



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Eagle Pharmacy; Decision and Order

On June 2, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Eagle Pharmacy of Houston, Texas (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 9. The OSC proposed the revocation of Registrant's DEA registration, No. FE4992257, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

Specifically, the OSC alleges that “[Registrant] repeatedly filled prescriptions for Schedule II through V controlled substances that contained multiple red flags indicative of diversion and/or abuse without addressing or resolving those red flags, and [that Registrant’s decision] to fill those prescriptions despite unresolved red flags, . . . [violated] federal and Texas law, including 21 C.F.R. §§ 1306.04(a) [and] 1306.06; and Tex. Health & Safety Code § 481.074(a).” RFAAX 2, at 4.

The OSC notified Registrant of its right to file with DEA a written request for hearing within 30 days after the date of receipt of the OSC. RFAAX 2, at 8 (citing 21 CFR 1301.43(a)). The OSC also notified Registrant that if it failed to file such a request, it would be deemed to have waived its right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43(c)(1)). The OSC further notified Registrant that “[a] default, unless excused, shall be deemed to constitute a waiver of the [Registrant’s] right to a hearing and an admission of the factual allegations of the [OSC].” *Id.* (citing 21 CFR 1301.43(e)).

Here, the OSC was served on Registrant and its counsel on June 5, 2023. RFAAX 7. On August 2, 2023, 58 days after service of the OSC, Registrant submitted to the DEA Office of Administrative Law Judges (OALJ) a Request for Hearing, a Motion of Leave to File Late Answer, and an Answer to Show Cause Order (Answer). RFAAX 3–5. On August 3, 2023, a

DEA Administrative Law Judge (ALJ) issued an Order Terminating Proceedings (Order), finding that Registrant was in default because Registrant had failed to timely request a hearing and had failed to timely show good cause to excuse the default. RFAAX 6. The ALJ's Order explained that "because [Registrant] filed its [hearing request] more than 45 days after receiving the OSC, . . . [Registrant] can only be excused from the default by the Office of the Administrator." *Id.* at 3 (citing 21 CFR 1301.43(c)(1)). To date, Registrant has not filed a motion to excuse the default with the Office of the Administrator. 21 CFR 1301.43(c)(1). Accordingly, Registrant remains in default.

"In the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), because Registrant has not timely requested a hearing, nor filed a motion with the Administrator seeking to excuse the default. *See also id.* § 1316.67.

I. Applicable Law

As already discussed, the OSC alleges that Registrant violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales v. Raich*, "the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to . . . dispense[] or possess any controlled substance except in a manner authorized by the CSA." 545 U.S. 1, at 12-13 (2005). In maintaining this closed regulatory system, "[t]he CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping." *Id.* at 14.

The OSC's allegations concern the CSA's "statutory and regulatory provisions . . . mandating . . . compliance with . . . prescription requirements" and, therefore, go to the heart of the CSA's "closed regulatory system" specifically designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances," and "to prevent the diversion of drugs from legitimate to illicit channels." *Id.* at 12-14, 27.

The Allegation That Registrant Filled Prescriptions Without Addressing or Resolving Red Flags of Abuse and/or Diversion

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a); *see Gonzales v. Oregon*, 546 U.S. 243, 274 (2006); *United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979), *rehearing den.*, 598 F.2d 620 (5th Cir. 1979), *cert. denied*, 444 U.S. 866 (1979); RFAAX 2, at 1-2. Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner. . . a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a); *United States v. Moore*, 423 U.S. 122, 136 n.12 (1975); *United States v. Armstrong*, 550 F.3d 382, 387 n.6 (5th Cir. 2008); RFAAX 2, at 1-2. The corresponding responsibility requires "pharmacists to identify and resolve suspicions that a prescription is illegitimate . . . before 'knowingly filling such a purported prescription.'" *Trinity Pharmacy II*, 83 FR 7304, 7331 (2018); RFAAX 2, at 2; *see also Suntree Pharmacy and Suntree Medical Equipment, LLC v. Drug Enf't Agency*, 2022 WL 444,357, *6 (11th Cir.) (upholding the Agency's revocation order, which was "[b]ased on [the] finding that Suntree violated its corresponding responsibility by filling prescriptions for controlled substances without resolving obvious red flags that the prescriptions lacked a legitimate medical purpose"). A registrant pharmacy "fail[s] to comply with its corresponding responsibility not to fill prescriptions written for illegitimate purposes" when it fails to "tak[e] and document[] steps to resolve . . . red flags or refus[e] to fill prescriptions with unresolvable red flags." *Pharmacy Doctors Enterprises Inc., d.b.a. Zion Clinic Pharmacy*, 789 F. App'x 724,

