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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Arenbii Pharmacy LLC; Decision and Order

On September 17, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Arenbii Pharmacy LLC of Missouri City, Texas (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 11. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, No. FA3529849, 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*. at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's DEA Certificate of 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)).[1] Specifically, the OSC/ISO alleged that as recently as May 12, 2025, Registrant violated federal and Texas state law by continuously filling Schedule II controlled substance prescriptions despite obvious red flags of abuse and/or diversion and without addressing or resolving those red flags.[2] RFAAX 1, at 1-2.

On February 5, 2026, the Government submitted an RFAA requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1-3. After carefully reviewing the entire record and conducting the analysis as set forth in more detail below, the Agency grants the Government's RFAA and revokes Registrant's registration.

[1] Based on the Government's submissions in its RFAA dated February 5, 2026, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on September 22, 2025, the OSC/ISO was personally served on Registrant at its registered address. RFAAX 2, at 1.

[2] The OSC/ISO also alleges that Registrant partially filled prescriptions in violation of federal law. RFAAX 1, at 2, 6-7. However, the OSC/ISO does not allege sufficient facts to support this allegation in a default final order.

I. 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/ISO] . . . 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/ISO]." 21 CFR 1301.43(e).

Here, the OSC/ISO notified Registrant of its right to file 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 10 (citing 21 CFR 1301.43). According to the Government's RFAA, Registrant failed to request a hearing. RFAA, at 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).

II. PUBLIC INTEREST

A. Applicable Law

As the Supreme Court stated in *Gonzales v. Raich*, 545 U.S. 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/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.

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 a controlled substance 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); 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." *Id*. Pursuant to the CSA's implementing regulations, only a pharmacist "acting in the usual course of his [or her] professional practice" may fill a prescription for a controlled substance. 21 CFR 1306.06; RFAAX 1, at 2.

As for state law, Texas regulations state that a Texas pharmacist "shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order" they dispense and "shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice." 22 Tex. Admin. Code Ann. § 291.29(a)-(b); *see also* 22 Tex. Admin. Code Ann. § 291.34(b)(1); RFAAX 1, at 3.

Texas Administrative Code § 291.29(f) states that "[a] pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility," and provides a list of nineteen "patterns (*i.e.,* red flag factors) [that] are relevant

to preventing the non-therapeutic dispensing of controlled substances." 22 Tex. Admin. Code § 291.29(f); RFAAX 1, at 4. The statute further states that these red flags "shall be considered by evaluating the totality of the circumstances rather than any single factor." 22 Tex. Admin. Code § 291.29(f); RFAAX 1, at 4. These "red flag factors" include:

> (1) the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .
>
> (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; . . .
>
> (5) 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; . . .
>
> (10) the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the person is being dispensed similar drugs at multiple pharmacies; [and]
>
> (11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner.

22 Tex. Admin. Code Ann. § 291.29(f); RFAAX 1, at 4.

Regarding the operational standards for a pharmacist filling a new prescription, the Texas Board of Pharmacy requires a pharmacist to: (i) review the patient's medication record and, at a minimum, identify clinically significant information such as "reasonable dose and route of administration; . . . drug-drug interactions; . . . and [] proper utilization, including overutilization or underutilization," (ii) "take appropriate steps to avoid or resolve [any] problem" identified,

"including consultation with the prescribing practitioner"; and (iv) resolve any questions with the prescriber and document the resolution. 22 Tex. Admin. Code Ann. § 291.33(c)(2)(A)(i)-(ii), (iv); RFAAX 1, at 3.[3]

Texas regulations further state that "[a] pharmacist may not: (1) dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice." Tex. Health & Safety Code Ann. § 481.074(a)(1); RFAAX 1, at 3.

B. Findings of Fact

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. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted and the Agency finds that from at least January 10, 2024, through at least May 12, 2025, Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. RFAAX 1, at 5-8.

