DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 19–17]

Peter J. Waidzunas, D.D.S.; Decision and Order

On March 4, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Peter J. Waidzunas, D.D.S. (hereinafter, Respondent), of Gurnee, Illinois. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BW7668835 on the ground that Respondent does "not have authority to handle controlled substances in Illinois, the state in which . . . [Respondent is] registered with the DEA." Id. (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that Respondent and the Illinois Department of Financial and Professional Regulation (hereinafter, IDFPR) entered into a Consent Order with Respondent on September 10, 2018. Id. at 1-2. According to the OSC, the Consent Order indefinitely suspended Respondent's Illinois dentist controlled substance license, because, according to joint stipulations in the Consent Order, Respondent "unlawfully issued prescriptions for controlled substances and failed to maintain dispensing records of controlled substances in violation of the Illinois Dental Practice Act, 225 ILCS 25 et seq. and the Illinois Controlled Substances Act, 720 ILCS 570 et seq." Id. at 1–2. The OSC notified Respondent of the

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated April 5, 2019, Respondent, pro se, timely requested a hearing.¹ Hearing Request, at 1. In his hearing request, Respondent did not address whether his Illinois dentist controlled substance license remained indefinitely suspended; however, he asserted that he "completely disagree[d] with the findings, compilations and inventories taken by the two DEA 'agents'" and argued that he has "at all times completely complied with all DEA and IDFPR rules and regulations." *Id.* Respondent's Hearing Request states that Respondent is "currently on Appeal with the Federal Court over the ruling of the judge." *Id.* at 2. Respondent also requested that all notices and mailings be directed to the dental office address provided in his letterhead. *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ). The Chief ALJ issued an Order Directing the Filing of Government Evidence Regarding Its Lack of State Authority Allegation and Briefing Schedule (hereinafter, Briefing Order) dated April 8, 2019. In his Briefing Order, the Chief ALJ advised Respondent that, pursuant to 21 CFR 1316.50, he has the right to seek representation by a qualified attorney at his own expense. *Id.* at 1, n.2. The Chief ALJ also ordered the Government to provide evidence to support its allegation that Respondent lacks state authority to handle controlled substances and to set a briefing schedule for any motion for summary disposition on that basis, as well as any reply by Respondent. *Id.* at 1–2. The Government timely complied with the Briefing Order by filing a Motion for Summary Disposition on April 19, 2019. Government's Motion for Summary Disposition and Argument in Support of Finding that Respondent Lacks State Authorization To Handle Controlled Substances (hereinafter, MSD). In its MSD, the Government stated that Respondent lacks authority to handle controlled substances in Illinois, the State in which he is registered with the DEA and argued that, therefore, DEA must revoke his registration. Id. Respondent did not answer the MSD, and the Chief ALJ deemed the Government's motion unopposed. Order Granting Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision dated May 15, 2019 (hereinafter, R.D.),

The Chief ALJ granted the Government's Motion, finding that "there is no dispute of material fact in this case." R.D. at 4. The ALJ recommended that Respondent's registration be revoked because "the Government submitted evidence from the IDFPR and the Consent Order which show that the Respondent can no longer prescribe[] controlled substances" and "[t]his fact is not challenged by the Respondent." Id. I issue this Decision and Order based on the entire record

before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. BW7668835 at the registered address of 501 North Riverside Drive, Suite 119, Gurnee, Illinois. MSD, Attachment 1 (Certificate of Registration). Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Respondent's registration expires on May 31, 2020. *Id.*

The Status of Respondent's State License

On September 11, 2018, the IDFPR Division of Professional Regulation issued a Consent Order entered into between the IDFPR and Respondent.² MSD, Attachment 2 (Consent Order), at 1. According to the Consent Order, IDFPR alleged that Respondent's actions and/or omissions in his practice of dentistry constitute violations of the Illinois Dental Practice Act and the Illinois Controlled Substances Act, and which, if proven true, would constitute grounds for discipline. Id. at 2-3. (Citations omitted.) Specifically, IDFPR alleged that Respondent prescribed Vicodin and Tramadol, on a monthly basis between 1996 and 2018, to treat a patient with temporomandibular joint dysfunction ("TMJ") syndrome, and failed to obtain ongoing diagnostic and/ or radiological studies to verify and confirm the extent of that patient's continued TMJ symptoms, as well as authorizing numerous prescriptions for controlled substances without properly evaluating and monitoring the patient for signs and symptoms of drug addiction or abuse. Id. at 1.