731 (11th Cir. 2020). DEA regulations further require that a “prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his [or her] professional practice.” 21 CFR 1306.06; RFAAX 2, at 1-2.

Texas regulations have a similar requirement that pharmacists ensure that controlled substance prescriptions are “issued for a legitimate medical purpose by a practitioner in the course of medical practice.” 22 Tex. Admin. Code section 291.29(b); RFAAX 2, at 2; *see also* Tex. Health & Safety Code sections 481.074(a), 481.128(a)(1). If the pharmacist observes any problem that raises doubts about the legitimacy of a prescription, the pharmacist must “verify the order with the practitioner prior to dispensing.” *Id.* section 291.29(a); RFAAX 2, at 2.

Texas regulations set forth various “red flag factors” that a pharmacist must consider in preventing the non-therapeutic dispensing of controlled substances. 22 Tex. Admin. Code section 291.29(f); RFAAX 2, at 3-4. Pharmacists should consider these red flags “by evaluating the totality of the circumstances rather than any single factor.” 22 Tex. Admin. Code section 291.29(f). These red flags include instances where:

- (f)(1) “the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances . . . ,”
- (f)(3) “prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs,”
- (f)(5) “prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities . . . , indicating a lack of individual drug therapy in prescriptions issued by the practitioner,”
- (f)(6) “dangerous drugs or over-the-counter products . . . are consistently added by the prescriber to prescriptions for controlled substances presented to the pharmacy, indicating a lack of individual drug therapy in prescriptions issued by the practitioner,”
- (f)(10) “the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the persons [sic] is being dispensed similar drugs at multiple pharmacies,”
- (f)(12) “persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.”

RFAAX 2, at 3-8. In addition to evaluating these red flag factors, a Texas pharmacist may not fill a prescription when a pharmacist has reason to believe that a prescription is inaccurate, inauthentic, or not issued for a legitimate medical purpose. *See* 22 Tex. Admin. Code section 291.29(a), (b).

Texas regulations further require pharmacists to “review the patient’s medication record” to ensure the “therapeutic appropriateness” of the prescription, and if a problem is observed, the pharmacist must “avoid or resolve the problem including consultation with the prescribing practitioner.” 22 Tex. Admin. Code sections 291.33(c)(2)(A)(i)–(ii); RFAAX 2, at 3. A pharmacist must resolve all problems raised by a prescription before dispensing it and must document how the problem was resolved. *Id.* section 291.33(c)(2)(A)(iv); RFAAX 2, at 3; *see also* section 291.33(c)(2)(C) (outlining the information that such documentation must include).

II. Findings of Fact

The Allegation That Registrant Filled Prescriptions Without Addressing or Resolving Red Flags of Abuse and/or Diversion

The Agency finds that, in light of Registrant’s default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted and the Agency finds that from August 7, 2020 to December 6, 2022, Registrant filled numerous controlled substance prescriptions without resolving red flags of abuse and diversion raised by those prescriptions. RFAAX 2, at 2–8. Registrant is further deemed to have admitted and the Agency finds that from August 7, 2020 to December 6, 2022, Registrant repeatedly filled prescriptions outside the usual course of professional pharmacy practice in Texas and beneath the standard of care in Texas. *Id.* at 1, 4.

