

certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Stepan Company registration as a manufacturer of those controlled substances.

**SUPPLEMENTARY INFORMATION:** By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22555, Stepan Company, Natural Products Department, 100 W. Hunter Avenue, Maywood, New Jersey 07607 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Stepan Company to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cocaine (9041) .....	II
Ecgonine (9180) .....	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Dated: April 4, 2016

**Louis J. Milione,**

*Deputy Assistant Administrator.*

[FR Doc. 2016-08576 Filed 4-13-16; 8:45 am]

**BILLING CODE 4410-09-P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.**

**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 in accordance with 21 CFR 1301.33(a) on or before June 13, 2016.

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

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated her 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 Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on January 13, 2016, Patheon API Manufacturing, Inc., 309 Delaware Street, Building 1106, Greenville, South Carolina 29605 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360) .....	I
Tetrahydrocannabinols (7370) .....	I
Noroxymorphone (9668) .....	II

The company plans to manufacture the above-listed controlled substances as Active Pharmaceutical Ingredients (API) for clinical trials.

In reference to drug codes 7360 (marihuana), and 7370 (THC), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drug codes are authorized for this registration.

Dated: March 29, 2016.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. 16-7]

**Rezik A. Saqer, M.D.; Decision and Order**

On October 1, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Rezik A. Saqer, M.D., (Respondent). The Show Cause Order proposed the revocation of Respondent's DEA Certificates of Registration BS4072637 and FS1975359, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the respective registered locations of 11037 FM 1960 West, Suite B1, Houston, Texas, and 3074 College Park Drive, Conroe, Texas. Show Cause Order, at 1. The Show Cause Order further proposed the denial of any applications to renew or modify either registration, as well as the denial of any other application for a DEA registration. *Id.*

More specifically, the Show Cause Order alleged that "[e]ffective September 28, 2015, the Texas Medical Board issued an Order of Temporary Suspension . . . which suspended [Respondent's] medical license," and therefore, he is currently "without authority to handle controlled substances in Texas, the State in which [he is] registered with" DEA. *Id.* at 2. The Show Cause Order thus advised Respondent that "DEA must revoke [his] registrations based upon [his] lack of authority to handle controlled substances in the State of Texas." *Id.* (citing 21 U.S.C. 802(21), 823(f), and 824(a)(3)).

On October 2, 2015, a Diversion Investigator served the Show Cause Order by travelling to Respondent's registered location in Houston, and leaving it with a medical assistant, who provided a signed receipt for the Order. Affidavit of DI, at 1. On November 5, 2015, Respondent, through his counsel, requested a hearing on the allegations of the Show Cause Order.<sup>1</sup> The matter was then placed on the docket of the Office of Administrative Law Judges, and

<sup>1</sup> While Respondent's request was untimely, Respondent's counsel subsequently filed a motion which established that his secretary had attempted to file the hearing request by UPS overnight delivery, but had provided an incorrect address. DEA has previously held that this type of inadvertence may establish "good cause" to excuse an untimely hearing request, at least when the party promptly moves to rectify the omission. *Tony Bui*, 75 FR 49979, 49980 (2010).

assigned to the Chief Administrative Law Judge (hereinafter, CALJ).

In the same filing which contained his hearing request, Respondent also sought a “brief stay” of the proceeding, stating that a hearing on the Texas Medical Board’s (TMB) emergency suspension order was to commence on November 19, 2015. Respondent further expressed his expectation that “[o]n or shortly after that date . . . the [TMB] will issue an order regarding his challenge to the temporary suspension.” Respondent’s Req. for Hrng. and Mot. for Brief Stay of Admin. Proceedings, at 1.

The next day, the CALJ denied Respondent’s request for a stay and ordered the Government to provide evidence in support of the allegation that Respondent lacks state authority and any accompanying motion, no later than 2 p.m. on November 23, 2015. CALJ Order, at 2 (Nov. 6, 2015). The CALJ also ordered that if the Government filed such a motion, Respondent’s Reply would be due no later than 2 p.m. on December 3, 2015. *Id.*

On November 18, 2015, the Government filed its Motion for Summary Disposition. Therein, the Government argued that it was undisputed that Respondent’s medical license has been suspended by the State, and while Respondent argued that the TMB was to hold a hearing on the suspension, whether and when the TMB would lift its order was “a matter of speculation.” Mot. at 3. The Government thus argued that even where a registrant’s state authority has been temporarily suspended, revocation of his registration is still warranted because the registrant must possess authority to handle controlled substances under state law in order for the Agency to maintain his registration. *Id.* at 3–4. As support for its Motion, the Government attached the Order of Temporary Suspension (Without Notice of Hearing), which was issued to Respondent by the TMB’s Disciplinary Panel on September 28, 2015.

