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UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17-38]

David A. Ruben, M.D.; Decision and Order

On June 12, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to David A. Ruben, M.D. (Respondent), of Tucson, Arizona. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration No. AR9258434 on the ground that he "do[es] not have authority to handle controlled substances in the State of Arizona, the [S]tate in which [he is] registered with the DEA." Order to Show Cause, at 1 (citing 21 U.S.C. §§ 823(f) and 824(a)(3)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. AR9258434 "as a data-waived DW/30 practitioner in schedules II through V," at the registered address of 2016 South 4th Avenue, Tucson, Arizona. *Id.* The Order also alleged that this registration does not expire until April 30, 2020. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on April 6, 2017, Respondent's "authority to prescribe and administer controlled substances in the State of Arizona was suspended," and that Arizona is "the [S]tate in which [he is] registered with the DEA." *Id.* Based on his "lack of authority to [dispense] controlled substances in . . . Arizona," the Order asserted that "DEA must revoke" his registration. *Id.* (citing 21 U.S.C. 823(f)(1) and 824(a)(3)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing "[w]ithin 30 days after the date of

receipt of this Order to Show Cause," (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id*. at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of his right to submit a corrective action plan (hereinafter, CAP) to the Assistant Administrator, Diversion Control Division, and the procedure for doing so. *Id.* at 2-3.

On July 18, 2017, Respondent submitted his CAP by letter from his counsel (dated July 12, 2017) to the Agency. In his CAP, Respondent explained:

> Dr. Ruben intends to continue to pursue and to prevail on the appeal of the underlying order issued by [t]he Arizona Medical [B]oard . . . . Alleged violation of that order is the basis of the Arizona Medical Board suspension dated April 6, 2017. The underlying matter is on appeal in Maricopa County Arizona Superior Court . . .
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> At least part of that Order being appealed stems from an Arizona license restriction of Dr. Ruben as to Schedule [II] drugs which was imposed partly as punishment for an earlier Certificate [of] Suspension by the DEA,[1] which itself was based upon the earlier same Arizona suspension dating from 2009 and 2010. The entire matter is ludicrous, and will result in the lifting of the suspension of concern here, as this is the fourth iteration of punishment by the Arizona Medical Board and the DEA cannibalizing one another's actions in order to inflict multiple punishments for the same acts from 2009 and 2010.
>
> All remaining bases of the Arizona suspension will also be overturned as unsupported by the evidence. The DEA [Show Cause Order] is premature and unnecessary and any hearing should be continued pending the outcome of the remaining state matters on appeal.

CAP, at 1. On December 4, 2017, the Acting Assistant Administrator rejected Respondent's CAP and further "determined there is no potential modification of your []CAP that could or would alter my decision in this regard." *See* Letter from Acting Assistant Administrator

[1] On June 18, 2013, the Agency suspended Respondent's DEA Certificate of Registration for one year and imposed four conditions on his registration for two years. *David A. Ruben, M.D.*, 78 FR 38363, 38387-88 (2013). The Ninth Circuit Court of Appeals denied his petition for review of the Agency's decision. 617 Fed. Appx. 837 (9th Cir. 2015) (unpublished).

Demetra Ashley to Respondent (dated December 4, 2017) (hereinafter CAP Rejection Ltr or CAP Rejection Letter), at 1.[2]

On July 18, 2017, Respondent also filed a letter with the Office of Administrative Law Judges (OALJ) pursuant to which he requested a hearing on the allegation of the Show Cause Order. Letter from Respondent's Counsel to Hearing Clerk (dated July 12, 2017) (hereinafter, Hearing Request). The matter was placed on the OALJ's docket and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ). On July 21, 2017, the ALJ issued an order entitled "Briefing Schedule for Lack of State Authority Allegations" in which the ALJ found, *inter alia*, that "[t]he Respondent filed a timely Request for Hearing." Briefing Schedule for Lack of State Authority Allegations (hereinafter, Briefing Order), at 1.[3]

Pursuant to 21 CFR 1301.43(a), "any person entitled to a hearing . . . and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, . . . file with the Administrator a written request for a hearing." *Accord* Show Cause Order, at 2. The ALJ did

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[2] Respondent's CAP was attached as Exhibit 1 to Respondent's counsel's letter requesting a hearing. CAP, at 1 (attached as "EXHIBIT 1 TO REQUEST FOR HEARING" to Letter from Respondent's Counsel to Hearing Clerk (dated July 12, 2017). The letter setting forth Respondent's request for a hearing (hereinafter, Hearing Request) was addressed to the Office of Administrative Law Judges (OALJ) as well as to the Assistant Administrator, Diversion Control Division, Louis Milione. Hearing Request, at 1. As discussed more fully *infra*, the record reflects that the OALJ received this letter on July 18, 2018. *See id.* In addition, the Acting Assistant Administrator's CAP Rejection Letter attached a copy of Respondent's Hearing Request (and a copy of the CAP) date-stamped "Jul 18, 2017" and a handwritten notation above it stating "DC received." The CAP Rejection Letter stated that her office did not receive the CAP until September 29, 2017. CAP Rejection Ltr, at 1. The record does not reflect facts explaining why the CAP Rejection Letter states that the CAP was not received by DEA's Diversion Control Division until September 29, 2017.

