

(total number of respondents) * .5 (30 minutes).

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Dated: May 3, 2017.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17-12]

Judson J. Somerville, M.D.; Decision and Order

On October 20, 2016, the Assistant Administrator, Division of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Judson J. Somerville, M.D. (Respondent), of Laredo, Texas. The Show Cause Order proposed the revocation of Respondent's Certificates of Registration, on the ground that he "do[es] not have authority to handle controlled substances in Texas, the [S]tate in which [he is] registered with the" Agency. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is registered as a practitioner in schedules II through V, pursuant to Certificate of Registration No. BS3909718, at the address of Saguaro Anesthesia Associates, d/b/a The Pain Clinic, 9114 McPherson Road, Suite 2508, Laredo, Texas.¹ *Id.* The Show Cause Order alleged that this registration expires on February 28, 2018. *Id.* The Order also alleged that Respondent is registered as a practitioner in schedules II through V, pursuant to Certificate of Registration No. FS3571660, at the address of 4646 Corona Drive, Corpus Christi, Texas. *Id.* at 2. The Show Cause Order alleged that this registration expires on February 28, 2019. *Id.*

As to the substantive ground for the proceeding, the Show Cause Order alleged that on October 6, 2016, the

Texas Medical Board entered an Order of Temporary Suspension suspending Respondent's Texas Medical License effective the same day, "which 'shall remain in effect until it is superseded by a subsequent Order of the Board,'" and that this "order prohibits [him] from practicing medicine in the State of Texas." *Id.* The Order then alleged that "[d]ue to the Order and under state law, [Respondent] lack[s] authority to handle controlled substances in Texas, the [S]tate in which [he is] registered" and this "constitutes grounds to revoke [his] [r]egistration." *Id.* (citing 21 U.S.C. 802(21) and 824(a)(3)) (other citations omitted).²

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). On November 22, 2016, the CALJ ordered the Government to submit evidence to support the allegation and any motion for summary disposition no later than December 7, 2016. *See* Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1. In the order, the ALJ also directed Respondent to file a response to any motion for summary disposition no later than December 21, 2016. *Id.*

On December 2, 2016, the Government filed its Motion for Summary Disposition. Therein, it argued that it is undisputed that based on the Texas Medical Board's October 6, 2016 Order of Temporary Suspension, Respondent is prohibited from practicing medicine in the State of Texas and that his license remains suspended as of the date of its Motion. Gov. Motion, at 5. The Government further argued "that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engaged in professional practice is a fundamental condition for both obtaining and maintaining a practitioner's registration," and that under the Agency's precedents, revocation is warranted even where a State has invoked summary process to suspend a practitioner's state authority and has yet to provide the practitioner with a

² The Show Cause Order also notified Respondent of his right to request a hearing or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. Show Cause Order, at 3 (citing 21 CFR 1301.43). Also, the Show Cause Order notified Respondent of his right to submit a Corrective Action Plan and the procedures for doing so. *Id.* (citing 21 U.S.C. 824(c)(2)(C)).

hearing where he may prevail. Mot. for Summ. Disp., at 3-7 (citations omitted). As support for its motion, the Government attached a copy of the Medical Board's Order of Temporary Suspension and a printout from the Medical Board's Web site showing that his license status was "SUSPENDED, ACTIVE." *Id.* at GXs C & D.

Respondent did not dispute that his medical license has been suspended by the Texas Board. Resp.'s Reply to Gov. Mot. for Summ. Disp., at 1. Instead, he argued that the Board's Order cannot "serve as a predicate for summary disposition" because the Order is not a "permanent action[] of the Board" and is "not valid until and unless the matters in the . . . order[] are brought before a panel of the Medical Board for an 'Informal Settlement Conference' and if not resolved at the . . . conference, [a] formal adjudication[] . . . which must be initiated as soon as possible." *Id.* at 1-2. Respondent argued that the Medical Board has acted in violation of Texas law by exempting itself from the requirement that it initiate proceedings within 30 days from the date of the issuance of a summary suspension order. *Id.* at 2-3. He further argued that subsequent to the issuance of the Board's Order, there has been no settlement conference and the Board did not commence formal administrative proceedings either within the 30 day period or "'as soon as practicable' as mandated by Texas" law. *Id.* at 4. Respondent thus maintains that the Government's Motion is based on the illegal actions of the Board. *Id.* Respondent requested that the CALJ deny the Government's Motion and "hold in abeyance any decision on the Government's application until the proper exhaustion of administrative and judicial channels takes place in Texas." *Id.* at 5.