On December 3, 2015, Respondent filed its Opposition to the Government’s Motion. Therein, he argued that both the Controlled Substances Act (CSA) and DEA’s regulations require that if a registrant “requests a hearing, the agency is required to provide such a hearing.” Resp. Opp., at 1 (citing 21 U.S.C. 824(c); 21 CFR 1301.36(d) and 1301.37(d)). He also argued that “[t]here are no provisions in DEA’s regulations or the CSA that allow for summary disposition whereby Respondent’s right to a hearing is denied.” *Id.* And he argued that Title 5 (the Administrative Procedure Act) “requires an ‘agency

hearing’ in every case in which a statute requires adjudication to be determined on the record,” and that 5 U.S.C. 554 does not contain “an exception for ‘summary disposition.’” *Id.* at 2.

Respondent also argued that the Agency’s position that the possession of state authority is a condition for maintaining a DEA registration is based on a misreading of the term “practitioner,” *id.* at 3–4, which the CSA defines as meaning “a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices to . . . dispense . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). More specifically, Respondent argued that because the definition uses the disjunctive “or,” rather than the conjunctive of “and,” this “clearly signals Congress’ intent that a practitioner is one who either has state authority or federal authority to prescribe or dispense controlled substances.” *Id.* at 4. And finally, Respondent argued that under 21 U.S.C. 843(a), the Agency “may revoke a registration based on the suspension or revocation of state authority to dispense controlled substances, not that it must revoke based on those allegations.” *Id.* at 5. Respondent then contended that granting summary disposition was “inappropriate” because he “intend[ed] to present evidence that his registration is consistent with the public interest notwithstanding the status of [sic] state license,” and he “is challenging the loss of his state authority and until his rights are exhausted, there exists a real prospect that his state authority will be reinstated.” *Id.*

Finding that “no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances,” the CALJ concluded that because Respondent lacks such authority, “Agency precedent dictates that he is not entitled to maintain his DEA registration.” Order Granting Govt. Mot. for Summ. Disp., at 9. Noting that “there is no contested factual matter adducible at a hearing that would, in the Agency’s view, provide authority to allow the Respondent to continue to hold his” registration, the CALJ granted the Government’s motion for summary disposition and recommended that his “registration be revoked” and that “any pending applications for renewal be denied.” *Id.* at 9–10 (bold and capitalization deleted).

Respondent filed Exceptions to the CALJ’s Order and the Government filed a Response to Respondent’s Exceptions. Thereafter, the record was forwarded to

me for Final Agency Action. Having considered the record including Respondent’s Exceptions, I adopt the CALJ’s finding that Respondent lacks authority under Texas law to handle controlled substances, and his conclusion of law that Respondent is not entitled to maintain his registration. For reasons explained below, I will also adopt the ALJ’s recommendation but only with respect to Respondent’s Certificate of Registration BS4072637. I make the following findings.

### Findings of Fact

Respondent is the holder of DEA Certificate of Registration BS4072637, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the address of 11037 FM 1960 West, Suite B1, Houston, Texas. Mot. for Summ. Disp., at Attachment 2. Under this registration, Respondent is also authorized to treat up to 100 patients as a DATA-waived physician. *Id.* This registration does not expire until February 28, 2018. *Id.*

Respondent also previously held DEA Certificate of Registration FS1975359, pursuant to which he was authorized to dispense controlled substances in schedules II through V, as a practitioner, at the address of 3074 College Park Drive, Conroe, Texas. Mot. for Summ. Disp., at Attachment 3. This registration was due to expire on February 29, 2016, *id.*, and according to the registration records of this Agency of which I take official notice, Respondent has not filed a timely renewal application (let alone any application to renew this registration).<sup>2</sup> Accordingly, I find that this registration has expired. See 21 CFR 1301.36(i).

Respondent is also the holder of Texas Medical License No. K–2282. *In re Saqer*, Order of Temporary Suspension (Without Notice of Hearing), at 1 (Tex. Med. Bd. Sept. 28, 2015). However, on September 28, 2015, the Disciplinary Panel of the Texas Medical Board entered an Order of Temporary Suspension against Respondent’s medical license following an *ex-parte* hearing on the Board’s Application for

<sup>2</sup> 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 and DEA’s regulations, Respondent 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 Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within ten calendar days of service of this order which shall commence on the date this order is mailed.

Temporary Suspension (Without Notice of Hearing). *Id.* at 4.

