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).

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 May 14, 2025.

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 4–11–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mariste Pharmacy; Decision and Order

On May 20, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Mariste Pharmacy (Registrant) of Richmond, Texas. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, Control No. FM2279431, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

Specifically, the OSC/ISO alleged that Registrant ''repeatedly filled Schedule II–V controlled substance prescriptions that contained red flags indicative of diversion and/or abuse, without appropriately addressing or resolving those red flags, . . . [in] violation of both federal and Texas law, including 21 CFR 1306.04(a) and 1306.06; and Texas Health & Safety Code Ann. § 481.074(a).'' RFAAX 1, at 5. The OSC/ISO also alleged that Registrant ''had numerous record keeping violations and improperly stored controlled substances at a non-registered location,'' in violation of 21 CFR 1304.11(a)–(c) and 1304.21(a), (d). *Id.* at 5–6.

The OSC/ISO 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/ISO. *Id.* at 10–11 (citing 21 CFR 1301.43(a)). The OSC/ISO 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), (d), (e)).

To date, Registrant has not filed a hearing request with the OALJ Hearing Clerk,[1] has not provided good cause for its failure to timely request a hearing, and has not filed a motion to excuse the default with the Office of the Administrator.[2] 21 CFR 1301.43(c)(1). Accordingly, the Agency finds that Registrant is in default.

''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/ISO].'' 21 CFR 1301.43(e). Further, ''[i]n 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.'' *Id.* § 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), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

I. Applicable Law

As already discussed, the OSC/ISO 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/ISO's allegations concern the CSA's ''statutory and regulatory provisions . . . mandating . . . compliance with . . . security controls to guard against diversion, recordkeeping and reporting obligations, and 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 1, at 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 1, at 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); *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''); RFAAX 1, at 2. A respondent 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 1, at 2.

As for state law, 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); *see also* Tex. Health & Safety Code sections 481.074(a), 481.128(a)(1); RFAAX 1, at 3. Texas regulations also specify that ''[a] pharmacist may not dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code section 481.074(a); RFAAX 1, at 3.

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 1, at 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)(11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner; and (f)(12) persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance. RFAAX 1, at 4. Texas regulations also identify ''the geographical distance between the practitioner and the patient'' as a ''reason[ ] to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship or in violation of the practitioner's standard of practice.'' 22 Tex. Admin. Code section 291.29(c)(4); RFAAX 1, at 8. Further, under Texas regulations, ''[a] pharmacist shall not dispense a prescription drug if the pharmacist knows or should know the prescription drug order is fraudulent or forged.'' 22 Tex. Admin. Code section 291.29(f). 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 1, at 3. A pharmacist must resolve all problems raised by a prescription before dispensing it and must document how the problem was resolved. 22 Tex. Admin. Code section 291.33(c)(2)(A)(iv);

[1] According to the Government's representations in the RFAA, Registrant filed a letter on June 19, 2024, in which it ''admitted, denied and/or further expounded on the allegations charged in the [OSC/ISO].'' RFAA, at 2. The Government represented that ''absent in this letter was a request for hearing'' and that ''DEA has not received any other correspondence from Registrant, or any attorney acting on her behalf, concerning the [OSC/ISO].'' *Id.*

[2] A party found in default may file a motion showing good cause to set aside the default no later than 30 days from the date of issuance of a final order. 21 CFR 1301.43(f)(3). Such motion must be filed with the Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov.*

see also id. section 291.33(c)(2)(C) (outlining the information that such documentation must include); RFAAX 1, at 3–4.

The Allegation That Registrant Failed to Adequately Maintain Complete and Accurate Records

Federal law also imposes recordkeeping and security requirements on pharmacies. For example, the CSA requires pharmacies to keep accurate and timely records of inventory and dispensing. 21 CFR 1304.11(a)–(c); RFAAX 1, at 5. This includes conducting and maintaining an ''initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,'' as well as conducting and maintaining a ''biennial inventory . . . of all stocks of controlled substances on hand.'' 21 CFR 1304.11(a)–(c); RFAAX 1, at 5. Pharmacies must retain these inventories ''for at least 2 years from the date of such inventory or records, for inspection and copying.'' 21 CFR 1304.04; RFAAX 1, at 3. The CSA also requires pharmacies to ''maintain, on a current basis, a complete and accurate record of each substance . . . received,'' and the pharmacy must ''record[ ] . . . the date on which the controlled substances are actually received.'' 21 CFR 1304.21(a); RFAAX 1, at 3.

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/ISO are deemed admitted.[3] 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted and the Agency finds that Registrant repeatedly dispensed prescriptions in violation of the minimum practice standards that govern pharmacy practice in Texas. RFAAX 1, at 6–9. Specifically, from at least February 2021 through March 2024, Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving the red flags. *Id.*

Cash Payments

As discussed above, *see supra* Section I, 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 1, at 6. Registrant is deemed to have admitted that it failed to identify and resolve the red flag of cash payments. RFAAX 1, at 6. Specifically, between February 2021 and March 2024, Registrant filled 1,273 prescriptions for oxycodone 30 mg (a Schedule II opioid), and approximately 1,272 of those prescriptions were paid for in cash or cash equivalents. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled approximately 1,272 controlled substance prescriptions without first resolving the red flag arising from cash payments.

