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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 15-13]

Sharad C. Patel, M.D.
Decision and Order

On March 11, 2015, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (cited as R.D.). Thereafter, on April 1, Respondent filed a pleading entitled as "Objections to Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge (hereinafter, Resp. Objections). Therein, Respondent objected to the entry of the ALJ's Recommended Decision, on the ground that "he was never properly, or sufficiently, served with the [Government's] initial motion" for summary disposition and therefore "did not respond to the . . . [m]otion . . . because he was unaware of any such motion until the ALJ's Order granting such motion." Objections, at 1.

Respondent argues that in his request for hearing, his attorneys provided both a mailing address and e-mail address for receiving the "notices to be sent pursuant to the proceeding." 21 CFR 1316.47(a); Objections at 1. Respondent did not, however, provide a fax number. Id. at 2.

Thereafter, Respondent received the ALJ's Order for Briefing on Allegations Concerning Respondent's Lack of State Authority" by First Class Mail. Id. The ALJ's Order specified the date (Mar. 2, 2015) by which the Government was to provide its evidence and arguments (as well as its motion for summary disposition) in support of its contention that Respondent does not possess "state authority to handle controlled substances," as well as the date by which Respondent was to file his response (Mar. 9) to any such motion. Id.

On March 2, the Government filed its Motion for Summary Disposition with the Office of Administrative Law Judges. Motion for Summ. Disp., at 1. In the Certificate of Service, the Government represented that it had served the Motion by facsimile, but not by first class mail or e-mail.[1] Id. at 4. In its Objections, Respondent asserts that he "did not respond to the DEA Motion for Summary Disposition because he was unaware of any such motion until the ALJ's Order granting such motion." Objections, at 1.

As stated above, on March 11, the ALJ issued his Recommended Decision. Therein, the ALJ noted that the Government had attached a copy of the Emergency Order of Suspension issued by the Kentucky Board of Medical Licensure; the Order, which was issued on November 24, 2014, suspended Respondent's Kentucky medical license "effectively immediately upon its receipt." Mot. For Supp. Disp., Attachment 1, at 18.

In his Recommended Decision, the ALJ noted that Respondent had not filed a response to the Government's motion. R.D. at 2. However, the ALJ also noted that in his hearing request, Respondent had "admit[ted] that his license is temporary [sic] suspended" but that "he expects to prevail before the medical board at an upcoming hearing on May 18, 2015." Id. at 3. As explained in his decision, the ALJ found that there was no dispute that Respondent "is not authorized to handle controlled substances in the State in which he maintains his registration" and is therefore not a practitioner within the meaning of the Controlled Substances Act. Id. The ALJ thus recommended that Respondent's registration be revoked and that any pending application be denied.

[1] Respondent's contention regarding the inadequacy of service is not without merit. Of note, Respondent did not consent to the service of pleadings by facsimile and the ALJ's Order for Briefing on Allegation Concerning Respondent's Lack of State Authority did not authorize service of pleadings in this manner. Moreover, while the use of electronic means has the advantage of faster service – at least where the transmission is successful – a hard copy should still be sent by mail, courier, or third party commercial carrier unless the serving party contacts the other party and affirmatively determines that the entire document was received.

Thereafter, the ALJ forwarded the record to me, noting in his letter that Respondent's objections were not timely filed. Letter from ALJ to Administrator (Apr. 7, 2015), at 2. The ALJ also provided a copy of a Transmission Verification Report showing that the Recommended Decision was successfully faxed to Respondent's counsel on March 11. Thus, Respondent's Objections (which I have treated as his Exceptions) were not received until day twenty-one, one day after they were due.[2] See 21 CFR 1316.66(a). Having offered no explanation for why his Objections were late, I agree with the ALJ's finding that Respondent's Objections were out of time.

In any event, in his Objections, Respondent does not dispute that he remains without authority to handle controlled substances in State of Kentucky. Objections, at 3. Rather, he seeks a delay in responding to the Government's Motion until July 1, 2015 on the ground that the State's "suspension is temporary [and] was not issued after a full and fair hearing on the issues," and that "[t]he sole support for the Government's Motion . . . is the temporary action taken by the state medical board." Id. He further contends that he "is vigorously defending himself from the unwarranted suspension of his Kentucky medical license and believes he will ultimately prevail" and have his medical license and state controlled substance authority restored. Id.

However, the Agency has long held that "a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances." James L. Hooper, 76 FR 71371 (2011), pet. for rev. denied, Hooper v. Holder, 481 F. App'x 826 (4th Cir. 2012). This holding is derived from the plain meaning of two provisions of the Controlled Substances Act.