A. Pattern Prescribing, Substances of Abuse, and Strength and Quantity

As discussed above, *see supra* Section I, Texas regulations identify the following prescribing patterns as red flag factors: “[T]he pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances”; “[P]rescriptions . . . are routinely for controlled substances commonly known to be abused

drugs”; and “[P]rescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities” 22 Tex. Admin. Code sections 291.29(f)(1), (3), (5); RFAAX 2, at 4–5.

Registrant is deemed to have admitted and the Agency finds that Registrant filled a total of 359 prescriptions that raised the red flags of pattern prescribing, prescriptions for controlled substances commonly known to be abused, and prescriptions for controlled substances in their highest strengths and/or in large quantities. RFAAX 2, at 4–7. Specifically, among these prescriptions, from September 2020 to August 2022 Registrant filled 127 prescriptions for hydrocodone¹ 10 mg and 122 prescriptions for carisoprodol² 350 mg issued by Dr. J.R. to 11 individuals. *Id.* at 5–6. The hydrocodone prescriptions ranged from 100 to 110 tablets each and the carisoprodol prescriptions ranged from 30 to 66 tablets each. *Id.*

Additionally, from August 2020 to January 2023 Registrant filled six prescriptions for hydrocodone 10 mg and 90 prescriptions for oxycodone³ 30 mg issued by Dr. B.R. to five individuals. *Id.* at 6. The hydrocodone prescriptions were for 110 tablets each and the oxycodone prescriptions ranged from 100 to 110 tablets each. *Id.* Finally, from May 2022 to December 2022 Registrant filled 14 prescriptions for oxycodone 30 mg issued by Dr. R.V. to four individuals. *Id.* at 6–7. These prescriptions ranged from 100 to 110 tablets each. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled 359 prescriptions without first resolving the red flags of pattern prescribing, prescriptions for controlled substances commonly known to be abused, and prescriptions for controlled substances in their highest strengths and/or in large quantities. *Id.* at 4, 8.

B. Lack of Individualized Therapy

Texas regulations identify the following prescribing pattern as a red flag factor:

“[D]angerous drugs or over-the-counter products [OTC] . . . are consistently added by the

¹ Hydrocodone is a schedule II opioid. 21 CFR 1308.12(b)(1)(vi).

² Carisoprodol is a schedule IV depressant. 21 CFR 1308.14(c)(7).

³ Oxycodone is a schedule II opioid. 21 CFR 1308.12(b)(1)(xiv).

prescriber to prescriptions for controlled substances presented to the pharmacy, indicating a lack of individual drug therapy” 22 Tex. Admin. Code section 291.29(f)(6); RFAAX 2, at 7. Registrant is deemed to have admitted that from August 2020 to December 2022 Registrant filled numerous prescriptions that combined dangerous drugs and OTC products for 16 individuals. RFAAX 2, at 7. Respondent admits that these prescriptions raise a red flag for a lack of individualized therapy, and further admits that the prescriptions were dispensed without documentation or resolution of that red flag. RFAAX 2, at 7.

Accordingly, the Agency finds substantial record evidence that Registrant filled numerous prescriptions without first resolving the red flag of lack of individualized therapy. *Id.* at 4, 7–8.

C. Long Distances

Registrant is deemed to have admitted and the Agency finds that individuals who travel long distances to obtain controlled substances is a well-known red flag of abuse or diversion. RFAAX 2, at 7. Registrant is deemed to have admitted that on three separate occasions in April 2022, June 2022, and July 2022, Registrant filled three prescriptions for hydrocodone 10 mg and three prescriptions for carisoprodol 350 mg for an individual who traveled 201 miles one-way to visit the pharmacy. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled six prescriptions without resolving the red flag of individuals traveling long distances. *Id.* at 4, 7–8.

D. Cash Payments

Texas regulations identify the following prescribing pattern as a red flag factor: “[P]ersons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.” 22 Tex. Admin. Code section 291.29(f)(12); RFAAX 2, at 7–8. Registrant is deemed to have admitted that all but three of the above-mentioned prescriptions were paid for in cash. RFAAX 2, at 4–8. In addition, Registrant is deemed to have admitted that Registrant filled these prescriptions without first identifying and resolving the red

flag of cash payments, which is a common red flag because it allows a patient to avoid the scrutiny associated with the use of insurance. *Id.* at 7–8.