The CALJ rejected Respondent's contentions, noting that "the Controlled Substances Act (CSA) requires that, in order to obtain or maintain a DEA registration, a practitioner must be authorized to handle controlled substances in the State in which he practices." R.D. at 3-4 (citing 21 U.S.C. 823(f) and 802(21) (quotations omitted)). While he was "not unmindful of Respondent's arguments regarding the legality of the Board's actions," the CALJ explained that "it is not within this tribunal's authority to evaluate the lawfulness of the basis of a registrant's lack of state authority, and the validity of other entities' actions is not what is at issue in these proceedings." *Id.* at 4. The CALJ then explained that the "disposition of the Government's Motion is wholly dependent upon the

¹ In the Show Cause Order, the Government listed the number of this registration as BP3909718. Show Cause Order, at 1. However, on December 2, 2016, the Government notified the CALJ that the correct number was BS3909718. *See* Gov. Notice of Correction for the Order to Show Cause, at 1.

single issue of whether or not the Respondent currently possesses the requisite authority under state law to handle controlled substances—which he does not.” *Id.* The CALJ further denied Respondent’s request to hold the proceeding in abeyance pending the exhaustion of his state remedies.³ *Id.* at 4.

The CALJ then found that there was no dispute over the material fact that “Respondent currently lacks state authority to handle controlled substances in Texas due to the Board[’s] Order dated October 6, 2016, which temporarily suspended his state license to practice medicine.” *Id.* at 6. Reasoning that “[b]ecause . . . Respondent lacks state authority at the present time . . . he is not entitled to maintain his . . . registrations,” the CALJ granted the Government’s motion and recommended that his registrations be revoked and that any pending applications be denied. *Id.*

Neither party filed exceptions to the CALJ’s Recommended Decision. Thereafter, the record was forwarded to

³ The CALJ noted that the Agency has previously held “that a stay in administrative enforcement proceedings is ‘unlikely to ever be justified’ due to ancillary proceedings involving the Respondent.” R.D. 5 (quoting *Grider Drug #1 & Grider Drug #2*, 77 FR 44070, 44104 n.97 (2012)). I agree with this statement of the Agency’s precedents. However, the CALJ also cited *Odette L. Campbell*, 80 FR 41062 (2015), as contrary authority. *See id.* The CALJ characterized *Campbell* as “holding revocation proceedings in abeyance at the post-hearing adjudication level for a lengthy period pending the resolution of both criminal fraud charges and concurrent state administrative proceedings against the respondent.” *Id.* I respectfully disagree with the CALJ’s reading of *Campbell*. In *Campbell*, the respondent failed to comply with the Agency’s regulation which, because she was subject to an Order to Show Cause, required her to file her renewal application at least 45 days before the expiration of her registration. 80 FR 41063. Of note, the respondent’s registration expired one week after the evidentiary hearing, and she did not file a renewal application until three months later, after she received a largely favorable decision from the ALJ. *Id.* Thus, at the time the proceeding was held in abeyance, the proceeding did not involve a revocation as the respondent no longer held a registration. *See* 21 CFR 1301.36(i).

Most significantly, one week before the evidentiary hearing, the respondent was indicted on 30 counts of Health Care Fraud, as well as five counts of altering records during a federal investigation. 80 FR at 41063. Had the respondent been convicted of Health Care Fraud, she would have been subject to mandatory exclusion from federal healthcare programs under 42 U.S.C. 1320a-7(a) and her application would have been subject to denial on that basis. *Id.* at 41064 (citing 21 U.S.C. 824(a)(5)). Moreover, even after the respondent successfully completed pre-trial diversion and the charges were dismissed, the state medical board brought a proceeding against her license, and had the board suspended or revoked her medical license, denial of her application would have been required under the CSA. *Id.* (citing 21 U.S.C. 802(21) & 823(f)). Given the pending proceedings, *Campbell* was the rare case where withholding the issuance of a final decision was warranted.

my Office for Final Agency Action. Having reviewed the record, I adopt the CALJ’s finding that by virtue of the Texas Board’s Order, Respondent is currently without authority to handle controlled substances in Texas, the State in which he holds his registrations with the Agency, and is thus, not entitled to maintain his registrations. I further adopt the CALJ’s recommendation that I revoke his registrations and deny his pending applications. I make the following factual findings.