[2] It is further noted that Respondent did not mail his Objections until March 31, 2015. Objections, at 4. DEA's regulation provides that "[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk." 21 CFR 1316.45. This case does not raise any issue of delay being attributable to the physical address of the Office of Administrative Law Judges being different from the mailing address of that Office.

The first is section 102(21), which defines the term "practitioner" to "mean[] a physician . . . 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). The second is section 303(f), which sets forth the criteria for obtaining a practitioner's registration and which explicitly provides 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." Id. § 823(f) (emphasis added). Based on these provisions, the Agency has long held 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 Gary Alfred Shearer, 78 FR 19009 (2013); see also Newcare Home Health Services, 72 FR 42126, 42127 n.2 (2007) (collecting cases and holding that "ALJ properly rejected . . . request for stay" and that "[i]t is not DEA's policy to stay proceedings under section 304 while registrant litigate in other forums").

According to the allegations of the Show Cause Order, Respondent's registration was not due to expire until March 31, 2015. Thus, at the time the ALJ issued his decision, Respondent still held a DEA registration. However, at the time the case was forwarded to my Office, the record contained no evidence as to whether Respondent had filed a timely renewal (or even an untimely renewal) application and whether his registration remained in effect.[3]

In his request for hearing, Respondent contended that "he is prohibited from applying for his DEA certificate until the Kentucky medical board acts upon his suspension." R.D. at 3. The

[3] Even in summary disposition proceedings which are based on a lack of state authority, the ALJ is obligated to make a finding establishing that the Agency has jurisdiction. Moreover, where it is unclear whether a respondent may have allowed his registration to expire during the course of the proceeding, the ALJ is obligated to determine whether the respondent has filed a renewal application before forwarding the record to the Administrator.

ALJ rejected Respondent's contention, stating that under 21 CFR 1301.36(i), "the existing registration of an applicant for reregistration will be automatically extended until the Administrator issues her order if the applicant applies for reregistration." Id.

According to the registration records of the Agency – of which I have taken official notice[4] – Respondent filed a renewal application on March 23, eight days before the expiration date of his registration. However, contrary to the ALJ's explanation of 21 CFR 1301.36(i), where a registrant-applicant has been issued an order to show cause, the regulation actually provides:

> [i]n the event an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order.

21 CFR 1301.36(i) (emphasis added).

To be sure, the regulation also provides that a registration may be extended "under the circumstances contemplated in this section even through the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety." 21 CFR 1301.36(i). However, based on the Kentucky Board's Emergency Suspension order and the extensive findings (which include allegations related to his prescribing of controlled substances) made therein, I find that the extension of Respondent's registration would be "inconsistent with the public health and safety." See Paul H. Volkman, 73 FR 30630, 30641 (2008) (declining to extend registration of practitioner subject to order to show

[4] See 21 CFR 1316.59(e). Respondent may refute my finding by filing a properly supported motion for reconsideration no later than fifteen (15) calendar days from the date of issuance of this Decision and Order.

cause who did not file his renewal application until nineteen days before expiration of the registration but finding that the application remained pending before the Agency).

Accordingly, I hold that Respondent's registration has expired but that his application remains pending before the Agency. However, because Respondent is not currently authorized to dispense controlled substances under the laws of the State of Kentucky, the State in which he seeks registration, he is not entitled to be registered. See 21 U.S.C. §§ 823(f) & 802(21).

I therefore adopt the ALJ's finding that Respondent is not currently authorized to dispense controlled substances in Kentucky, the State in which he seeks registration, and is therefore not a practitioner within the meaning of the CSA. I further adopt the ALJ's order granting the Government's Motion for Summary Disposition. However, I adopt the ALJ's Recommendation only with respect to the denial of Respondent's pending application to renew his registration.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Sharad C. Patel, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effectively immediately.

Dated: May 1, 2015.

Michele M. Leonhart,
Administrator.

Brian Bayly, Esq., for the Government.

Marc S. Murphy, Esq., and Michael Denbow, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION

AND

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDED DECISION OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Christopher B. McNeil. On January 29, 2015, the Deputy Assistant Administrator of the Drug Enforcement Administration issued an Order to Show Cause as to why the DEA should not revoke DEA Certificate of Registration Number FP2719245 issued to Sharad C. Patel, M.D., the Respondent in this matter. The Order seeks to revoke Respondent's registration pursuant to 21 U.S.C. §§ 824(a)(3) and 823(f), and to deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f). As grounds for denial, the Government alleges that Respondent is "without authority to handle controlled substances in Kentucky, the state in which [Respondent is] registered with the DEA."