As the basis for the Order, the Panel found that on September 22, 2015, a search warrant was executed at a pain management clinic owned by Respondent, during which DEA agents “obtained evidence establishing that Respondent pre-signed treatment notes, pre-signed prescriptions and illegally maintained schedule II controlled substances in his personal office.” *Id.* at 2. The Panel also found “that patients of [the clinic] were sometimes seen by unlicensed individuals that would fill in the records and prescriptions to make it appear that Respondent had seen the patient and written the prescription.” *Id.* The Panel thus found that “Respondent engaged in illegal activities related to his operation of [the clinic], and engaged in the inappropriate prescribing, dispensing, or administering of controlled substances, and therefore Respondent has committed violations of state and federal law, including the Medical Practice Act and Board Rules.” *Id.*

The Panel concluded that “Respondent’s continued practice of medicine, including improper and illegal activities related to his operation of a pain management clinic, and including the method and manner in which controlled substances were prescribed and maintained, poses a continuing threat to public welfare.” *Id.* Based on these findings, the Panel found “a continuing threat to the public health, safety, or welfare that requires immediate effect of this Order of Temporary Suspension on the date rendered.” *Id.* And after setting forth its legal conclusions that Respondent violated multiple provisions of the Medical Practice Act, the Panel ordered that Respondent’s medical license be suspended. *Id.* at 3–4.

On November 19, 2015, the Disciplinary Panel conducted a hearing at which Respondent appeared and was represented by counsel. *In re Saqer*, Order of Temporary Suspension (With Notice of Hearing), at 1 (Tex. Med. Bd. Nov. 19, 2015). However, following the hearing, the Board made the same factual findings and legal conclusions as it had at the *ex parte* proceeding, *see id.* at 1–4, and it again ordered the temporary suspension of Respondent’s medical license. *Id.* According to the online records of the Texas Medical Board, the suspension remains in effect. I therefore find that Respondent is currently without authority to dispense controlled substances in Texas, the State in which he is engages in professional practice and holds his DEA registration.

## Discussion

### *Respondent’s Contention That DEA Cannot Use Summary Disposition to Adjudicate This Matter*

As explained above, in his Opposition to the Government’s Motion, Respondent contends that because he requested a hearing, under the Agency’s regulation, the Agency was required to provide him with a hearing. *Opp.* at 1–3. He further contends that there are no provisions in either the CSA or the Agency’s regulations that allow for summary disposition, thereby denying him his right to a hearing. *Id.* at 2–3.

However, numerous courts, including the Supreme Court, have held that even where a statute directs an agency to provide a party with a hearing, the agency can nonetheless resolve the matter on summary disposition when there are no material facts in dispute. *See, e.g., Veg-Mix, Inc. v. Department of Agriculture*, 832 F.2d 601, 607 (D.C. Cir. 1987). As the DC Circuit explained in *Veg-Mix*, “[c]ommon sense suggests the futility of hearings where there is no factual dispute of substance.” *Id.*<sup>3</sup> *See also NLRB v. International Ass’n of Bridge, Structural and Ornamental Ironworkers*, 549 F.2d 634, 639 (9th Cir. 1977) (“‘It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory, even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks.’”) (quoting *United States v. Consolidated Mines & Smelting Co., Ltd.*, 455 F.2d 432, 453 (9th Cir. 1971)).<sup>4</sup> *Cf. Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 620–22 (1973) (upholding agency’s authority to dispense with a formal hearing where applicant has not

<sup>3</sup> While Respondent noted that the Agency’s rules regarding the conduct of hearings do not include a provision which expressly authorizes the use of summary disposition, this Agency has used summary disposition to resolve proceedings based on a registrant’s loss of his/her state authority for nearly 40 years. *See, e.g., Alfred Tennyson Smurthwaite, N.D.*, 43 FR 11873 (1978). There are hundreds of such cases reported in the **Federal Register**. Contrary to Respondent’s contention that the Agency cannot rely on summary disposition in the absence of a regulation which expressly allows for it, “[i]t is well established that agencies are free to announce and develop rules in an adjudicatory setting.” *Puerto Rico Aqueduct and Sewer Auth. v. EPA*, 35 F.3d 600 607 (1st Cir. 1994) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974)).

<sup>4</sup> *See also Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994) (quoting *Consolidated Mines*, 455 F.2d at 453).

provided any evidence that it meets statutory standards).

Notably, while Respondent was given the opportunity to demonstrate the existence of a factual dispute as to whether he retains state authority, he could not do so, as even after he was allowed to appear before the Board and challenge the temporary suspension of his license, the Board re-imposed the suspension. However, even in the absence of a disputed material fact, Respondent contends that “summary disposition [was] inappropriate,” because he “intend[ed] to present evidence that his registration is consistent with the public interest notwithstanding the status of [his] state license.” *Opp.* at 5. The short answer to this argument is that even if Respondent could show that his registration is consistent with the public interest, his lack of state authority precludes his continued registration under the CSA, and it is the Government and not Respondent who decides what ground or grounds to pursue when seeking the revocation of his registration.