The stipulations in the Consent Order also included allegations that DEA Diversion Investigators (DIs) conducted an inspection of Respondent's dental practice and discovered that he prescribed Ambien and Codeine to his wife without documenting the prescriptions or dental exam necessity for those prescriptions in her chart. Id. at 2. He also stipulated that the DIs conducted a count of controlled substances and found a substantial amount of substances unaccounted for, including: A shortage of 1,034 Hydrocodone 5/500mg tablets, a shortage of 500 tablets Hydrocodone 5/ 325 tablets, and a shortage of 1,960 tablets Diazepam 5mg. Id. In addition,

¹ The OSC was filed with the Office of Administrative Law on March 5. Briefing Order, at 1. With no other evidence presented to the contrary, I find that the Respondent's Request for a Hearing was timely.

 $^{^2}$ The Consent Order demonstrates that Respondent was represented by an attorney in the proceeding. Id.

according to the Consent Order, Respondent was unable to produce a biennial inventory, he failed to adequately maintain dispensing records for controlled substances, and he failed to maintain inventory records of controlled substances for two years. Id. The DIs also determined that: (a) Everyone in Respondent's dental office had access to the controlled substances cabinet; (b) Respondent kept a fivehundred count bottle of Vicodin, a onehundred count bottle of Halcion, and a five-hundred count bottle of Valium in his home, a non-registered address; and (c) Respondent kept a one-hundred count bottle of Vicodin in his desk drawer. Id.

Respondent also failed to complete the required nine hours of continuing education in sedation techniques for the 2009–2012 renewal cycle, and failed to ensure that his staff had completed the requisite training to assist him in dental sedation procedures. *Id.*

Respondent and the IDFPR agreed, in the Consent Order, that Respondent's Illinois dentist controlled substance license would be indefinitely suspended, and that his Illinois dentist license would be placed on indefinite probation with conditions for a minimum period of two years. *Id.* at 4. The Consent Order became effective on September 11, 2018, upon the approval and signature of the Director of the Division of Professional Regulation for the IDFPR. *Id.* at 7–8.

According to the online records for the state of Illinois, of which I take official notice, Respondent's Illinois dentist controlled substance license remains suspended.³ https://ilesonline.idfpr.illinois.gov/DFPR/Lookup/LicenseLookup.aspx (last visited September, 12, 2019).

Accordingly, I find that Respondent is not currently licensed to dispense controlled substances in Illinois, the State in which Respondent is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) "upon a finding that the Respondent . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also 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, M.D., 76 FR 71371 (2011), pet. for rev. denied, 481 Fed. Appx. 826 (4th Cir. 2012); Frederick Marsh Blanton, M.D., 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense. controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. See, e.g., Hooper, supra, 76 FR at 71371-72; Sheran Arden Yeates, M.D., 71 FR 39130, 39131 (2006); Dominick A. Ricci, M.D., 58 FR 51104, 51105 (1993); Bobby Watts, M.D., 53 FR 11919, 11920 (1988); Blanton, supra, 43 FR at 27617.

Pursuant to the Illinois Controlled Substances Act, a dentist is specifically included in the definition of a practitioner. "'Practitioner' means a physician licensed to practice medicine in all its branches, dentist . . . or other person licensed, registered, or otherwise lawfully permitted by the United States

or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 720 Ill. Comp. Stat. Ann. 570/102(kk) (Westlaw P.A. 100–863). Illinois law requires that "[e]very person who manufactures, distributes, or dispenses any controlled substances . . . must obtain a registration issued by the Department of Financial and Professional Regulation in accordance with its rules." *Id.* at 570/302(a).

Further, under Illinois law, the Illinois Controlled Substances Act authorizes the IDFPR to discipline a practitioner holding a dentist controlled substance license. "A registration under Section 303 to manufacture, distribute, or dispense a controlled substance . . . may be denied, refused renewal, suspended, or revoked by the Department of Financial and Professional Regulation." *Id.* at 570/304(a).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to handle controlled substances as a dentist in Illinois. As already discussed, a dentist must hold a valid dentist controlled substance license to dispense a controlled substance license to dispense a controlled substance in Illinois. Thus, because Respondent lacks authority to handle controlled substances in Illinois, Respondent is not eligible to maintain a DEA registration. Accordingly, I order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BW7668835 issued to Peter J. Waidzunas, D.D.S. This Order is effective October 21, 2019.

Dated: September 9, 2019.

Uttam Dhillon,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 2019–10]

John Yolman Salinas, M.D.; Decision and Order

On December 18, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or

³ Under the Administrative Procedure Act. an agency "may take official notice of facts at any stage in a proceeding-even in the final decision.' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a motion, the Government shall have 15 calendar days to file a response.