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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Pine Pharmacy; Decision and Order

I. INTRODUCTION

On April 9, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Shreeji 16 Inc. d/b/a Pine Pharmacy, of Ocala, Florida (Registrant). 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, No. FS1451222, 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*. at 1-2 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

More specifically, the OSC/ISO alleged that as recently as December 5, 2024, Registrant repeatedly filled prescriptions for Schedule II through V controlled substances without addressing, resolving, and/or documenting resolution of red flags of abuse and diversion prior to dispensing. *Id.* The OSC/ISO alleges that filling these prescriptions violated federal and Florida state law. *Id*. (citing 21 CFR 1306.04(a), 1306.06; Fla. Admin. Code Ann. r. 64B16-27.810, 64B16-27.831).[1] The OSC/ISO also alleges that Registrant allowed a non-certificate holder to use Registrant's digital certificate and private key to order controlled substances in the Controlled Substances Ordering System (CSOS), in violation of 21 CFR 1311.30(a) and (b). *Id.* at 9. Finally, the OSC/ISO alleges that Registrant maintained a collection bin for pharmaceutical drugs without the authorization required under 21 CFR 1317.40(a). *Id.*

[1] The Agency need not adjudicate the criminal violations alleged in the OSC/ISO. *Ruan v. United States*, 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

On June 3, 2025, the Government submitted a request for final agency action (RFAA) requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1-4. After carefully reviewing the entire record and conducting the analysis as set forth in more detail below, the Agency grants the Government's request for final agency action and revokes Registrant's registration.

II. DEFAULT DETERMINATION

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request "within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default" unless "good cause" is established for the failure. 21 CFR 1301.43(a) & (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is "deemed to have waived their right to a hearing and to be in default." 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute "an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Here, the OSC/ISO notified Registrant of its right to file with DEA a written request for hearing and 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. RFAAX 1, at 11 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 1.[2] Thus, the Agency finds that Registrant is in default and therefore has admitted to the factual allegations in the OSC/ISO. 21 CFR 1301.43(e); 21 CFR 1301.43(c)(1).

III. APPLICABLE LAW

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC/ISO alleges that Registrant violated provisions of the CSA and its implementing regulations. As the Supreme Court stated in *Gonzales v. Raich*, 545 U.S. 1

[2] Based on the Government's submissions in its RFAA dated June 3, 2025, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the RFAA represents that the OSC/ISO was personally served on Registrant, RFAA, at 1, and attaches a DEA Form 12 Receipt for Cash or Other Items signed by the Pharmacist in Charge. RFAAX 2, at 1.

(2005), "the main objectives of the [Controlled Substances Act (CSA)] were to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances." 545 U.S. at 12. *Gonzales* explained that:

> Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA . . . . The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

Id. at 12-14.

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.

B. The Allegation that Registrant Improperly Dispensed Controlled Substances

According to the CSA's implementing regulations, a lawful controlled substance prescription 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). While the "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." *Id*.

To prove that a pharmacist violated his corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) ("[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.") (emphasis added). DEA has consistently interpreted the corresponding responsibility regulation such that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and

thereby avoid [actual] knowledge of the real purpose of the prescription." *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4,729, 4,730 (1990) (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.*, 80 Fed. Reg. 28,667, 28,670-72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter).

Pursuant to their corresponding responsibility, pharmacists must exercise "common sense and professional judgment" when filling a prescription issued by a physician. *Bertolino*, 55 Fed. Reg. at 4,730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id*.; *see also Med. Shoppe-Jonesborough v. Drug Enf't Admin.*, 300 Fed. Appx. 409, 412 (6th Cir. 2008) ("When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.").

As for state law, Florida Administrative Code § 64B16-27.810 requires that, prior to dispensing, a pharmacist "review the patient record and each new and refill prescription . . . to promote therapeutic appropriateness by identifying: (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; [and] (g) Clinical abuse/misuse." Fla. Admin. Code § 64B16-27.810. The regulation further states that "[u]pon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber." *Id*. § 64B16-27.810(2).

Additionally, Florida Administrative Code § 64B16-27.831 states that "in filling valid prescriptions for controlled substances," pharmacists should "exercise[e] sound professional judgment," and "dispens[e] controlled substances for a legitimate medical purpose in the usual

course of professional practice" considering "each patient's unique situation." Fla. Admin. Code § 64B16-27.831.