Shared Addresses

Texas regulations identify the following prescribing pattern as a red flag factor: ''[M]ultiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner.'' 22 Tex. Admin. Code section 291.29(f)(11); RFAAX 1, at 7. Registrant is deemed to have admitted that it failed to identify and resolve the red flag of multiple persons with the same address presenting the same prescriptions from the same practitioner. RFAAX 1, at 7–8. Specifically, between February 2021 and August 2023, Registrant filled controlled substance prescriptions for two groups of patients who shared the same address[4] and presented prescriptions for the same controlled substance (oxycodone 30 mg) from the same practitioner (Dr. V.M.). *Id.* at 8.[5]

Accordingly, the Agency finds substantial record evidence that Registrant filled numerous controlled substance prescriptions without first resolving the red flag of shared addresses.

Long Distances

Texas regulations identify ''the geographical distance between the practitioner and the patient'' as a ''reason[ ] to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship or in violation of the practitioner's standard of practice.'' 22 Tex. Admin. Code section 291.29(c)(4); RFAAX 1, at 8. Registrant is deemed to have admitted that it repeatedly filled prescriptions without identifying and resolving the red flag of patients traveling long distances to obtain controlled substance prescriptions. RFAAX 1, at 8–9. Specifically, Registrant is deemed to have admitted that between February 2021 and June 2022, it filled numerous prescriptions for four individuals (A.S.W., De.D.G., J.G., and C.R.) who traveled more than 45 miles one way to obtain their controlled substance prescriptions, and for three individuals (D.A., F.G., and R.D.) who traveled more than 70 miles one way to obtain their prescriptions. *Id.* at 9.

Accordingly, the Agency finds substantial record evidence that Registrant filled numerous controlled substance prescriptions without first resolving the red flag arising from long distances traveled.[6]

[3] The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan* v. *United States,* 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

[4] These patients included T.C., R.L.C., and T.G., who shared the same address, and H.E., Z.J., and Di.P. who shared the same address.

[5] The OSC/ISO contains additional allegations of patients with a shared address presenting prescriptions for the same controlled substance from the same prescriber. RFAAX 1, at 7–8. However, each of these allegations identifies multiple prescribers and multiple patients, and it is unclear which prescribers issued prescriptions to which patients. Thus, it is not clear from substantial record evidence or an admission that patients sharing the same address were receiving the same controlled substance from the same prescriber. Accordingly, the remaining allegations regarding the red flag of pattern prescribing are not sustained. The Agency finds that the founded allegations in this decision are more than sufficient to support the Government's requested sanction of revocation under these circumstances.

[6] The OSC/ISO additionally alleged that Registrant filled numerous prescriptions for controlled substances for certain patients that were issued by practitioners engaging in ''pattern prescribing.'' RFAAX 1, 6–7. For example, the OSC/ISO alleges, and it is therefore admitted, that ''Between February 1, 2021, and until at least March 6, 2024, the Pharmacy filled prescriptions for Patients V.R., B.A.C., R.B., V.S., R.J.H., B.R., L.K., K.K., C.D.G., R.F., H.W, and De.G. who presented prescriptions for oxycodone 30 mg from multiple practitioners, in violation of Texas law.'' *Id.* at 7. The OSC/ISO implies that this conduct violates 22 Texas Administrative Code section 291.29(f)(10), which identifies as a potential red flag factor that ''the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners.'' It is not clear from substantial record evidence or an admission whether each of the 12 patients listed was receiving prescriptions from multiple practitioners, or if there were multiple prescribers who issued prescriptions to this group of 12 patients. Accordingly, this allegation is not sustained.

The OSC/ISO also alleged, and it is therefore admitted, that ''Between February 1, 2021, and until at least March 6, 2024, the Pharmacy filled oxycodone 30 mg prescriptions for Patients B.A.C., D.Y., K.M.K., Z.J., S.D.W., R.B., V.R., and H.W. which were for only the highest strength and in high quantities, in violation of Texas law.'' RFAAX 1, at 6–7. The OSC/ISO implies that this conduct violates 22 Texas Administrative Code section 291.29(f)(5), which identifies as a potential red flag factor that ''prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner.'' *Id.* at 7.

Continued

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.* The expert further concluded, and Registrant admits that, ''[t]hese red flags were not adequately 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.* Registrant further admitted that none of the above-referenced controlled substance prescriptions was filled for a legitimate medical purpose. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant dispensed the above-referenced prescriptions without first resolving the red flags of cash payments, long distances, and/or shared addresses, and that Registrant's dispensing of these prescriptions was outside the usual course of professional practice. Additionally, the Agency finds substantial record evidence that none of the above-referenced controlled substance prescriptions was filled for a legitimate medical purpose.