Pattern Prescribing, Controlled Substances Known to Be Abused, and Highest Strength/Large Quantities

Registrant admits that "pattern prescribing" occurs when practitioners prescribe the same controlled substances in identical or substantially similar quantities, thus indicating a lack of individualized care. RFAAX 1, at 5. Registrant admits that DEA has recognized pattern

[3] Such documentation must be "on the prescription or in the pharmacy's data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation." 22 Tex. Admin. Code Ann. § 291.33(c)(2)(C); RFAAX 1, at 3.

prescribing as a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing. *Id*. (citing *The Med. Shoppe*, 79 Fed. Reg. 59504, 59512 (2014)).

Further, as discussed above, *see* Section III.A., Texas regulations have recognized pattern prescribing as a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing. 22 Tex. Admin. Code Ann. § 291.29(f)(1); RFAAX 1, at 4. Texas regulations have also recognized that prescriptions for controlled substances commonly known to be abused (such as opioids and narcotics) and prescriptions for controlled substances prescribed at the highest strength and/or in large quantities (*e.g.*, a monthly supply) are red flags consistent with abuse and/or diversion that need to be addressed prior to dispensing. 22 Tex. Admin. Code Ann. § 291.29(f)(3), (5); RFAAX 1, at 5.

Registrant admits that from at least January 2023 through at least February 2025, Registrant repeatedly failed to appropriately identify and resolve red flags associated with pattern prescribing of controlled substances that are commonly known to be abused and prescribed at the highest strength and/or in large quantities. RFAAX 1, at 5-6.

Specifically, Registrant admits that between April 20, 2022, and May 12, 2025, more than 90% of the controlled substance prescriptions it filled for Schedule II opioids were issued by the same doctor, Dr. M.Q. Registrant admits that these prescriptions were written for similar strength and quantity and they exhibited a pattern of simultaneously changing medication strength or type in the same way for multiple patients. These red flag prescriptions included prescriptions written by Dr. M.Q. for the following patients:

Patient Tr.H.: Registrant filled oxycodone prescriptions for Patient Tr.H. on June 28, 2024 (100 tablets, 30 mg), July 26, 2026 (100 tablets, 30 mg), August 27, 2024 (100 tablets, 10 mg), and on five additional occasions between September 25, 2024, and February 24, 2025 (100 tablets, 15 mg).

Patient A.Lo.: Registrant filled oxycodone prescriptions for Patient Tr.H. on three occasions between May 14, 2024, and July 15, 2024 (100 tablets, 30 mg), on August 26, 2024

(100 tablets, 10 mg), and on six occasions between September 25, 2024, and February 21, 2025 (100 tablets, 15 mg).

Patient Ti.H.: Registrant partially filled oxycodone prescriptions for Patient Ti.H. on three occasions between May 10, 2024, and July 15, 2024 (110 tablets prescribed, 100 tablets dispensed, 30 mg), on August 26, 2024, (110 tablets prescribed, 100 tablets dispensed, 10 mg), and on four occasions between September 25, 2024, and December 20, 2024, (110 tablets prescribed, 100 tablets dispensed, 15 mg). Registrant also filled oxycodone prescriptions for Patient Ti.H. on January 23, 2025, and February 20, 2025 (100 tablets, 30 mg).

Patient W.G.: Registrant partially filled oxycodone prescriptions for Patient W.G. on seven occasions between January 10, 2024, and July 22, 2024 (104 tablets prescribed, 100 tablets dispensed, 30 mg), and on six occasions between September 11, 2024, and February 14, 2025 (104 tablets prescribed, 100 tablets dispensed, 15 mg). Registrant also filled an oxycodone prescription for Patient W.G. on August 26, 2024 (104 tablets, 10 mg).

Patient E.B.: Registrant partially filled oxycodone prescriptions for Patient E.B. on seven occasions between January 25, 2024, and August 26, 2024, (108 tablets prescribed, 100 tablets dispensed, 30 mg), and on six occasions between September 12, 2024, and February 13, 2025 (108 tablets prescribed, 100 tablets dispensed, 15 mg).