C. The Allegation that Registrant Permitted Unauthorized Use of Its Digital Certificate for CSOS

Under the CSA's implementing regulations, a person must "obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances." 21 CFR 1311.10. A person is eligible to obtain a CSOS digital certificate only if he/she: (1) is the person who "signed the most recent registration application or renewal application," (2) is "a person authorized to sign a registration application," or (3) has been "granted power of attorney by [the] registrant to sign orders for one or more schedules of controlled substances." *Id.* The regulations further provide that "[o]nly the certificate holder may access or use his or her digital certificate and private key," and "[a] certificate holder must ensure that no one else use the private key" and "prevent unauthorized use of that private key." *Id.* § 1311.30.

D. The Allegation that Registrant Maintained An Unregistered Drug Collection Receptacle

The CSA's implementing regulations provide that "retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with [21 CFR] § 1301.51 of this chapter." 21 CFR 1317.40(a). The regulations further provide that collection may only occur at the "registered locations . . . that are authorized for collection" and "[l]ong-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles." *Id.* 1317.40(b).

IV. FINDINGS OF FACT

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are deemed admitted.

A. The Allegation that Registrant Improperly Dispensed Controlled Substances

Registrant is deemed to have admitted and the Agency finds that from March 2023 through December 2024 Registrant repeatedly filled prescriptions for Schedule II through V controlled substances that evidenced multiple red flags indicative of diversion and/or abuse, without addressing, resolving, and/or documenting resolution of those red flags prior to dispensing. RFAAX 1, at 1-3.

Long-term Use of Immediate-Release Opioids and High Opioid Dosages

As discussed above, *see supra* Section I, Florida law requires pharmacists to identify and address the red flag of over-utilization. *See* Fla. Admin. Code Ann. r. 64B16-27.810. Registrant is deemed to have admitted that DEA has found that extended use of immediate-release opioids is a red flag of abuse or diversion because extended-release opioids are generally more appropriate for treatment of chronic pain. RFAAX 1, at 3 (citing *Pharmacy 4 Less*, 86 Fed. Reg. 54,550 (2021)). Registrant is deemed to have admitted that high dosages of opioids can be a red flag because they can significantly increase the risk of overdose and death. *Id.*

Registrant admits that it repeatedly filled prescriptions for oxycodone, an immediate-release Schedule II opioid, to the following individuals without addressing or resolving the red flag of extended use of immediate-release opioids:

A.G.: Between April 16, 2024, and December 5, 2024, Registrant filled approximately nine prescriptions for A.G. for oxycodone 30 mg (90 tablets). *Id.* at 4.

T.M.: Between August 15, 2023, and November 27, 2024, Registrant filled approximately 15 prescriptions for T.M. for oxycodone 30 mg (90 tablets). *Id.*

R.R.: Between April 8, 2024, and November 26, 2024, Registrant failed approximately nine prescriptions for R.R. for oxycodone 30 mg (90 tablets). *Id.*

C.P.: Between April 29, 2024, and November 21, 2024, Registrant filled approximately eight prescriptions for C.P. for oxycodone 7.5 mg (120 tablets). *Id.*

J.J.: Between August 21, 2023, and November 18, 2024, Registrant filled approximately 14 prescriptions for J.J. for oxycodone 30 mg (90 tablets). *Id.* In addition, Registrant filled prescriptions for J.J. on September 20, 2023, for oxycodone 30 mg (42 tablets), and on October 3, 2023, for oxycodone (48 tablets). *Id.*

A.R.: Between August 9, 2023, and June 12, 2024, Registrant filled approximately 11 prescriptions for A.R. for oxycodone 20 mg (120 tablets). *Id.* On November 28, 2023, Registrant filled a prescription for A.R. for oxycodone 30 mg (90 tablets). *Id.*

J.P.: Between July 31, 2023, and May 6, 2024, Registrant filled approximately 10 prescriptions for J.P. for oxycodone 30 mg (90 tablets). *Id.*

C.R.: Between August 7, 2023, and April 5, 2024, Registrant filled approximately nine prescriptions for C.R. for oxycodone 30 mg (90 tablets). *Id.*

M.Sw.: Between March 16, 2023, and February 5, 2024, Registrant filled approximately 12 prescriptions for M.Sw. for oxycodone 30 mg (84 tablets). *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled at least 100 oxycodone prescriptions without first resolving and documenting resolution of the red flag arising from extended use of immediate-release opioids.