Findings of Fact

Respondent is a physician who holds Texas Medical License No. H-6622. GX C, at 1. However, on October 6, 2016, the Disciplinary Panel of the Texas Medical Board issued an Order of Temporary Suspension to Respondent based on its finding that “Respondent’s continuation in the practice of medicine would constitute a continuing threat to the public welfare.” *Id.* at 5. The Panel further ordered that the suspension be “effective on the date rendered” and “shall remain in effect until it is superseded by a subsequent Order of the Board.” *Id.* Respondent offered no evidence in its Opposition to the Government’s Motion or at any time thereafter showing that the Board has lifted the suspension. Based on the above, I find that Respondent does not currently have authority under the laws of Texas to dispense controlled substances.

Respondent is also the holder of two DEA Certificates of Registration, pursuant to which he was authorized to dispense controlled substances in schedules II through V as a practitioner. Pursuant to Registration No. BS3909718, Respondent was authorized to dispense controlled substances at the address of Saguario Anesthesia Associates, d/b/a The Pain Management Clinic, 9114 McPherson Road, Suite 2508, Laredo, Texas. GX A. This registration does not expire until February 28, 2018. *Id.* Pursuant to Registration No. FS3571660, Respondent was authorized to dispense controlled substances at the address of 4646 Corona Drive, Suite 256, Corpus Christi, Texas. GX B. According to the declaration of a Diversion Investigator, this registration does not expire until February 28, 2019. GX F, at 2.

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 (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).

Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA 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 Texas Medical Board has employed summary process in suspending Registrant’s state license and that Respondent may prevail at the hearing schedule for late June.

Respondent further argues that the Board’s order cannot be the basis for revoking his registration because the Board has acted in violation of Texas law when it neither provided Respondent with an informal settlement conference nor commenced formal administrative proceedings within the time frame required by Texas law. DEA,

however, “accepts as valid and lawful the actions of a state regulatory board unless that action is overturned by a state court . . . pursuant to state law.” *Kamal Tiwari*, 76 FR 71604, 71607 (2011) (quoting *George S. Heath*, 51 FR 26610 (1986)). Rather, Respondent’s challenge to the lawfulness of the Texas Board’s Suspension Order must be raised in the forums provided by the State. *Id.* (quoting 51 FR at 26610). See also *Calvin Ramsey*, 76 FR 20034, 20036 (2011) (quoting *Hicham K. Riba*, 73 FR 75773, 75774 (2008) (“DEA has repeatedly held that a registrant cannot collaterally attack the results of a state criminal or administrative proceeding in a proceeding brought under section 304 [21 U.S.C. 824] of the CSA.”)).

Here, there is no dispute over the material fact that Respondent is no longer currently authorized to dispense controlled substances in Texas, the State in which he is registered. Accordingly, he is not entitled to maintain his registrations. I will therefore adopt the CALJ’s recommendation that I revoke Respondent’s registrations and deny any pending applications to renew his registrations. R.D. 6.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(3) and 28 CFR 0.100(b), I order that DEA Certificates of Registration Nos. BS3909718 and FS3571660 be, and they hereby are, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f), I order that any applications to renew the above registrations be, and they hereby are, denied. This Order is effective immediately.⁴

Dated: May 1, 2017.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15-24]

Roberto Zayas, M.D., Decision and Order

On May 18, 2015, the Deputy Assistant Administrator, of the then-Office of Diversion Control, issued an Order to Show Cause to Roberto Zayas, M.D. (hereinafter, Respondent), of