Patient C.B.: Registrant partially filled oxycodone prescriptions for Patient C.B. on seven occasions between January 25, 2024, and July 22, 2024, (105 tablets prescribed, 100 tablets dispensed, 30 mg), and on six occasions between September 11, 2024, and February 13, 2025 (105 tablets prescribed, 100 tablets dispensed, 15 mg). Registrant also filled an oxycodone prescription for Patient C.B. on August 26, 2024 (105 tablets, 10 mg).

RFAAX 1, at 6.

Accordingly, the Agency finds substantial record evidence that Registrant filled at least 67 oxycodone prescriptions over a three-year period without first resolving the red flags arising

from pattern prescribing of controlled substances known to be abused, at their highest strength and/or in large quantities.

Registrant also admits that it filled prescriptions for promethazine with codeine (a Schedule V narcotic) in large quantities that are significantly more than is necessary for the duration of a single patient's cough symptoms. RFAAX 1, at 8. Specifically, Registrant admits that on at least 30 occasions between October 22, 2024, and April 30, 2025, Registrant dispensed 240 milliliters (equivalent to approximately eight ounces) or more of promethazine with codeine. *Id.* Accordingly, the Agency finds substantial record evidence that Registrant filled at least 30 prescriptions for promethazine with codeine without addressing or resolving the red flag of controlled substances prescribed in their highest strength and/or in large quantities.

Shared Address

Registrant admits that it is a red flag of abuse and/or diversion when multiple individuals presenting prescriptions for controlled substances share the same address. RFAAX 1, at 8. As discussed above, Texas regulations identify the following as a red flag factor of abuse and/or diversion that must be addressed and resolved before filling a prescription for a controlled substance: "multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner." 22 Tex. Admin. Code § 291.29(f)(11); RFAAX 1, at 4. DEA has recognized multiple individuals presenting the same or similar controlled substance prescriptions to be a red flag consistent with abuse and/or diversion that needs to be addressed prior to dispensing. *See Suntree Pharmacy and Suntree Med. Equip.*, 85 Fed. Reg. 73753, 73770 (2020); *Pharmacy Doctors Enters. d/b/a/ Zion Clinic Pharmacy*, 83 Fed. Reg. 10876, 10866 (2018); RFAAX 1, at 8.

Registrant admits that between at least May 2, 2024, and December 26, 2024, it filled multiple prescriptions from the same prescriber for two patients living at the same address in Houston, Texas, and these prescriptions fit a similar pattern in dosage and quantity. RFAAX 1, at 9-10. Specifically, Registrant admits that it filled prescriptions for

hydrocodone/acetaminophen 7.5/325 mg for Patients D.B. and M.F. with the same address on the following occasions in 2024: May 2, May 31, June 28, July 26, September 3, October 28, November 25, and December 26. These prescriptions ranged from 90 tablets to 110 tablets. *Id.* On at least six of these occasions, Registrant admits that it received a record from the prescribing physician showing that these prescriptions had been issued within 25 minutes of each other. *Id.*

Accordingly, the Agency finds substantial record evidence that Registrant filled at least 16 prescriptions for hydrocodone/acetaminophen for Patients D.B. and M.F. without first resolving the red flag that the patients shared the same address.

Expert Review

DEA retained an independent pharmacy expert to review, among other materials, Registrant's prescription data and patient profiles. *Id.* at 9. The pharmacy expert concluded, and Registrant admits, that the prescriptions presented multiple red flags that were highly indicative of abuse and diversion. *Id.* The expert 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 binding minimal standards that govern the practice of pharmacy in Texas." *Id.* Finally, the expert concluded, and Registrant admits, that "the Pharmacy's practice of filling prescriptions issued predominantly by one physician, together with the failure to resolve the red flags those prescriptions presented, violated the binding minimal standards that govern the practice of pharmacy in Texas." *Id.*

In consideration of all of the above, the Agency finds substantial record evidence that Registrant repeatedly dispensed the above-referenced prescriptions without first resolving the above-referenced red flags, in violation of the standard of care in Texas.