On February 20, 2015, the DEA's Office of Administrative Law Judges received Respondent's written request for a hearing, which is dated February 19, 2015. Respondent states that his medical license is "temporarily suspended" by the state's medical board and that he plans to challenge the suspension in an upcoming state administrative hearing scheduled for May 18, 2015.

On February 23, 2015 this Office issued an Order for Briefing on Allegations Concerning Respondent's Lack of State Authority. In the Order, I mandated that the Government provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances and if appropriate file a motion for summary disposition no later than 2:00 p.m. Eastern Standard Time (EST)

on March 2, 2015. On March 2, 2015, the Government timely submitted a brief in support of the allegation regarding state authority and filed a Motion for Summary Disposition. According to the Government's brief, the Board of Medical Licensure of the Commonwealth of Kentucky issued an Emergency Order of Suspension suspending Respondent's license to practice medicine, effective November 24, 2014. The Government attached the emergency order pertaining to Respondent to the Motion for Summary Disposition. Based on this suspension, the Government moved for a summary disposition of these proceedings.

In my Order for Briefing on Allegations Concerning Respondent's Lack of State Authority, I also provided Respondent the opportunity to respond to the Government's allegations with a brief due not later than 2:00 p.m. EST on March 9, 2015. As of today, no brief was received and therefore the Government's Motion for Summary Disposition will stand unopposed. In Respondent's Request for Hearing, Respondent admits that his license is temporary suspended. Respondent further states that he expects to prevail before the medical board at an upcoming hearing on May 18, 2015. Finally he notes that his DEA Certificate of Registration will expire by its own terms on March 31, 2015, and alleges that he is prohibited from applying for his DEA certificate until the Kentucky medical board acts upon his suspension.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's DEA Certificate of Registration must be revoked because Respondent does not have a medical license issued by the state in which he practices — a fact which Respondent does not deny. Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which he maintains his DEA registration.[1] Pursuant to 21 U.S.C. § 823(f), only a "practitioner" may

[1] See 21 U.S.C. §§ 801(21), 823(f), 824(a)(3); see also House of Medicine, 79 FR 4959, 4961 (DEA Jan. 30, 2014); Deanwood Pharmacy, 68 FR 41662-01 (DEA July 14, 2003); Wayne D. Longmore, M.D., 77 FR 67669-02 (DEA Nov. 13, 2012); Alan H. Olefsky, M.D., 72 FR 42127-01 (DEA Aug. 1, 2007); Layfe Robert Anthony, M.D., 67 FR 15811 (DEA May 20, 2002); George Thomas, PA-C, 64 FR 15811-02 (DEA Apr. 1, 1999); Shahid Musud Siddiqui, M.D., 61 FR

receive a DEA registration. Under 21 U.S.C. § 802(21), a "practitioner" must be "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]" Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to maintain a practitioner's registration if that practitioner is not authorized to dispense controlled substances.[2] As noted by the Government in its Motion for Summary Disposition, Respondent's concern regarding the impending expiration of his DEA registration is unfounded. Under 21 C.F.R. § 1301.36(i), incorrectly cited by the Government as 21 C.F.R. § 1306.36(i), the existing registration of an applicant for reregistration will be automatically extended until the Administrator issues her order if the applicant applies for reregistration.[3]

As detailed above, only a "practitioner" may receive a DEA registration. Therefore, I will recommend the revocation of Respondent's DEA registration.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a "practitioner" as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which he seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I **GRANT** the Government's Motion for Summary Disposition.

14818-02 (DEA April 4, 1996); Michael D. Lawton, M.D., 59 FR 17792-01 (DEA Apr. 14, 1994); Abraham A. Chaplan, M.D., 57 FR 55280-03 (DEA Nov. 24, 1992). See also Bio Diagnosis Int'l, 78 FR 39327-03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other "practitioners" in the context of summary disposition analysis).

[2] See Abraham A. Chaplan, M.D., 57 FR 55280-03, 55280 (DEA Nov. 24, 1992), and cases cited therein. In Chaplan, DEA Administrator Robert C. Bonner adopts the ALJ's opinion that "the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances." Id.

[3] See also Ronald J. Riegel, D.V.M., 63 FR 67132-01, 67132 (DEA Dec. 4, 1998).

Upon this finding, I **ORDER** that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be **REVOKED** and any pending application for the renewal or modification of the same should be **DENIED**.

Dated: March 11, 2015

s/CHRISTOPHER B. MCNEIL

Administrative Law Judge

[FR Doc. 2015-12025 Filed: 5/18/2015 08:45 am; Publication Date: 5/19/2015]