

and long distances. RD, at 62–64; *supra*, at Findings of Fact C. For many of these patients, the prescriptions filled contained multiple unresolved red flags at once. *See, e.g.*, RD 38–40 (Patient D.M. on January 23, 2019, Respondent dispensed two short-acting opioids along with a benzodiazepine, which raised red flags for both therapeutic duplication and cocktail prescribing, and on March 20, 2020, Respondent dispensed hydrocodone six days early along with alprazolam, which raised red flags for both early refills and cocktail prescribing). Accordingly, the Agency agrees with the RD that the Government has established by substantial evidence that Respondent filled numerous prescriptions to seventeen patients outside the usual course of professional practice and without fulfilling its corresponding responsibility in violation of 21 CFR 1306.04(a) and 1306.06. Further, the Government established by substantial evidence that Respondent acted in violation of Texas law as set forth in 22 Texas Admin. Code §§ 291.29 and 291.33 and Texas Health & Safety Code § 481.074(a). *See* RD, at 64. The Government has made a *prima facie* case that the Respondent has committed acts that render its registration inconsistent with the public interest, and its misconduct supports the revocation of its registration. RD, at 64.

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the respondent to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33,738, 33,746 (2021).

Here, Respondent has failed to unequivocally accept responsibility. Respondent did admit that it violated its corresponding responsibility with

respect to retail patients J.C. and C.G., Tr. 1087, 1091, but then proceeded to deny that retail patient J.T.'s prescriptions presented a red flag based on distance in spite of clear Texas law to the contrary. RD, at 66 (internal citations omitted). Respondent also consistently denied that the controlled substance prescriptions for its hospice patients presented any red flags. Tr. 1377–78; ALJ Ex. 30, at 2–5; *see also, e.g.*, Tr. 1093–94, 1097, 1120–21, 1124–28, 1130, 1132–34, 1140, 1142–46, 1148–50, 1204–23, 1273–76, 1279–80, 1290, 1293; RD, at 66. For example, PIC Thomas denied that Patient D.M.'s prescriptions presented red flags, despite his own expert testifying to the contrary. *Compare* Tr. 1105–06 (PIC Thomas), *with* Tr. 725–29, 731–32 (Ms. Head). A registrant's acceptance of responsibility for misconduct is not adequate when the registrant does not understand what the law requires. *See Zion Clinic Pharmacy*, 83 FR 10,876, 10,903 (2018).¹²

Furthermore, Respondent's misconduct was far from a one-time occurrence. Respondent filled multiple prescriptions for Schedule II controlled substances presenting numerous red flags. *See Noah David, P.A.*, 87 FR 21,165, 21,174 (2022); *see also Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases) (“The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.”)

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.*, 74 FR 10,083, 10,095 (2009); *Singh*, 81 FR at 8248. The Agency finds that considerations of both specific and

¹² When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ahuja*, 84 FR at 5498 n.33; *Daniel A. Glick, D.D.S.*, 80 FR 74,800, 74,801, 74,810 (2015); *see also Jones Total Health Care Pharmacy, LLC, SND Healthcare, LLC*, 881 F.3d 823, 833 (11th Cir. 2018) (upholding DEA's refusal to consider pharmacy's remedial measures given lack of acceptance). The Agency agrees with the ALJ that even if the Agency were to consider Respondent's remedial measures, they would not affect the ultimate decision in this matter. RD, at 67. Here, Respondent has made no showing of remedial measures as to the hospice patients, because it denies any error that requires remediation. *Id.* As to the retail patients, Respondent's PIC testified that he does in-house training, including “ten-minute huddles” on a daily basis to emphasize the need for documentation. Tr. 1379–80; RD, at 67. He also testified that the pharmacy has a new software system that allows pharmacists to scan and attach documents to the electronic patient file. Tr. 1074, 1253; RD, at 67. The Agency does not find such measures to be adequate in addressing the nature of the violations found here. *See* RD, at 67.

general deterrence weigh in favor of revocation in this case. A sanction less than revocation would send a message to the current and prospective registrant community that compliance with core controlled-substance legal principles is not a condition precedent to receiving and maintaining a DEA registration. Further, there is simply no evidence that Respondent's behavior is not likely to recur in the future such that the Agency can entrust it with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction. Accordingly, the Agency shall order the sanctions the Government requested, as contained in the Order below.

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 FL1670341 issued to Rayford ACP. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of Rayford ACP for registration in Texas. This order is effective October 17, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 8, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,
Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–19988 Filed 9–14–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Reginald James Newsome, M.D.; Decision and Order

On March 16, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government)

issued an Order to Show Cause (hereinafter, OSC) to Reginald James Newsome, M.D. (hereinafter, Registrant). OSC, at 1 and 4. The OSC proposed the revocation of Registrant's Certificate of Registration No. FN0738344 at the registered address of 8865 Davis Blvd., Suite 100A, Keller, Texas 76248. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is "without authority to handle controlled substances in the State of Texas, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its Request for Final Agency Action (RFAA), submitted July 18, 2022.¹

Findings of Fact

On February 15, 2022, the Texas Medical Board issued an Order of Temporary Suspension suspending Registrant's license to practice medicine in Texas. RFAAX C (Temporary Suspension Order), at 6. According to Texas's online records, of which the Agency takes official notice, Registrant's Texas medical license is still suspended.² Texas Medical Board Verification, <https://profile.tmb.state.tx.us/Search.aspx?d2678354-aafa-4f28-a2a0-96b1f74b617a> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not currently licensed to engage in the practice of medicine in

Texas, the state in which he 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 registrant . . . 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 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27616 27617 (1978).³

According to Texas statute, "dispense" means "the delivery of a controlled substance in the course of professional practice or research, by a practitioner or person acting under the lawful order of a practitioner, to an ultimate user or research subject. The term includes the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for delivery." Tex. Health & Safety Code § 481.002(12) (2022). Further, a "practitioner" means a "a physician, . . . licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of

professional practice or research in this state." *Id.* at § 481.002(39)(A).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in Texas. A person must be a licensed practitioner to dispense a controlled substance in Texas. Thus, because Registrant lacks authority to practice medicine in Texas and, therefore, is not authorized to handle controlled substances in Texas, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant'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. FN0738344 issued to Reginald James Newsome, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Reginald James Newsome, M.D., to renew or modify this registration, as well as any other pending application of Reginald James Newsome, M.D., for additional registration in Texas. This Order is effective October 17, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 8, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,
Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–9]

Bernadette U. Iguh, M.D.; Decision and Order

On November 10, 2021, the Drug Enforcement Administration (hereinafter, DEA or Government),

¹ Based on the Declaration from a DEA Diversion Investigator that the Government submitted with its RFAA, the Agency finds that the Government's service of the OSC on Registrant was adequate. RFAA, Exhibit (hereinafter, RFAAX) B, at 2–3. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC and Registrant has neither requested a hearing nor submitted a written statement or corrective action plan and therefore has waived any such rights. RFAA, at 3; *see also* 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C).

² 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, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.usdoj.gov.

³ 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., James L. Hooper*, 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); *Frederick Marsh Blanton*, 43 FR at 27617.