C. Legal Background on Public Interest Determinations

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)). The Attorney General's "discretion in exercising [the authority to register and deregister practitioners] is spelled out in very broad terms." *Id.* at 292 (Scalia, J., dissenting); *see also Neumann's Pharmacy, L.L.C. v. Drug Enf't Admin.*, No. 25-60068, 2026 WL 411942 (5th Cir. Feb. 13, 2026) ("DEA unquestionably has broad authority to deregister pharmacies and substantial discretion to shape policy within statutory bounds."). In executing this broad mandate, DEA must continuously balance the CSA's public interest goals of curbing the "illegal . . . distribution[] and possession[,] and improper use of controlled substances[, which has] a substantial and detrimental effect on the health and general welfare of the American people," while ensuring that the public has access to medications that "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1), (2); *see* Joanna R. Lampe, Cong. Rsch. Serv., R45948, The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress (2025), https://www.congress.gov/crs-product/R45948.

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] Just as the phrase "inconsistent with the public interest" is broad, the five factors that Congress directed DEA to consider in determining the public interest are similarly broad, suggesting that Congress intended for DEA to have discretion and flexibility to interpret this language as necessary to implement its critical mission to protect the public from drug abuse and diversion. *See Loper Bright Enters. v. Raimondo*, 603 U.S 369, 394-95 (2024) (noting that "[i]n a case involving an agency . . . the

[4] The five factors 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.

21 U.S.C. 823(g)(1)(A-E).

statute's meaning may well be that the agency is authorized to exercise a degree of discretion," such as where the statute uses terms or phrases like 'appropriate or reasonable'" (internal citations omitted)). Indeed, courts have recognized the Agency's broad discretion to deny applications and deregister practitioners for a wide variety of conduct that the Agency has determined is inconsistent with the public interest. *See, e.g.*, *Orusa v. Drug Enf't Admin.*, No. 22-3132, 2023 WL 3886403 (6th Cir. June 8, 2023) (physician issuing prescriptions outside the usual course of professional practice and beneath the standard of care); *St. Croix v. Drug Enf't Admin.*, No. 21-1116, 2022 WL 2092177 (D.C. Cir. June 10, 2022) (physician failing to maintain adequate records, prescribing controlled substances without a legitimate medical purposes, storing controlled substances at an unregistered location, failing to provide effective controls to guard against theft or diversion of these substances); *Suntree Pharmacy v. Drug Enf't Admin.*, No. 20-14626, 2022 WL 444357 (11th Cir. Feb. 14, 2022), cert. denied, 143 S. Ct. 305 (2022) (pharmacy filling prescriptions outside the usual course of practice).

The CSA's five public interest 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. 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 Fed. Reg. 37507, 37508 (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 37508, 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. 33207, 33208 (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 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), and the Agency must make its findings based on "substantial [record] evidence." 5 U.S.C. 556(d); *see* 5 U.S.C. 706(2); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that Registrant's registration is not in the public interest, then the burden shifts to Registrant to rebut the Government's case. *Pharmacy Doctor Enters., Inc. v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 729 (11th Cir. 2019) (citing *Jones Total Health Care Pharmacy*, 881 F.3d at 830).

Registrant is registered in Texas, and the OSC/ISO has alleged violations of state laws in Texas. RFAAX 1, at 2-5. Accordingly, the Agency must evaluate the Government's evidence under Texas law. *See Henry Emery, M.D.*, 90 Fed. Reg. 46927, 46929 (2025) (explaining the Agency analyzes public interest allegations according to the laws in the state where registrant is registered with DEA); *see also* 21 U.S.C. 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a

positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.").