In the CAP Rejection Letter, the Acting Assistant Administrator states that she was responding to Respondent's CAP "in connection with an Order to Show Cause . . . issued by the Assistant Administrator on June 29, 2017." *Id.* As already noted, however, the Show Cause Order was issued on June 12, 2017. Show Cause Order, at 1. The CAP Rejection Letter does attach, *inter alia*, a copy of Respondent's Hearing Request and CAP in connection with the June 12, 2017 Show Cause Order. *See* Attachment to CAP Rejection Ltr at 2-4. Thus, I find that the CAP Rejection Letter's reference to a June 29, 2017 Show Cause Order was merely a scrivener's error and that the Acting Assistant Administrator intended to refer to the June 12, 2017 Show Cause Order.

[3] Although the date next to the ALJ's signature states "June 21, 2017," *id.* at 2, the ALJ's Docket Sheet indicates that this order was signed on "July 21, 2017." I find that the date in the Briefing Order was a scrivener's error and that in fact the ALJ signed the order on July 21, 2017 as reflected in the ALJ's Docket Sheet.

not indicate in his Briefing Order or in his Recommended Decision – and the rest of the administrative record does not indicate – when Respondent received the Show Cause Order. Without any evidence in the record establishing when Respondent received the Show Cause Order, the only way in which I could find that Respondent's Hearing Request was timely is if it had been filed with the Administrator within 30 days of the June 12, 2017 date of the Show Cause Order. However, the OALJ did not receive Respondent's Hearing Request until July 18, 2017.[4] Hearing Request, at 1. Accordingly, I find that Respondent's Hearing Request was not timely filed pursuant to 21 CFR 1301.43(a), and as a result, Respondent waived his right to a hearing.

In the absence of a timely hearing request, I also find that the ALJ consequently lacked jurisdiction to hear the case. *See Brown's Discount Apothecary BC, Inc., and Bolling Apothecary, Inc.*, 80 FR 57393, 57394 (2015) ("in the absence of a hearing request, the ALJ had no authority to rule on the issue of whether its registration should be revoked"). I therefore cancel the hearing *nunc pro tunc* held by the ALJ by summary disposition. *See* 21 CFR 1301.43(e). Accordingly, I will treat this case as a Request for Final Agency Action and issue this Decision and Order based on the relevant evidence forwarded to my office by the ALJ on September 18, 2017.[5] *See id.* I make the following findings.

[4] Although the front of Respondent's Hearing Request is stamped "Received" by the Office of Administrative Law Judges on July 18, 2017, the photocopy of the envelope that purportedly contained Respondent's Hearing Request reveals a "Received/Date" of "July 17, 2017." *Compare* Hearing Request, at 1, *with id.* at 4. In any event, neither date is within 30 days of the June 12, 2017 date of the Show Cause Order.

[5] In his Briefing Order, the ALJ ordered the Government to file evidence to support its allegation that Respondent lacks state authority to handle controlled substances, and any motion for summary disposition on these grounds, on August 3, 2017. Briefing Order at 1. The ALJ also directed Respondent to file his response to any summary disposition motion on August 10, 2017. *Id.* On August 3, 2017, the Government filed its Motion for Summary Disposition, and the Respondent filed his response on August 10, 2017. *See* Government's Motion for Summary Disposition (hereinafter Govt. Mot.); Response to Motion for Summary Disposition (hereinafter Resp. Br.). On August 15, 2017, the ALJ issued his Order granting summary disposition and Recommended Decision. Order Granting Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, Recommended Decision or R.D.). Neither party filed exceptions to the ALJ's Recommended Decision.