### **Respondent’s Challenge to the Agency’s Authority To Revoke His Registration**

Respondent nonetheless maintains that the Agency’s rule that a practitioner’s loss of his “state authority is an automatic bar to maintaining a DEA registration” is based “on a misreading of the CSA.” *Resp. Exceptions*, at 1–2. In his *Exceptions*, Respondent contends that “[f]or proceedings seeking the revocation of a DEA registration, the [A]gency derives its authority from 21 U.S.C. 824, not 21 U.S.C. 823, and 21 U.S.C. 824 does not support the [A]gency’s position that it must revoke a DEA registration in all instances where a registrant lacks state authority.” *Id.* at 2.

To be sure, section 824(a) states, in relevant part, that “[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or list I chemical may be suspended or revoked . . . upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution or dispensing of controlled substances or list I chemicals.” 21 U.S.C. 824(a)(3). Thus, Respondent is correct that section 824 grants the Attorney General discretion and does not mandate the revocation of a “registration in all instances where a registrant lacks state authority.” *Resp. Exceptions*, at 2.

Indeed, in *Bio-Diagnostic International*, 78 FR 39327 (2013), a

case involving a list I chemical distributor which did not possess state authority, the Agency held that granting summary disposition to the Government on this basis was improper because neither the provision setting forth the standards for the registration of list I distributors, nor the definition of a distributor, requires that a distributor possess state authority in order to be registered.<sup>5</sup> While *Bio-Diagnostic* involved an application, in a footnote, the decision explained that while “section 824(a)(3) authorizes revocation where a registrant ‘has had [its] State license suspended, revoked, or denied by competent state authority and is no longer authorized by State law to engage in the manufacturing [or] distribution of . . . list I chemicals[.]’ [this] does not mean that revocation is warranted in all instances.” *Id.* at 39330 n.6. Continuing, the decision explained that “[t]his provision grants the Agency discretionary authority to impose an appropriate sanction; the failure to consider factors such as the egregiousness of the misconduct and mitigating factors in imposing the sanction would render the sanction arbitrary and capricious.” *Id.*

Respondent is not, however, a List I chemical distributor. Rather, he is a practitioner, and by contrast to the CSA’s provisions applicable to list I distributors, both the CSA’s definition of the term “practitioner” and the registration provision applicable to practitioners make clear that a practitioner must be currently authorized to dispense controlled substances by the State in which he practices in order to obtain and maintain a registration.

As for the registration provision applicable to practitioners, it provides, in relevant part, 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). As the Supreme Court explained in *United States v. Moore*, 423 U.S. 122, 140–41 (1975), “[r]egistration of physicians and other practitioners is mandatory if the applicant is authorized to dispense drugs . . . under the law of the State in which he practices. [21 U.S.C.] § 823(f). In the case of a physician, this scheme contemplates that he is authorized by

the State to practice medicine and to dispense drugs in connection with his professional practice.”<sup>6</sup>

Thus, the CSA defines “[t]he term ‘practitioner’ [to] mean[] a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices to . . . dispense . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). As noted above, in his Opposition, Respondent argued that “[t]he use of the disjunctive ‘or’ clearly signals Congress’ intent that a practitioner is one who either has state authority or federal authority to prescribe or dispense controlled substances[.]” and that “[h]ad Congress required that a practitioner maintain both state and federal authority to handle controlled substances, it would have used the word ‘and.’” Resp. Opp. at 4. Continuing, Respondent argued that “[w]hile it is not entirely clear why Congress took this approach . . . the clear statutory language” refutes the Government’s argument that “a lack of state licensure [is] an automatic bar to maintaining a DEA registration.” *Id.*

Respondent is mistaken. As for why Congress used the disjunctive rather than the conjunctive in defining the term practitioner, notwithstanding the absence of any relevant discussion in the CSA’s legislative history, there is an explanation. While the overwhelming majority of practitioners who practice medicine (or dentistry and veterinary medicine) are subject to regulation by the State in which they practice their professions, multiple federal Departments and Agencies (*e.g.*, the Department of Defense, Veterans Administration, Bureau of Prisons, United States Public Health Service, and Indian Health Service) employ practitioners. However, by virtue of the Supremacy Clause, these health-care professionals are not subject to regulation by the State in which the federal facility is located as long they confine their practice to the facility. See *Taylor v. United States*, 821 F.2d 1428, 1431 (9th Cir. 1987) (noting that under the Supremacy Clause, a State “lacks power to require licensing of federal health care providers and physicians” and that “[t]he United States has essentially deemed [an] Army [h]ospital and its staff fit to provide health care services”); *United States v. Composite State Bd. of Med. Exmn’rs*, 656 F.2d

131, 135 n.4 (5th Cir. 1981) (citing *Sperry v. Florida ex rel. Florida Bar*, 373 U.S. 379 (1963)) (“A State may not enforce licensing requirements that, though valid in the absence of federal regulation, give the state’s licensing board a virtual power of review over the federal determination that a person is qualified to perform certain functions.”).