D. Discussion

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 primarily implicates Factors B and D. RFAA, at 5-6; RFAAX 1, at 5. Evidence is considered under Factor B when it reflects experience dispensing controlled substances and under Factor D when it reflects compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.*, 87 Fed. Reg. 21156, 21162 (2022). Although Factors B and D have some overlap such that the Agency has frequently analyzed them together, Congress must have intended Factor B to encompass conduct that is not captured under Factor D. *See Kungys v. United States*, 485 U.S. 759, 778 (1988) (referencing the "cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant").

i. Factor B

As already discussed, the CSA gives the Attorney General authority to revoke a registration if he determines that the registrant "has committed such acts as would render his registration . . . inconsistent with the public interest as determined under [section 823]." 21 U.S.C. 824(a). One of the five factors that the Attorney General must consider in making this determination is the registrant's "experience in dispensing . . . controlled substances." 21 U.S.C. 823(g)(1)(B) (Factor B). Neither the statute nor the implementing regulations defines the term "experience" or places any limitations on the type of conduct that may be considered as "experience" under Factor B.[5]

[5] The only limitation discussed in the legislative history on DEA's authority under Factor B is that DEA should not "construe[this factor] in any way to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances." H.R. REP. NO. 98-835, pt. 1, at 14 (1984).

Historically, the Agency's Factor B[6] analysis considered "both the qualitative manner and quantitative volume of the [practitioner's] experience . . . as expressed through his patients and employees," and concluded that the record must contain quantitative evidence regarding the practitioner's experience for the Agency to find that Factor B weighs against a practitioner. *E.g.*, *Clair L. Pettinger*, 78 Fed. Reg. 61592, 61619 (2013). In 2015, the Agency abandoned this language, observing that the text of Factor B did not require DEA to consider the practitioner's "quantity" of prescribing. *See JM Pharmacy Group, Inc.*, 80 Fed. Reg. 28667, 28667-68 (2015); *see also Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14982 (2017). The Agency reviewed dictionary definitions of "experience," including:

> (1) The "direct observation of or participation in events as a basis for knowledge," (2) "the fact or state of having been affected by or gained knowledge through direct observation or participation," (3) "practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity," and (4) "the length of such participation."

80 Fed. Reg. at 28667 n.2 (citing *Webster's Collegiate Dictionary* 409 (10th ed. 1998); *The Random House Dictionary of the English Language* 681 (2d ed. 1987)).

The word "dispense" means "to deliver a controlled substance[] to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing or administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery." 21 U.S.C. 802(10). This definition encompasses, among other things, practitioners who prescribe controlled substances and pharmacies who fill controlled substance prescriptions. *Id.* The term "controlled substance" simply means "a drug or other substance . . . included in schedule I, II, III, IV, or V . . . ." 21 U.S.C. 802(6). Thus, the phrase "experience in dispensing" means the direct participation in the act of delivering, prescribing, dispensing, or administrating a controlled substance to an ultimate user.

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[6] Historically, the Agency referred to "Factor B" as "Factor Two." Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the CSA and other statutes. Relevant to this matter, the MRA redesignated the public interest factors outlined at 21 U.S.C. § 823(f)(1-5), which the Agency referred to as Factors One through Five, as 21 U.S.C. § 823(g)(1)(A-E), which the Agency now refers to as Factors A through E. Accordingly, this Decision cites to the current designation, 21 U.S.C. § 823(g)(1)(B), "Factor B."

The phrase "experience in dispensing" must be considered within the context of DEA's broad mandate under 21 U.S.C. 824(a) to deregister practitioners who "ha[ve] committed such acts as would render [their] registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4). In other words, in determining what type of conduct is relevant under Factor B, DEA's primary focus is to determine whether a registrant's "experience in dispensing" is "inconsistent with the public interest" or whether a registrant's dispensing constitutes "acts" that are inconsistent with the public interest. 21 U.S.C. 823(g)(1), 824(a)(4).

The word "inconsistent" is not defined in the CSA, but it is commonly defined as "lacking consistency: such as (a) not compatible with another fact or claim, [and] (b) containing incompatible elements." *Inconsistent*, Merriam-Webster, https://www.merriam-webster.com/dictionary/inconsistent (last visited on the date of signature). "Public interest" is not explicitly defined in the CSA, but Congress identifies the primary "public interest" goals in the CSA's introductory section as ensuring access to controlled substances used for a "legitimate medical purpose" while protecting the public from the "illegal . . . distribution . . . and improper use of controlled substances[, which] have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(1) & (2).