The Allegation That Registrant Failed to Adequately Maintain Complete and Accurate Records

Registrant is deemed to have admitted that it failed to adequately maintain an initial inventory and a biennial inventory, which prevented DEA from conducting an audit. RFAAX 1, at 5. Accordingly, the Agency finds substantial evidence that Registrant failed to adequately maintain an initial and biennial inventory.

Further, Registrant is deemed to have admitted that between February 2021 and February 2023, it failed to adequately maintain complete and accurate continuing records regarding its inventory of controlled substances. *Id.* at 6. Specifically, Registrant admits that it failed to adequately maintain a record of the receipt of controlled substances, and that it was unable to provide DEA with even the most basic required documentation concerning its on-hand controlled substance inventory. *Id.*

Accordingly, the Agency finds substantial evidence that Registrant failed to maintain a complete and accurate record of each substance received.[7]

I. 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).[8] 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. Allegation That Registrant's Registration Is Inconsistent With the Public Interest

Factors B and/or D—Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

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).

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 1, at 5–9. Registrant has further admitted and the Agency finds that none of the above-referenced controlled substance prescriptions were filled for a legitimate medical purpose in the usual course of professional practice. *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.

Additionally, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant failed to maintain an initial and biennial inventory. As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1304.11(a)–(c) and 1304.04.[9] Finally, Registrant has

It is not clear from substantial record evidence or an admission that any of these patients shared the same practitioner. Accordingly, this allegation is not sustained. The Agency finds that the founded allegations in this decision are more than sufficient to support the Government's requested sanction of revocation under these circumstances.

[7] The OSC/ISO additionally alleged, and it is therefore admitted, that ''on or about February 14, 2023, [Registrant's] owner was discovered to be storing large amounts of controlled substances at a personal residence that is not a registered location,'' and that ''DEA discovered that the controlled substances were being transported back and forth between the registered pharmacy location and the unregistered personal residence.'' RFAAX 1, at 6. The OSC/ISO implies that this conduct violates 21 CFR 1301.75(b), which states that ''Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.'' It is not clear from substantial record evidence or an admission that Registrant's transporting of controlled substances means that Registrant was not storing controlled substances in a ''securely locked, substantially constructed cabinet.'' Further, 21 CFR 1301.75(b) does not state that controlled substances must be stored at a ''registered location,'' and the OSC/ISO does not identify additional statutory support for this requirement. Accordingly, this allegation regarding the failure to adequately store controlled substances is not sustained. The Agency finds that the founded allegations in this decision are more than sufficient to support the Government's requested sanction of revocation under these circumstances.

[8] 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 applicant's experience in dispensing, or conducting research with respect to controlled substances. (c) The applicant'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.

[9] The OSC/ISO alleges that Registrant's failure to maintain an initial and biennial inventory and its failure to maintain records of receipt of controlled substances also violated 22 Texas Administrative Code section 291.75(a)(l), (c)(4)–(5). RFAAX 1, at 5.

admitted and the Agency finds that it failed to maintain complete and accurate records of each controlled substance received. As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1304.21(a).

The Agency further finds that Factors B and D weigh in favor of denial of Registrant's application and that Registrant's 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).

II. 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 or properly request a hearing and was deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–9. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in the OSC and has not otherwise availed itself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to its future compliance with the CSA nor made any demonstration that it can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted.

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

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. FM2279431 issued to Mariste 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 Mariste Pharmacy to renew or modify this registration, as well as any other pending application of Mariste Pharmacy for additional registration in Texas. This Order is effective May 14, 2025.

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. 2025–06312 Filed 4–11–25; 8:45 am]

BILLING CODE 4410–09–P

However, the OSC/ISO does not contain sufficient factual or legal analysis to enable to Agency to assess the relevance or applicability of these statutes. Section (a)(1)(A) pertains to institutional pharmacies, and the OSC/ISO does not allege that Registrant is an institutional pharmacy. Section (c)(4) outlines requirements for patient records of Schedule II controlled substances to be maintained separately from patient records of controlled substances in other schedules, and it outlines additional requirements related to distribution records and institutional pharmacies. Finally, Section (c)(5) pertains to floor stock records.

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[OMB Control No. 1230–0014]

Proposed Extension of Information Collection: Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation

AGENCY: Office of Disability Employment Policy, United States Department of Labor.

ACTION: Notice of information collections and request for comments.

SUMMARY: The Department of Labor (DOL) Office of Disability Employment Policy is soliciting comments regarding this ODEP-sponsored information collection for the Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation. As part of its continuing effort to reduce paperwork and respondent burden, DOL conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed.

DATES: Comments pertaining to this information collection are due on or before June 13, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submission: Submit electronic comments in the following way:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket, with no changes. Because your comment will be made public, you