Drug Cocktails and Commonly Abused Drugs

As discussed above, *see supra* Section I, Florida law requires pharmacists to identify and address the red flag of drug-drug interactions and clinical abuse or misuse. RFAAX 1, at 5; Fla. Admin. Code Ann. r. 64B16-27.810. Registrant admits that DEA has long recognized the prescribing of so-called "drug cocktails" as a red flag of abuse or diversion. RFAAX 1, at 5 (citing *Jones Total Health Care Pharmacy, LLC*, 81 Fed. Reg. 79,188, 79,199 (2016)). Drug cocktails arc combinations of controlled substances that are widely known to be abused or diverted and that significantly increase the risk of serious medical consequences. *Id.* These risks require pharmacists to carefully review whether the prescriptions were issued for a legitimate medical purpose. *Id.*

Common drug cocktails include the combination of an opioid and a benzodiazepine, an opioid and a stimulant, or an opioid and a muscle relaxant. *Id.* Registrant admits that DEA has long held that these cocktails are highly abused and associated with diversion. *Id.* (citing Craig Rosenblum, MD., 87 Fed. Reg. 21, 18 l, 21,189 (2022); *Jacobo Dreszer, MD.*, 76 Fed. Reg. 19,386, 19,389 (2011)).

Registrant admits that it repeatedly filled prescriptions for the following individuals without addressing, resolving, or documenting the resolution of the red flag of "drug cocktails":

A.G.: On at least eight occasions between April 16, 2024, and December 5, 2024, Registrant filled prescriptions for A.G. for a drug cocktail consisting of oxycodone and cyclobenzaprine (an unscheduled muscle relaxer). *Id.* These prescriptions were filled on

the same day or in close succession. *Id.* Registrant admits that this combination of controlled substances is a red flag associated with abuse, overdose, and death. *Id.*

R.R.: On at least eight occasions between May 13, 2024, and November 26, 2024, the Pharmacy filled prescriptions for R.R. for a drug cocktail consisting of oxycodone and cyclobenzaprine. *Id.* These prescriptions were filled on the same day or in close succession. *Id.*

C.R.: On at least eight occasions between September 7, 2023, and April 5, 2024, Registrant filled prescriptions for C.R. for a drug cocktail consisting of oxycodone and cyclobenzaprine. *Id.* These prescriptions were filled on the same day or in close succession. *Id.*

A.R.: On at least 11 occasions between August 9, 2023, and June 12, 2024, Registrant filled prescriptions for A.R. for a drug cocktail consisting of oxycodone and pregabalin (a Schedule V anticonvulsant). *Id.* at 6. These prescriptions were filled on the same day or in close succession. *Id.* Registrant admits that this combination of controlled substances is a red flag associated with abuse, overdose, and death. *Id.*

C.P.: On at least three occasions between August 27, 2024, and December 6, 2024, Registrant filled prescriptions for C.P. for a drug cocktail consisting of oxycodone and carisoprodol (a Schedule IV muscle relaxer). *Id.* Although not filled on the same day, each prescription was written for a 30-day supply and filled on a near-monthly schedule. *Id.* Registrant admits that this combination of controlled substances is a red flag associated with abuse, overdose, and death. *Id.*

Accordingly, the Agency finds that Registrant filled at least 38 prescriptions without first resolving and documenting resolution of the red flag arising from drug cocktails.

Long Distances

Registrant admits that DEA has found that traveling abnormally long distances to obtain or fill controlled substance prescriptions is a well-known red flag of abuse or diversion because patients ordinarily should be able to get their prescriptions filled without having to travel abnormally long distances. *Id.* (citing *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,164 (2010)).

Registrant admits that it repeatedly filled controlled substance prescriptions for individuals whose addresses revealed they had traveled abnormally long distances to obtain and fill prescriptions, and Registrant admits that it consistently failed to resolve this red flag prior to dispensing. *Id.* Specifically, Registrant admits that it filled prescriptions for the following individuals, whose record addresses show that they traveled long distances:

T.M. at Fort Lauderdale Address: On at least eight occasions between August 15, 2023, and April 11, 2024, Registrant dispensed oxycodone to T.M. *Id.* T.M. had an approximately 634-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* This trip included approximately 314 miles from T.M.'s address in Fort Lauderdale, Florida, to the prescribing physician's office, approximately 41 miles from the prescribing physician's office to Registrant, and approximately 279 miles from Registrant back to T.M.'s address. *Id.*

T.M. at Gainesville Address: On at least eight occasions between May 10, 2024, and November 27, 2024, Registrant dispensed oxycodone to T.M. *Id.* at 7. T.M. had an approximately 86-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* This trip included approximately 3 miles from T.M.'s address in Gainesville, Florida, to the prescribing physician's office, approximately 41 miles from the prescribing physician's office to Registrant, and approximately 42 miles from Registrant back to T.M.'s address. *Id.*

J.J.: On at least 17 occasions between August 21, 2023, and November 18, 2024, Registrant dispensed oxycodone to J.J. *Id.* J.J. had an approximately 88-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* This trip included approximately six miles from J.J.'s address in Gainsville, Florida, to the prescribing physician's office, approximately 41 miles from the prescribing physician's office to Registrant, and approximately 41 miles from Registrant back to J.J.'s address. *Id.*