Accordingly, the Agency finds substantial record evidence that Registrant filled controlled substance prescriptions without first resolving the red flag arising from cash payments.

E. Expert Review

DEA retained an independent pharmacy expert who concluded that the above prescription data presented multiple red flags that were highly indicative of abuse and diversion. *Id.* at 8. The expert further concluded, and Registrant admits that, “[t]hese red flags were not properly documented or resolved by a pharmacist acting in the usual course of professional practice prior to dispensing, and, therefore, each prescription was filled outside the standard of care of pharmacy practice in Texas.” *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant dispensed each of the above-referenced prescriptions without first resolving the red flags of pattern prescribing, prescriptions for controlled substances commonly known to be abused, prescriptions for controlled substances in their highest strengths and/or in large quantities, lack of individualized therapy, individuals traveling long distances, and/or individuals paying with cash or cash equivalents. The Agency finds substantial record evidence that Registrant’s dispensing of these prescriptions was outside the usual course of professional practice and beneath the standard of care in Texas.

III. Discussion

A. The Five Public Interest Factors

Under Section 304 of the CSA, “[a] registration . . . to . . . distribute[] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.” 21 U.S.C.

824(a)(4). In the case of a “practitioner,” which is defined in 21 U.S.C. 802(21) to include a “pharmacy,” Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A-E).⁴ The five factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. at 292-93 (2006) (Scalia, J., dissenting) (“It is well established that these factors are to be considered in the disjunctive,” citing *In re Arora*, 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *Penick Corp. v. Drug Enf’t Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall*, 412 F.3d. at n.2; *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Agency finds that the Government’s evidence in support of its *prima facie* case is confined to Factors B and D. *See* RFAAX 1, at 6. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 823(g)(1).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance or non-compliance with federal and local laws related to controlled substances and experience dispensing controlled substances. 21 U.S.C. 823(g)(1)(B) and (D); *see also Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022).

⁴ The five factors of 21 U.S.C. 823(g)(1)(A-E) are: (a) The recommendation of the appropriate State licensing board or professional disciplinary authority. (b) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances. (c) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances. (d) Compliance with applicable State, Federal, or local laws relating to controlled substances. (e) Such other conduct which may threaten the public health and safety.

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant repeatedly filled prescriptions for controlled substances that contained red flags of abuse and/or diversion without addressing or resolving those red flags. RFAAX 2, at 4-8. Registrant has further admitted and the Agency finds that all of the above-referenced prescriptions were filled outside the usual course of professional practice and beneath the standard of care in Texas. *Id.* As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1306.04, 1306.06, Texas Health & Safety Code section 481.074, and 22 Texas Administrative Code sections 291.29, 291.33.

The Agency further finds that Factors B and D weigh in favor of revoking Registrant's registration as continued registration would be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). Accordingly, the Agency finds that the Government established a *prima facie* case, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 823(g)(1).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Registrant to show why it can be entrusted with a registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at

833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830-31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the specific registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972-73.

Here, Registrant did not timely request a hearing and was deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAAX 6, at 2. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). The only submission that addresses the topic of mitigating evidence is Registrant's untimely Answer, which primarily denies the Government's allegations. RFAAX 4. As such, the record does not contain any evidence from Registrant demonstrating future compliance with the CSA, trustworthiness regarding the responsibilities of holding a DEA registration, acceptance of responsibility, or remedial measures.

Accordingly, the Agency will order the revocation of Registrant's registration.

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. FE4992257 issued to Eagle Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Eagle Pharmacy to renew or modify this registration, as well as any other pending application of Eagle Pharmacy for additional registration in Texas. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 8, 2025, by Acting Administrator Derek Maltz. 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. 2025-06311 Filed: 4/11/2025 8:45 am; Publication Date: 4/14/2025]