Considering these goals, DEA's Factor B analysis primarily concerns whether a registrant's "experience in dispensing" reflects illegal distribution or improper use of controlled substances that is inconsistent with the public interest. *Id.* In the context of a pharmacy, this would require the Agency to evaluate whether a pharmacy has dispensed controlled substances in a manner that is improper, illegal, or inconsistent with the public interest; for example, by ignoring indicators that a prescription lacked a legitimate medical purpose or would be improperly used, by filling a prescription in a manner that is inconsistent with state law or the

state's standards of practice, or by distributing controlled substances in a way that creates a risk of diversion.[7]

Of course, the Agency is not only concerned with acts of intentional diversion,[8] as DEA has explained that "[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . ." *Samson K. Orusa, M.D.*, 87 Fed. Reg. 2986, 3018 (2022) (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51592, 51602 (1998)); *Bradley H. Chesler, M.D.*, 87 Fed. Reg. 4917-01 (citing *Bienvenido Tan*, 76 Fed. Reg. 1763, 17689 (2011)); *Dewey C. MacKay, M.D.*, 75 Fed. Reg. 49956, 49974 n.35 (2010) ("Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion."). Indeed, neither 21 U.S.C. 824(a) nor 21 U.S.C. 823(g) requires DEA to find that a registrant has intentionally diverted controlled substances. Ultimately, a registrant whose dispensing practices create an environment that encourages or is indifferent to the abuse or diversion of controlled substances is acting outside the public's interest. As the opioid epidemic surges and other controlled substances, such as amphetamines, ketamine, and benzodiazepines, are increasingly abused, DEA must remain vigilant to protect the public against registrants who fail to employ the CSA's safeguards to ensure the health and general wellness of the American public.

Registrants "may continue to introduce evidence as to . . . lawful . . . dispensing activities."[9] However, the Agency has found that "evidence that a practitioner has treated

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[7] Analysis of whether a prescription is illegally filled, distributed, or possessed also fits within Factor D, "Compliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. 823(g)(1)(D).

[8] Only criminally unlawful conduct requires an act of intentional diversion such as proof that a physician "used 'his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit' or some other illegitimate purposes, such as his own 'personal profit.'" *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006) (quoted in *Laurence T. McKinney*, 73 Fed Reg 43260, 43266 (2008). *Compare* 21 U.S.C. 823 and 824 *with* 21 U.S.C. 841, 842, 843.

[9] *Randall L. Wolff, M.D.*, 77 Fed. Reg. 5106, 5153 (2012) (finding that evidence of lawful prescribing is "entitled to some evidentiary weight only in cases where a practitioner credibly demonstrates an acceptance of responsibility and reform of past practices"); *see also Roberto Zayas, M.D.*, 82 Fed. Reg. 21410, 21422 n.27 (2017) ("[T]he Agency properly considers a [registrant's] evidence of a lengthy history of compliance after the Government makes

thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest."[10] *Krishna-Iyer*, 74 Fed. Reg. at 463. Accordingly, the Agency has consistently rejected registrants' arguments that acts of unlawful prescribing were mitigated by years of lawful prescribing. *See, e.g.*, *Syed-Jawed Akhtar-Zaidi*, 80 Fed. Reg. 42961, 42967 (2015), pet. for rev. denied, 841 F.3d 707, 713 (6th Cir. 2016) (rejecting Registrant's argument that he was denied a "fair adjudication" because the Government seized 400 patient files but only proved the illegality of a handful of prescriptions issued during undercover visits, and finding that "the physician's prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are inconsistent with the public interest") (internal quotations and citations omitted).[11]

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. Registrant has further admitted 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 binding minimal standards that govern the practice of pharmacy in Texas." RFAAX 1, at 9. The Agency finds that Registrant's failure to adhere to the minimum standards governing Texas pharmacy practice and its repeated issuance of prescriptions without addressing or resolving red flags reflects "experience in dispensing . . . controlled substances" that created an opportunity for the abuse or diversion of controlled substances and was outside the public

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out its *prima facie* case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions."). In other words, this evidence may be relevant to the Agency's sanctions analysis.