M.Sw.: On at least 11 occasions between April 27, 2023, and February 5, 2024, Registrant dispensed oxycodone to M.Sw. *Id.* M.Sw. had an approximately 151-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* This trip included approximately nine miles from M.Sw.'s address in Orlando, Florida, to the prescribing physician's office, approximately 69 miles from the prescribing physician's office to Registrant, and approximately 68 miles from Registrant back to M.Sw.'s address. *Id.*

C.R.: On at least nine occasions between August 7, 2023, and April 5, 2024, Registrant dispensed oxycodone to C.R. *Id.* at 8. C.R. had an approximately 176-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* at 7. This trip included approximately 58 miles from C.R.'s address in Green Cove Springs, Florida, to the prescribing physician's office, approximately 41 miles from the prescribing physician's office to Registrant, and approximately 77 miles from Registrant back to C.R.'s address. *Id.*

A.R.: On at least seven occasions between November 2, 2023, and June 12, 2024, the Pharmacy dispensed pregabalin to A.R., and on at least seven occasions between these dates, Registrant dispensed oxycodone to A.R. *Id.* at 8. A.R. had an approximately 82-mile round trip to obtain controlled substance prescriptions from his/her physician and fill them at Registrant. *Id.* This trip included approximately 38 miles from A.R.'s address in Belleview, Florida, to the prescribing physician's office, approximately 34 miles from the prescribing physician's office to Registrant, and approximately 10 miles from Registrant back to A.R.'s address. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled at least 67 prescriptions without resolving the red flag that customers were traveling abnormally long distances to obtain and fill controlled substance prescriptions.

Pattern Prescribing

Registrant admits that "pattern prescribing"—which occurs when a practitioner prescribes the same controlled substance in identical or substantially similar quantities to multiple individuals—is a red flag because it indicates a lack of individualized therapy for each patient and it indicates that the "prescriber is not prescribing the controlled substances for a legitimate medical purpose." *Id.* (citing *Pharmacy Place*, 86 Fed. Reg. 21,008, 21,011 (2021)). Registrant admits that while "pattern prescribing can manifest over an extended period of time and may not be immediately recognizable to a pharmacist," a pharmacist still has an obligation to resolve such controlled substances prescriptions and should refuse to fill them if the pharmacist is unable to resolve this red flag. *Id.* (citing *Pharmacy Place*, 86 Fed. Reg. at 21,011; *Med. Pharmacy*, 86 Fed. Reg. 72,030, 72,049 (2021)).

Registrant admits that it filled approximately 64 prescriptions issued by Dr. N.A. to six different individuals for 90 tablets of oxycodone 30 mg between July 31, 2023, and December 5, 2024.[3] *Id.* at 8-9. Registrant admits that Dr. N.A. was engaging in pattern prescribing. *Id.* at 8. Accordingly, the Agency finds substantial record evidence that Registrant filled approximately 64 prescriptions without addressing, resolving, and documenting resolution of the red flag of pattern prescribing.

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.

[3] These prescriptions included approximately nine prescriptions for A.G filled between April 16, 2024, and December 5, 2024; approximately 13 prescriptions for T.M. filled between November 14, 2023, and November 27, 2024; approximately nine prescriptions for R.R. filled between April 8, 2024, and November 26, 2024; approximately 14 prescriptions for J.J. filled between October 20, 2023, and November 8, 2024; approximately 10 prescriptions for J.P. filled between July 31, 2023, and May 6, 2024; and approximately nine prescriptions for C.R. filled between August 7, 2023, and April 5, 2024. RFAAX 1, at 8-9.

Id. at 9. The expert further concluded, and Registrant admits that, "[t]hese red flags were not 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 Florida." *Id*.

Accordingly, the Agency finds substantial record evidence that Registrant filled at least 269 prescriptions without first resolving the red flags of long-term use of immediate-release opioids, drug cocktails, long distances, and pattern prescribing, and that Registrant's filling of these prescriptions was outside the usual course of professional practice.

B. The Allegation that Registrant Permitted Unauthorized Use of Its Digital Certificate for CSOS

Registrant admits and the Agency finds substantial evidence that between May 15, 2023, and April 9, 2024, a non-certificate holder used Registrant's digital certificate and private key to order controlled substances in CSOS. *Id.* Registrant admits that the authorized holder for the certificate was not present at the time these controlled substances were ordered. *Id.*

C. The Allegation that Registrant Maintained An Unregistered Drug Collection Receptacle

Registrant admits and the Agency finds substantial record evidence that it maintained a collection bin for pharmaceutical drugs without the authorization required under 21 CFR 1317.40(a).