Thus, Congress used the word “or” only to distinguish between those practitioners who practice at federal facilities and are subject to the licensing requirements of the United States,<sup>7</sup> and the vast majority of practitioners who are subject to the licensing requirements of the State in which they practice their profession. And while the Agency has exempted from “[t]he requirement of registration . . . any official of” the military, the Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties,” 21 CFR 1301.23(a), these practitioners otherwise remain subject to the Act. See, *e.g.*, 21 U.S.C. 829(a) (“Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the [FDCA], may be dispensed without the written prescription of a practitioner, except [for] in emergency situations, as prescribed by . . . regulation . . . .”); 21 CFR 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”).

Respondent further asserts that “[h]ad Congress required that a practitioner maintain both state and federal authority to handle controlled substances, it would have used the word ‘and.’” Resp. Opp. at 4. Were this the case, any practitioner who is no longer

<sup>7</sup> As a general matter, federal entities that employ physicians require only that the physician hold a medical license in one of the 50 States. See U.S. Public Health Service, Job Requirements (available at [www.usphs.gov/profession/physician/requirements.aspx](http://www.usphs.gov/profession/physician/requirements.aspx)) (requiring that a physician have a “[c]urrent, unrestricted, and valid medical license to practice in one of the 50 states; Washington, DC; Commonwealth of Puerto Rico; U.S. Virgin Islands; or Guam”); Indian Health Service, Indian Health Manual, Part 3–1.4(C)(5) (“Members of the medical staff and others who must apply for clinical privileges must hold an active and unrestricted State license, certification, or registration, as applicable, to practice in their professional field.”); VA Careers (available at [www.vacareers.va.gov/careers/physicians/credentially.asp](http://www.vacareers.va.gov/careers/physicians/credentially.asp)) (“At VA, only one active, unrestricted state license is required to practice in every VA facility across all 50 States, the District of Columbia, and U.S. Territories.”).

<sup>5</sup> The decision did note, however, that where a list I distributor was required to obtain state authority and had not done so, this could be considered under the public interest factor which examines “compliance by the applicant with applicable Federal, State and local law.” 78 FR at 39330–31 (quoting 21 U.S.C. 823(h)(2)).

<sup>6</sup> While in 1984 Congress granted the Attorney General authority to deny a registration on public interest grounds, the provision did not alter the CSA’s requirement that a practitioner must be “authorized by the State to practice medicine” and dispense drugs in order to be registered.

authorized to practice medicine by his State (even those who engaged in drug dealing) would nonetheless still be allowed to dispense controlled substances under their federal registration. The argument is, however, refuted by the CSA's definition of the term "dispense" to "mean[] 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 and administering of a controlled substance." 21 U.S.C. 802(10) (emphasis added). Because Respondent is required to possess state authority to dispense controlled substances in Texas, and by virtue of the Board's Order, no longer holds such authority, he cannot issue a "lawful order" to deliver a controlled substance. And he therefore no longer meets the requirement for being a registered practitioner under the Act.

Respondent further argues that "had Congress wanted the lack of a state license to be an automatic bar to maintaining a DEA registration, it would have used the word 'shall'" rather than "may" in section 824. He argues that "if DEA understood that to be what Congress intended the agency could have added lack of state licensure to one of the grounds for immediate termination of a DEA registration found in 21 CFR 1301.52(a). It chose not to [sic], presumably because DEA knew it had no such authority." Resp. Opp. at 4–5.

It is not clear, however, why using the word "shall" rather than "may" would make any difference, as section 824(a) grants the Agency authority to either revoke or suspend. Moreover, were it the case that section 824(a) used the word "shall," the Agency would be mandated to either suspend or revoke a registration upon making one of the enumerated findings, regardless of how persuasive a registrant's showing was on issues of remediation where, as in a proceeding brought under the public interest authority, such a showing is authorized.

As this Agency has previously explained, Section 824(a)'s grant of authority to suspend or revoke a registration applies across all categories of registration, including manufacturers, distributors, importers, exporters, narcotic treatment programs, list I distributors, and practitioners. And it applies to five different grounds for sanctioning a registrant. As the Agency has previously explained, "this general grant of authority in imposing a sanction must be reconciled with the CSA's specific provisions which mandate that a practitioner hold authority under state law in order to

obtain and maintain a DEA registration." *James L. Hooper*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, *Hooper v. Holder*, 481 Fed. App'x 826 (4th Cir. 2012). *See also Gozlon-Peretz v. United States*, 498 U.S. 395, 407 (1991) ("A specific provision controls over one of more general application."); *Bloate v. United States*, 559 U.S. 196, 207 (2010) ("language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment.'").