[10] "[E]very registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [their] professional career." *Krishna-Iyer*, 74 Fed. Reg. at 463. Accordingly, except where the Agency has found in its decision that a prescription was issued outside the public interest or in violation of law, the Agency assumes that all controlled substance prescriptions dispensed by a pharmacy are dispensed for a legitimate medical purpose and in accordance with relevant laws. *See Dewey C. Mackay, M.D.*, 75 Fed. Reg. at 49977.

[11] In an unreported opinion, the Sixth Circuit affirmed DEA's conclusion that the Registrant's acts of unlawful prescribing outweighed his years of work experience. *Orusa v. Drug Enf't Admin.*, 2023 WL 3886403 at *5 ("Orusa's credentials and years of work experience, which the agency acknowledged, do nothing to disturb the agency's detailed review of his prescribing history—the relevant "experience in dispensing ... controlled substances.").

interest. Registrant did not request a hearing and thus did not provide the Agency with any evidence related to its "experience in dispensing" that served the public's interest. Accordingly, the Agency finds that Factor B weighs strongly against Registrant's continued registration.[12]

ii. Factor D

Under Factor D, the Agency considers a registrant's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. 823(g)(1)(D). Texas law establishes several factors that require resolution "to prevent[] the non-therapeutic dispensing of controlled substances"—in other words, diversion—a concern that goes to the heart of the CSA's public interest goal to ensure controlled substances stay in legitimate channels and outside of illicit channels. 22 Tex. Admin. Code § 291.29(f); 21 U.S.C. 801(1) & (2); *Gonzales v. Raich*, 545 U.S. at 12-13.

Here, an independent medical expert reviewed the evidence in this matter and concluded that Registrant's dispensing failed to prevent diversion insofar as Registrant failed to resolve concerns that Texas law establishes are indicative of diversion, and therefore, require resolution. RFAAX 1, at 9. To this extent, as the expert concluded, Registrant's repeated failure to resolve red flags—that are indicative of diversion per Texas law—violated "binding minimal standards that govern" the dispensing of controlled substances, standards which are designed to prevent diversion and that align with the CSA's public interest goals. *Id*. In this way, Registrant's dispensing failed to comply with applicable state law relating to controlled substances and the prevention of diversion. 21 U.S.C. 823(g)(1)(D).

Accordingly, as found above, Registrant is deemed to have admitted, and the Agency finds, that Registrant repeatedly dispensed controlled substances over a period of two years without resolving or documenting multiple red flags of drug abuse and/or diversion, as required

[12] While the Agency has determined that Registrant's dispensing conduct is relevant to Factors B and D, to the extent that the found conduct does not fall within these factors, it would nevertheless constitute "other conduct which may threaten the public health and safety." 21 U.S.C. § 823(g)(1)(E). Registrant's repeated dispensing of controlled substances without addressing or resolving red flags may threaten the public health and safety by creating the risk that controlled substances may leave the CSA's closed distribution system and be abused or diverted.

by state law. As such, the Agency finds substantial record evidence that Registrant violated Texas law by failing to resolve red flags that are indicative of diversion. 22 Tex. Admin. Code § 291.29(f).

The Agency finds that after considering the public interest factors of 21 U.S.C. 823(g)(1), Factors B and D weigh in favor of revocation of Registrant's registration. Accordingly, the Government has 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.

III. SANCTION

Where, as here, the Government has met the burden of showing that Registrant's 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. 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/ISO and has not otherwise availed itself of the opportunity to refute the Government's case. As such, Registrant has made no representations regarding its future compliance with the CSA nor made any demonstration that it can be trusted with registration. Moreover, the evidence presented by the Government shows that Registrant repeatedly filled controlled substance prescriptions outside the usual course of professional practice in Texas and in violation of the CSA, 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. FA3529849 issued to Arenbii Pharmacy LLC. 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 application of Arenbii Pharmacy LLC to renew or modify this registration as well as any other pending application of Arenbii Pharmacy LLC 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 September 30, 2026, by DEA 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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