FINDINGS OF FACT

Respondent is a holder of DEA Certificate of Registration No. AR9258434, as well as DATA-Waiver identification number XR9258434. Government Exhibit (GX) 1 to Govt. Mot. Pursuant to his registration, Respondent is authorized to dispense controlled substances in schedules III[6] through V as a practitioner, and he is authorized to dispense or prescribe schedule III-V narcotic controlled substances which "have been approved by the Food and Drug Administration . . . specifically for use in maintenance or detoxification treatment" for up to 100 patients. 21 CFR 1301.28(a) & (b)(1)(iii); *see* GX 1. Respondent's registered address is 2016 South 4th Avenue, Tucson, Arizona. GX 1. Respondent's registration and DATA-Waiver authority do not expire until April 30, 2020. *Id.*

On April 6, 2017, the Arizona Medical Board issued an Order stating the Respondent's "license to practice allopathic medicine in the State of Arizona . . . is summarily suspended." GX 2, at 7. The Board also prohibited Respondent "from practicing medicine in the State of Arizona" and "from prescribing any form of treatment including prescription medications or injections of any kind." *Id.* Finally, the Board stated that "Respondent is entitled to a formal hearing to defend these charges within 60 days after the issuance of this order." *Id.* Based on the above, I find that Respondent does not currently have authority under the laws of Arizona to dispense controlled substances.

DISCUSSION

Although the ALJ's Recommended Decision did not establish that the ALJ had jurisdiction in this case, I will nonetheless consider the administrative record that he submitted to me in its entirety.

[6] Although the Show Cause Order alleges that Respondent's registration authorizes him to dispense controlled substances "in Schedules II through V," *see* Show Cause Order, at 1, the record establishes that Respondent is not authorized to dispense any schedule II controlled substances. GX 1. In addition, to the extent that the Show Cause Order's statement that Respondent's status "as a data-waived DW/30 practitioner in Schedules II-V" suggests that this status authorized Respondent to dispense schedule II controlled substances, that suggestion is incorrect as a matter of law. 21 U.S.C. § 823(g)(2)(a) (limiting authority to dispense to "narcotic drugs in schedule III, IV, or V"); 21 CFR 1301.28(a) (same).

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 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). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, 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 engages in professional practice. *See, e.g., Calvin Ramsey*, 76 FR 20034, 20036 (2011); *Sheran*

Arden Yeates, M.D., 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988); *Blanton*, 43 FR at 27616.

Moreover, because "the controlling question" in a proceeding brought under 21 U.S.C. § 824(a)(3) is whether the holder of a practitioner's registration "is currently authorized to handle controlled substances in the [S]tate," *Hooper*, 76 FR at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State's use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the Arizona Medical Board summarily suspended Respondent's state medical license. What is consequential is the undisputed fact that Respondent is no longer currently authorized to dispense controlled substances in Arizona, the State in which he is registered.

As for Respondent's CAP, I conclude that there were adequate grounds for denying it. Specifically, Respondent's position in his CAP is that his DEA registration should not be revoked until the conclusion of his appeal of the Arizona Medical Board's decision. As already noted, however, revocation is warranted even where a practitioner has lost his state authority and the State has yet to provide a hearing to challenge the suspension. *See Bourne Pharmacy*, 72 FR at 18274; *Wingfield Drugs*, 52 FR at 27071. Thus, I agree with the Agency's denial of Respondent's CAP.

I will therefore reject Respondent's CAP and order that his registration (and DATA-Waiver number) be revoked.[7]

[7] The ALJ received and considered the Government's Motion for Summary Disposition and the "Response to Motion for Summary Disposition" filed by Respondent. In his responsive brief, Respondent argued that "[u]nder the terms of that [Arizona Medical] Board Order, the suspension was for 60 days beginning on April 6, 2017 until the matter was set for a formal hearing" before the Board. Resp. Br. at 1. However, as already noted above, the

ORDER

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. AR9258434 and DATA-Waiver Identification Number XR9258434, issued to David A. Ruben, M.D., be, and they hereby are, revoked. I further order that any pending application of David A. Ruben to renew or modify the above registration, or any pending application of David A. Ruben for any other registration, be, and it hereby is, denied. This Order is effective immediately.[8]

Dated: March 7, 2018.

Robert W. Patterson,

Acting Administrator.

Arizona Medical Board's Order "summarily suspended" Respondent "from prescribing any form of treatment including prescription medications or injections of any kind." GX 2, at 7. Thus, I agree with the ALJ that the fact that the Board gave Respondent the right to a formal hearing within 60 days of its April 6, 2017 Order "does not obviate the fact that the Respondent currently does not possess state authority to handle controlled substances in Arizona," the State in which he is registered. R.D. at 5. Accordingly, if the ALJ had the authority to issue his conclusion rejecting Respondent's argument, I would have adopted it, and I would have done so for the same reason.

[8] For the same reasons which led the Arizona Medical Board to revoke Respondent's medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

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