Thus, in *Hooper v. Holder*, a physician whose state authority was suspended for a period of one year, challenged the revocation of his registration, arguing that the Agency "failed to recognize the discretion under § 824(a) to revoke or suspend a registration and that it was impermissible for the [Agency] to conclude that the CSA requires revocation of a practitioner's DEA registration when the practitioner's State license is suspended." 481 Fed. App'x, at 826. The Fourth Circuit rejected the physician's challenge, explaining:

We find Hooper's contention unconvincing. Section 824(a) does state that the [Agency] may "suspend or revoke" a registration, but the statute provides for this sanction in five different circumstances, only one of which is loss of a State license. Because § 823(f) and § 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Agency's] decision to construe § 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA. The [Agency's] decision does not "read[] the suspension option" out of the statute, because that option may still be available for the other circumstances enumerated in § 824(a).

*Id.*<sup>8</sup> *See also Maynard v. DEA*, 117 Fed. Appx. 941, 945 (5th Cir. 2004) (upholding revocation of DEA registration after Texas DPS summarily suspended practitioner's controlled substance registration, noting that the Agency "has construed the CSA to require revocation when a registrant no longer possesses valid state authority to handle controlled substances"; "We agree with [the] argument that it may have been arbitrary and capricious had

<sup>8</sup> As for Respondent's contention that if Congress intended that lack of a state license should be an automatic bar, the Agency could have made this a ground for immediate termination without a hearing, the argument ignores that by requiring the Agency to serve a Show Cause Order on the registrant, and affording the registrant an opportunity to respond, the procedures reduce the risk of an erroneous deprivation. *See Mathews v. Eldridge*, 424 U.S. 319 (1976).

the DEA failed to revoke [the physician's] registration under the circumstances.'").

Indeed, DEA has interpreted the CSA in this manner for nearly 40 years. *See Frederick Marsh Blanton, M.D.*, 43 FR 27616 (1978). In *Blanton*, a physician's state license was suspended for a period of one year. *Id.* at 27616. The Agency nonetheless revoked the physician's registration, explaining that "it is the Administrator's finding and conclusion that there is a lawful or statutory basis for the revocation of the Respondent's DEA registration. *State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.* The Respondent's registration must, therefore, be revoked." *Id.* at 27617 (emphasis added). *See also Alfred Tennyson Smurthwaite*, 43 FR at 11873 (same). Moreover, on various occasions, Congress has amended the CSA, including in 1984, when it granted the Agency the authority to revoke a practitioner's registration on the ground that he had committed acts inconsistent with the public interest. *See Drug Enforcement Amendments to the Comprehensive Crime Control Act of 1984. See P.L. 98–473, § 512, 98 Stat. 1838, 2073 (1984).* Yet it has left the Agency's interpretation intact. *See NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 275 (1974).

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). Indeed, as this case demonstrates, state proceedings can go on for an extended period, and thus, it is not DEA's policy to hold revocation proceedings in abeyance while practitioners challenge Board decisions which suspend or revoke their state authority.

Respondent argues, however, that "the agency's decision [in *Odette Campbell*, 80 FR 41062 2015]] to remand the matter and allow administrative proceedings to be conducted by the ALJ (and ultimately hold proceedings in abeyance), pending the outcome of state board proceedings[,] undermines . . . the agency's notion that it must revoke a DEA registration in all instances where a registrant lacks state authority, rendering an administrative hearing unnecessary." Exceptions at 2. Respondent then asserts that "[w]hile the agency conjured up a Due Process

argument to support its decision in [*Campbell*], in doing so it implicitly held that lack of state authority is not an automatic bar to holding a DEA registration.” *Id.* Respondent further asserts that “[w]hile declaring that Due Process was the basis for this decision, the only outcome that could have been reached in that case, if the [A]gency followed its own case law, was the revocation of Dr. Campbell’s DEA registration as the DEA proceedings would not have changed the fact that she did not have state authority to handle state authority to handle controlled substances.” *Id.* at 2–3.