V. PUBLIC INTEREST DETERMINATION

A. Legal Background on the Public Interest Determination

When the CSA's requirements are not met, the Attorney General "may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be 'inconsistent with the public interest.'" *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006) (quoting 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 (Scalia, J., dissenting) ("It is well established that these factors are to be considered in the disjunctive," quoting *In re Arora*, 60 Fed. Reg. 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (1993); see *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as "applying a multi-factor test through case-by-case adjudication," quoting *LeMoyne-Owen Coll. v. N.L.R.B.*, 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.*, 58 Fed. Reg. at 37,508, and the Agency "may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied." *Morall*, 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 Fed. Reg. 33,207, 33,208 (2007)); *see also Penick Corp. v. Drug Enf't Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it "need not make explicit findings as to each one." *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U. S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). "In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the

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[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.

public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e).

B. Registrant's Registration Is Inconsistent with the Public Interest

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for sanction is confined to Factors B and D. RFAA 2-4, RFAAX 1. Evidence is considered under Factors B and D when it reflects compliance or non-compliance with laws related to controlled substances and experience dispensing controlled substances. *Kareem Hubbard, M.D.*, 87 Fed. Reg. 21,156, 21,162 (2022).

i. The Allegation that Registrant Improperly Dispensed Controlled Substances

Here, as found above, Registrant is deemed to have admitted and the Agency finds that between March 2023 and December 2024, Registrant repeatedly filled at least 269 prescriptions without addressing, resolving, and documenting red flags of drug abuse and diversion. RFAAX 2, at 5-8. Registrant has further admitted and the Agency finds that all of the above-referenced prescriptions were filled outside the usual course of professional practice, beneath the standard of care in Florida, and in violation of the pharmacy's corresponding responsibility.[5] *Id.* As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1306.04 and Fla. Admin. Code Ann. r. 64B16-27.810(1).

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[5] Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Morning Star Pharmacy and Medical Supply 1,*85 Fed. Reg. 51,045, 51,061 (2020) (pattern prescribing; distance; cash payments; high doses/quantities of high-alert controlled substances); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,*83 Fed. Reg. 10,876, 10,898 (2018), *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; cash payments); *Hills Pharmacy,*81 Fed. Reg. 49,816, 49,836-39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances); *The Medicine Shoppe,*79 Fed. Reg. 59,504, 59,507, 59,512-13 (2014) (unusually large quantity of a controlled substance; pattern prescribing).

ii. The Allegation that Registrant Permitted Unauthorized Use of Its Digital Certificate for CSOS

Further, as found above, Registrant is deemed to have admitted and the Agency finds that between May 15, 2023, and April 9, 2024, a non-certificate holder used Registrant's digital certificate and private key to order controlled substances in CSOS, while the authorized holder of the certificate was not present. *Id.* Accordingly, the Agency finds substantial record evidence that Registrant violated 21 CFR 1311.30(a), (c). *Id.*

iii. The Allegation that Registrant Maintained An Unregistered Drug Collection Receptacle

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant maintained a collection bin for pharmaceutical drugs without the authorization required under 21 CFR 1317.40(a). Accordingly, the Agency finds substantial record evidence that Registrant violated 21 CFR 1317.40(a). RFAAX 1, at 9.

The Agency further finds that after considering the factors of 21 U.S.C. 823(g)(1) Registrant's continued registration is "inconsistent with the public interest." 21 U.S.C. 824(a)(4). Accordingly, the Government satisfied its *prima facie* burden of showing that Registrant's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Registrant can be trusted with a registration.

VI. SANCTION

Where, as here, the Government has met the burden of showing that Registrant's continued registration is inconsistent with the public interest, 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, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,904 (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 Fed. Reg. 46,968, 46,972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant that has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *See Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 Fed. Reg. 82,639, 82,641 (2024); *Mohammed Asgar, M.D.*, 83 Fed. Reg. 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830-31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 830-31; *Hoxie*, 419 F.3d at 483-84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46,972-73.

Here, Registrant did not request a hearing and was deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1-2. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). 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 filled hundreds of prescriptions outside the usual course of professional practice in Florida and in violation of the CSA, further indicating that Registrant cannot be entrusted.

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) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FS1451222 issued to Pine Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Pine Pharmacy to renew or modify the named registrations, as well as any other pending application of Pine Pharmacy for additional registration in Florida. This Order is effective **[INSERT DATE THIRTY DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on January 8, 2026, by Administrator Terrance C. Cole. 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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