also alleged that this registration does not expire until February 29, 2020. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on May 10, 2018, the Virginia Board of Medicine issued "an Order of Summary Suspension" that suspended Registrant's Virginia osteopathic medical license. *Id.* The Show Cause Order alleged that, as a result, he is "currently without authority to handle controlled substances in the Commonwealth of Virginia, the [S]tate in which [he is] registered with the DEA." *Id.* Based on his "lack of authority to handle controlled substances in the Commonwealth of Virginia," the Order asserted that "DEA must revoke" his registration. *Id.* at 1-2 (citing 21 U.S.C. 824(a)(3); 21 CFR 1301.73(b)). *Id.*

The Show Cause Order notified Registrant of (1) his right to request a

hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id.* at 2. (citing 21 CFR 1301.43). The Order also notified Registrant of his right to submit a corrective action plan. *Id.* at 2-3 (citing 21 U.S.C. 824(c)(2)(C)).

With respect to service, a Task Force Officer (TFO) in the Roanoke Resident Office of DEA's Washington Field Division executed a Declaration on February 4, 2019, stating that she "personally served Registrant with the" Show Cause Order on November 20, 2018. GX 4 (Declaration of TFO) to RFAA, at 1.

On February 5, 2019, the Government forwarded its Request for Final Agency Action and evidentiary record to my Office. In its Request, the Government represents that more than 30 days have passed since Registrant had been served with the Show Cause Order and that "Registrant has not requested a hearing and has not otherwise corresponded or communicated with DEA regarding the Order served on him." RFAA, at 1. Based on the Government's representation and the record, I find that more than 30 days have passed since the Show Cause Order was served on Registrant, and he has neither requested a hearing nor submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(d). Accordingly, I find that Registrant has waived his right to a hearing or to submit a written statement and issue this Decision and Order based on relevant evidence submitted by the Government and the findings below. *See id.* I make the following findings.

Findings of Fact

Registrant is the holder of DEA Certificate of Registration No. FS4850459 pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner at the registered address of 445 Commonwealth Blvd. East, Suite A, Martinsville, Virginia. GX 1 (Certification of Registration Status) to RFAA, at 1. This registration does not expire until February 29, 2020. *Id.*

In addition, I take official notice of an "Order of Summary Suspension" (Suspension Order) on the Virginia Board of Medicine's website,¹ which

¹ *See* http://www.dhp.virginia.gov/Notices/Medicine/0102204264/0102204264_Order05102018.pdf. 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). In accordance with the APA

states that on May 10, 2018, the Executive Director of the Virginia Board of Medicine entered an order that Registrant's Virginia license to practice osteopathic medicine "is SUSPENDED." Suspension Order, at 1. In its Suspension Order, the Virginia "Board conclude[d] that a substantial danger to public health or safety warrants this action." *Id.* The Suspension Order also stated that it would apply to Registrant's "multistate licensure privilege, if any, to practice osteopathic medicine in the Commonwealth of Virginia." *Id.* Finally, the Suspension Order ordered "that a hearing be convened within a reasonable time of the date of entry of this Order to receive and act upon evidence in this matter." *Id.*

I also take official notice of the results of a search of the Virginia Board of Medicine's license verification web page showing that, as of the date of this Decision, Registrant's Virginia medical license remains suspended.² There is no evidence in the record that the Virginia Board of Medicine ever issued a superseding order or decision ending the suspension of Registrant's medical license. Accordingly, I find that Registrant currently does not possess a license to practice medicine in the Commonwealth of Virginia, 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 (CSA), "upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." Also, DEA has 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*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826

and DEA's regulations, Registrant is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Registrant the opportunity to refute the facts of which I take official notice, Registrant may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed. The Government also attached an identical (but unverified) copy of the Suspension Order as an exhibit to its Request for Final Agency Action. GX 3 (Suspension Order) to RFAA.

² *See* <https://dhp.virginiainteractive.org/Lookup/Detail/0102204264>. I take official notice pursuant to the authority set forth *supra* in footnote 1.

(4th Cir. 2012); *see also Frederick Marsh Blanton*, 43 FR 27616 (1978) (“State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.”).

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 Act, DEA has long held 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 engages in professional practice. *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); *Blanton*, 43 FR 27616 (1978).

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 at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State’s use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the Virginia Board of Medicine summarily suspended Registrant’s state medical license.

What is consequential is my finding that Registrant is no longer currently authorized to dispense controlled substances in the Commonwealth of Virginia, the State in which he is registered. Specifically, the Virginia Board of Medicine’s decision to suspend

Registrant’s medical license also means that Registrant is currently without authority to dispense controlled substances under the laws of Virginia. *See, e.g., Va. Code Ann. §§ 54.1–2409.1* (2017) (felony to prescribe controlled substances without a current valid license); 54.1–2900 (2017); 54.1–3401 (2016). Accordingly, Registrant is not entitled to maintain his DEA registration, and I will therefore order that his registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. FS4850459, issued to Joel A. Smithers, D.O., be, and it hereby is, revoked. I further order that any pending application of Joel A. Smithers to renew or modify the above registration, or any pending application of Joel A. Smithers for any other DEA registration in the Commonwealth of Virginia, be, and it hereby is, denied. This Order is effective April 17, 2019.

Dated: February 27, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–05013 Filed 3–15–19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Sharp (Bethlehem), LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 17, 2019. Such persons may also file a written request for a hearing on the application on or before April 17, 2019.

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, Virginia 22152. All requests for a hearing should also 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.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on January 04, 2019, Sharp (Bethlehem), LLC, 2400 Baglyos Circle, Bethlehem, Pennsylvania 18020 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
3,4-Methylenedioxymethamphetamine.	7405	I
Psilocybin	7437	I

The company plans to import the listed controlled substances for clinical trials. Approval of permit applications will occur only when the registrant’s activity is consistent with what is authorized under to 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: March 5, 2019.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

William A. Sanpablo, M.D.; Decision and Order

On December 3, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to William A. Sanpablo,