Respondent’s reliance on *Campbell* is unavailing because he ignores critical aspects of the case’s procedural history. For one, the case began when DEA issued an Order to Show Cause and Immediate Suspension of Registration (ISO) to the physician, which was based on allegations that she violated various provisions of the Controlled Substances Act. 80 FR at 41063 n.3. Thereafter, the Texas Medical Board suspended her medical license and the Texas Department of Public Safety suspended her state controlled substance registration based on the Agency’s issuance of the ISO. *Id.* The Government then moved for summary disposition on the ground that the physician lacked authority to dispense controlled substances under Texas law and the ALJ granted the motion. *Id.*

While the matter was under review, the physician submitted a letter to the ALJ (which was forwarded to the Administrator), in which she asserted that the Medical Board had reinstated her license. *Id.* After the Government responded by letter to the ALJ that the physician was still without state authority because her DPS registration had been revoked, Respondent submitted a letter to the ALJ asserting that her DPS registration could not be reinstated unless her DEA registration was reinstated. *Id.*

Noting that parties had directed their letters to each other and the ALJ, and that neither party had sought relief from her, the former Administrator directed the Government to file a properly supported motion seeking a final order based on the physician’s lack of state authority. *Id.* The Government filed its request, which Respondent opposed, arguing that because the DPS’s action was based on the unsubstantiated allegations of the ISO, it was fundamentally unfair and a denial of due process to revoke her DEA registration based on the DPS’s action. *Id.*

On further review, the former Administrator observed that “it

appeared that under Texas law and regulations, Respondent was not entitled to a hearing before the DPS to challenge either the DPS’s suspension or the denial of her application for a new registration.” *Id.* (citing Tex. Health & Safety Code § 481.063(e)(3) & (h); *id.* § 481.066(g); 37 Tex. Admin. Code § 13.272(h)). The Administrator then explained that “if this was so, revoking her [DEA] registration based on her lack of state authority would preclude her from ever being able to challenge the basis of the Immediate Suspension Order.” *Id.* The Administrator thus remanded the case, instructing the ALJ “to first determine whether the DPS would provide [the respondent] with a hearing on the allegations.” *Id.* The Administrator further instructed that if the DPS had provided or would provide respondent with a hearing, the Government could renew its motion for summary disposition. *Id.* However, if DPS would not provide her with a hearing, the ALJ was to conduct a hearing on the allegations of the Show Cause Order and ISO. *Id.*

In short, there was nothing “conjured up” in the Agency’s due process rationale, which recognized only that due to the vagaries of Texas law,<sup>9</sup> the Agency’s litigation strategy might well result in the respondent having no meaningful opportunity to challenge the allegations which both the Agency and the DPS had relied on in suspending their respective registrations. As for Respondent’s contention that revocation was “the only outcome that could have been reached . . . as the DEA proceedings would not have changed the fact that she did not have state authority to handle controlled substances,” Respondent ignores that DPS imposed its suspension based solely on the Agency’s ISO and that if the physician succeeded in challenging the ISO, the basis for the DPS’ suspension would no longer exist. And Respondent further ignores that in her remand order, the Administrator provided that the Government could move for summary disposition if it could show that DPS would provide the physician with a hearing.<sup>10</sup>

<sup>9</sup> See Tex. Health & Safety Code § 481.066(g) (State Administrative Procedure Act “does not apply to a . . . suspension of a registration for a cause described by Section 481.063 . . . (e)(3),” which includes the suspension of a registration under the CSA); 37 Tex. Admin. Code § 13.272(h) (“Under the Act, § 481.063(h), the [State Administrative Procedure Act] does not apply to a denial, suspension, or revocation of an application for registration if the denial is based on a denial or other disciplinary action taken by DEA under the Federal Controlled Substances Act.”).

<sup>10</sup> As for Respondent’s assertion that the Administrator’s decision to hold the *Campbell* case

Accordingly, I reject Respondent’s contentions.<sup>11</sup> Because Respondent lacks state authority to dispense controlled substances, he is not entitled to maintain his DEA registration. I will therefore order that his remaining registration be revoked.

### Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(3) and 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BS4072637 issued to Rezik A. Saqer, M.D., be, and it hereby is, revoked. I further order that any application by Rezik A. Saqer, M.D., for registration in the State of Texas, be, and it hereby is, denied. This Order is effective immediately.<sup>12</sup>

in abeyance, pending the outcome of state board proceedings, “undermines . . . the [A]gency’s notion that it must revoke a DEA registration in all instances where a registration lacks state authority.” Exceptions at 2. Respondent ignores that at the time the proceeding was held in abeyance, the physician (who had been indicted on multiple counts of health care fraud) had allowed her registration to expire and had only an application pending before the Agency. Moreover, the physician then held both a state license and state controlled substance registration. See 80 FR at 41063. The case thus does not support Respondent’s contention.

<sup>11</sup> Respondent also points to a provision of the DEA Pharmacist’s Manual, which allows an entity to obtain a registration for a pharmacy it is acquiring prior to the State’s issuance of a pharmacy license for that location. Opp. at 5. Respondent asserts that “[w]hile the Agency is permitted to interpret its regulations, it is not free to contradict its long-standing policy that a state license is not a prerequisite to obtaining a DEA registration when doing so is simply a convenient litigation position designed to prevent a registrant from proving that the underlying state action was erroneous.” *Id.* at 5–6.