⁴ For the same reasons which led the Texas Board to order the temporary suspension of Respondent’s medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Houston, Texas and Dover, Florida. ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent’s Certificates of Registration Nos. FZ2249743 and FZ2418401, the denial of any pending applications to renew or modify these registrations, and the denial of any applications for new registrations, on the ground that his “continued registration is inconsistent with the public interest.” *Id.* at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that Respondent is the holder of Registration No. FZ2249743, pursuant to which he is authorized to dispense schedule II through V controlled substances as a practitioner, at the registered address of 12121 Jones Road, Houston, Texas; the Order alleged that this registration was due to expire on May 31, 2016. *Id.* The Show Cause Order also alleged that Respondent is the holder of Registration No. FZ22418401, pursuant to which he is authorized to dispense schedule II through V controlled substances as a practitioner, at the registered address of 14222 Melouga Preserve Trail, Dover, Florida; the Order alleged that this registration is due to expire on May 31, 2017. *Id.*

As grounds for the proposed actions, the Show Cause Order alleged that on September 20, 2010, Respondent “signed a Memorandum of Agreement” (MOA) which “imposed requirements . . . regarding [the] operation, management and supervision of seven different clinics” he “own[s] and/or manage[s] and control[s]” which are located in various Texas cities. *Id.* at 1–2. The Show Cause Order alleged that “pursuant to paragraph 8 of the MOA, [Respondent] agreed that ‘[i]f controlled substances in Schedules II through V are purchased for any clinic, to be administered and/or dispensed to the clinic patient, [he] shall cause to be made and maintained all DEA required documents and information including records, reports, and inventories’” and that “[a]ll required documentation shall be maintained as required by federal and Texas laws and regulations.” *Id.* at 2. The Show Cause Order then alleged that pursuant to another part of paragraph 8, Respondent “agreed . . . that ‘[i]f any controlled substance is administered or dispensed at any clinic including the [seven clinics he owns or controls], the health care provider doing the administering and/or dispensing to the patient shall be registered at the clinic as required by 21 U.S.C. 822(a)(2) and 21 CFR 1301.12.’” *Id.* And with respect to paragraph 9 of the MOA, the Order alleged that Respondent was

required to submit to the DEA Houston Division Office “on a quarterly basis, the total number of controlled substances dispensed, to include the date dispensed, full name of patient, address of patient, name of controlled substance dispensed, quantity dispensed and [the] dispenser’s initials.” *Id.*

The Show Cause Order alleged that “[b]etween August 28 and September 13[,] 2013,” DEA conducted inspections of each of the clinics and “determined that [Respondent] repeatedly violated the terms of paragraphs 8 and 9 of the MOA.” *Id.* The Show Cause Order then alleged that “controlled substances were dispensed and/or administered at four of the [clinics] during periods when the individual doing the dispensing and/or administering was not registered . . . at the” clinic. *Id.* at 2.

The Show Cause Order also alleged that Respondent failed to make and maintain complete and accurate controlled substance inventories at six of the clinics; that he failed to make and maintain complete and accurate dispensing records at five of the clinics; and that he failed to make and maintain complete and accurate receipt records at several of the clinics. *Id.* at 3 (citing 21 CFR 1304.11(e)(3); *id.* § 1304(c); ¹ *id.* § 1304.22(c); and *id.* § 1304.22(a)(2)). The Show Cause Order further alleged that Respondent failed to timely submit 10 of the required quarterly dispensing reports, that 10 of the reports that were submitted “on July 20, 2013, were back-dated and hence, failed to indicate the true date they were prepared,” and that “[a]ll of these reports” falsely represented that “neither [Respondent] nor any of the . . . clinics . . . have dispensed any controlled substances to their patients for their medical needs.” *Id.*

Finally, the Show Cause Order alleged that Respondent “violated 21 CFR 1306.04(b) by issuing prescriptions ‘in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.’” *Id.* The Order then identified two instances in which Respondent allegedly issued prescriptions for testosterone products which listed him (and in one instance, a clinic) as the patient. *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. The matter was placed on the docket of the Office of

¹ While there is no such provision, this appears to be a mistaken citation to 21 CFR 1304.22(c), which sets forth the records required to be maintained by dispensers.