However, the Pharmacist’s Manual makes clear that provision applies only “[i]f the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred,” and that while the registrant may take possession of the controlled substances, “the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license.” DEA, Pharmacists Manual, at 10 (2010) (emphasis added). This policy exists because some States will not grant a pharmacy license to the acquiring pharmacy until DEA issues it a registration. However, the period in which the registrant is without the state license for the acquired pharmacy is typically of short duration.

As for Respondent’s assertion that the Agency’s position “is simply a convenient litigation position designed to prevent a registrant from proving that the underlying state action was erroneous,” not only is this refuted by nearly 40 years of precedent (and hundreds of cases), the Agency has also made clear in multiple cases that a challenge to a state board proceeding must be litigated in the forums provided by the State. See *Kamal Tiwari*, 76 FR 71604, 71606 (2011) (collecting cases); see also *George S. Heath*, 51 FR 26610 (1986).

<sup>12</sup> For the same reasons which led the Texas Board to order the emergency suspension of Respondent’s medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Dated: April 5, 2016.

**Chuck Rosenberg,**

*Acting Administrator.*

[FR Doc. 2016-08572 Filed 4-13-16; 8:45 am]

**BILLING CODE 4410-09-P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (16-027)]

### Notice of Intent To Grant a Partially Exclusive License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of intent to grant a partially exclusive license.

**SUMMARY:** This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the invention described and claimed in U.S. Patent Application Serial No. 14/196,203 entitled Vibration Damping Circuit Card Assembly to TopLine Corporation, having its principal place of business in Irvine, CA. The patent rights in these invention have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

**DATES:** The prospective partially exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

**ADDRESSES:** Objections relating to the prospective license may be submitted to Mr. James J. McGroary, Chief Patent Counsel/LS01, Marshall Space Flight Center, Huntsville, AL 35812, (256) 544-0013.

**FOR FURTHER INFORMATION CONTACT:** Mr. Sammy A. Nabors, Technology Transfer

Office/ZP30, Marshall Space Flight Center, Huntsville, AL 35812, (256) 544-5226. Information about other NASA inventions available for licensing can be found online at <http://technology.nasa.gov>.

**Mark P. Dvorscak,**

*Agency Counsel for Intellectual Property.*

[FR Doc. 2016-08546 Filed 4-13-16; 8:45 am]

**BILLING CODE 7510-13-P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (16-028)]

### Notice of Intent To Grant a Partially Exclusive License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of intent to grant a partially-exclusive license.

**SUMMARY:** This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the invention described and claimed in U.S. Non-Provisional Patent Application, Application No. 14/714,756, titled "Auto-Tracking Antenna Platform," NASA Case No. DRC-013-031, and any issued patents or continuations-in-part resulting therefrom, to Mobile Antenna Platform Systems, Inc. having its principal place of business in Navarre, Florida. Certain patent rights in this invention have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

**DATES:** The prospective partially exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated partially exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

**ADDRESSES:** Objections relating to the prospective license may be submitted to Patent Counsel, NASA Management Office, Jet Propulsion Laboratory, 4800 Oak Grove Drive, M/S 180-800C, Pasadena, CA 91109, (818) 854-7770 (phone), 818-393-2607 (fax).

**FOR FURTHER INFORMATION CONTACT:**

Mark Homer, Patent Counsel, NASA Management Office, Jet Propulsion Laboratory, 4800 Oak Grove Drive, M/S 180-800C, Pasadena, CA 91109, (818) 854-7770 (phone), 818-393-2607 (fax). Information about other NASA inventions available for licensing can be found online at <http://technology.nasa.gov>

**Mark P. Dvorscak,**

*Agency Counsel for Intellectual Property.*

[FR Doc. 2016-08547 Filed 4-13-16; 8:45 am]

**BILLING CODE 7510-13-P**

## NUCLEAR REGULATORY COMMISSION

[Docket No. 50-382; NRC-2016-0078]

### Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License renewal application; receipt.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has received an application for the renewal of operating license NPF-38, which authorizes Entergy Operations, Inc. (the applicant) to operate the Waterford Steam Electric Station, Unit 3 (Waterford 3). The renewed license would authorize the applicant to operate Waterford 3 for an additional 20-year period beyond the period specified in the current license. The current operating license for Waterford 3 expires at midnight on December 18, 2024.

**DATES:** The license renewal application referenced in this document is available on April 14, 2016.

**ADDRESSES:** Please refer to Docket ID NRC-2016-0078 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0078. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER**