DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Baijes Bissonnet Pharmacy; Decision and Order

On December 15, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Baijes Bissonnet Pharmacy of Stafford, Texas (Applicant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 9. The OSC proposed the denial of Applicant's application for DEA registration, Control No. W22147152A, alleging that Applicant's registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1)).

Specifically, the OSC/ISO alleges that ''[Applicant] repeatedly filled prescriptions for Schedule II through V controlled substances that contained multiple red flags indicative of diversion and/or abuse without addressing or resolving those red flags, and [Applicant's decision] to fill those prescriptions despite unresolved red flags, . . . [violated] federal and Texas law, including 21 CFR 1306.04(a), 1306.06; Tex. Health & Safety Code sections 481.074(a), 481.128; 22 Tex. Admin. Code sections 291.33(c)(2)(A)(ii), (iv), 291.29(f).'' RFAAX 1, at 4.

The OSC notified Applicant of its right to file with DEA a written request for hearing within 30 days after the date of receipt of the OSC. *Id.* at 8 (citing 21 CFR 1301.43(a)). The OSC also notified Applicant 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) through (e)). The OSC further instructed Applicant that a hearing request should be submitted to the DEA Office of Administrative Law Judges (OALJ) email inbox.[1] *Id.*

On December 19, 2023, a DEA Diversion Investigator personally served the OSC on Applicant's owner and pharmacist-in-charge (PIC).[2] RFAAX 2, at 2. Based on this date of service, the deadline for filing a hearing request was January 18, 2024. RFAAX 1, at 8; *see also* 21 CFR 1301.37(d)(1), 1301.43(a). The day before the filing deadline, January 17, 2024, Applicant mailed a hearing request letter through the U.S. Postal Service (USPS). RFAAX 3, at 5.[3] Contrary to the OSC's clear instructions to send mail to the OALJ Hearing Clerk at the specific address listed in the OSC, Applicant addressed the letter to the DEA Hearing Facility in Arlington, Virginia, a building that does not accept mail. RFAA, at 4; RFAAX 3, at 5. Because Applicant sent the hearing request to the wrong address, it was returned to Applicant without ever being received by the OALJ Hearing Clerk. RFAA, at 4; RFAAX 3, at 6.

On February 29, 2024, Applicant sent a second hearing request letter through USPS, which was delivered on March 4, 2024, nearly two months after the deadline for filing a hearing request had passed. RFAA, at 3; RFAAX 3, at 1; RFAAX 4, at 1. Although Applicant mailed its second hearing request letter to the correct mailing address, Applicant addressed the letter to the wrong DEA office, specifically the Office of Chief Counsel (CC). RFAA, at 3, 5; RFAAX 3, at 1. The second hearing request was also never received by the OALJ Hearing Clerk. *Id.*

To summarize, the OSC, which was personally served on Applicant's owner/PIC, contained clear instructions detailing how to file a hearing request, where to send the hearing request, and the deadline for doing so. Nonetheless, Applicant mailed its first hearing request letter to the wrong mailing address and wrong recipient. Even if Applicant's first hearing request letter had been sent to the correct mailing address, it likely would have been received, and therefore filed, several days after the filing deadline. Further, although Applicant mailed a second hearing request letter to the DEA mailing address, Applicant again failed to address it to the OALJ Hearing Clerk as instructed by the OSC. The second hearing request letter was sent nearly a month and a half after the filing deadline.

To date, Applicant has not filed a hearing request with the OALJ Hearing Clerk, has not provided good cause for its failure to timely request a hearing,[4] and has not filed a motion to excuse the default with the Office of the Administrator.[5] 21 CFR 1301.43(c)(1). Accordingly, the Agency finds that Applicant is in default.

''A default, unless excused, shall be deemed to constitute a waiver of the [applicant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e). Further, ''[i]n the event that [an applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Applicant's default pursuant to 21 CFR 1301.43(d), (e), (f)(1), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

I. Applicable Law

As already discussed, the OSC/ISO alleges that Applicant 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 . . . 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.

[1] Alternatively, the OSC instructed that a hearing request could be mailed to the OALJ Hearing Clerk. RFAAX 1, at 8–9; *see also* 21 CFR 1316.47, 1321.01. The OSC also informed Applicant that a hearing request is filed once it is received by the OALJ Hearing Clerk. *Id.* at 9 (citing 21 CFR 1316.45).

[2] Applicant's owner/PIC signed a Form DEA–12 acknowledging receipt of the OSC on December 19, 2023. RFAAX 2, Attachment 1, at 1.

[3] The USPS receipt indicates that the expected delivery date was January 22, 2024, four days after the 30-day deadline for requesting a hearing. *Id.*

[4] In its second letter, Applicant acknowledged that the first letter was returned by USPS because it used the incorrect mailing address. RFAAX 3, at 4. Under these facts, using the incorrect address does not constitute good cause for failing to timely file a hearing request, especially when the OSC clearly informed Applicant to send hearing requests to the OALJ email inbox or the ''Hearing Clerk, [OALJ, DEA], 8701 Morrissette Drive, Springfield, VA 22152''; moreover, the hearing request was projected to be untimely even had it been addressed correctly. RFAAX 1, at 8–9; RFAAX 3, at 5; 21 CFR 1316.45; *see also Keith Ky Ly, D.O.,* 80 FR 29025, 29028 (2015) (finding good cause was not shown where a registrant mailed a hearing request to the incorrect address).

[5] 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.*

The Allegation That Applicant 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); RFAAX 1, at 2; *see also Suntree Pharmacy and Suntree Medical Equipment, LLC* v. *Drug Enf't Agency,* 2022 WL 444,357, *6 (11th Cir.) (upholding the Agency's revocation order, which was ''[b]ased on [the] finding that Suntree violated its corresponding responsibility by filling prescriptions for controlled substances without resolving obvious red flags that the prescriptions lacked a legitimate medical purpose''). A 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); RFAAX 1, at 2, 4; *see also* Tex. Health & Safety Code sections 481.074(a), 481.128(a)(1). If the pharmacist observes any problem that raises doubts about the legitimacy of a prescription, the pharmacist must ''verify the order with the practitioner prior to dispensing.'' *Id.* section 291.29(a); RFAAX 1, at 4.

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 3. Pharmacists should consider these red flags ''by evaluating the totality of the circumstances rather than any single factor.'' 22 Tex. Admin. Code section 291.29(f). These red flags include instances where:

(f)(1) ''the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances . . . ,''

(f)(3) ''prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs,''

(f)(10) ''the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the persons [sic] is being dispensed similar drugs at multiple pharmacies,'' and

(f)(12) ''persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.''

RFAAX 1, at 2–3, 5–7. In addition to evaluating these red flag factors, a Texas pharmacist may not fill a prescription when a pharmacist has reason to believe that a prescription is inaccurate, inauthentic, or not issued for a legitimate medical purpose. *See* 22 Tex. Admin. Code section 291.29(a), (b).

Texas regulations further require pharmacists to ''review the patient's medication record'' to ensure the ''therapeutic appropriateness'' of the prescription, and if a problem is observed, the pharmacist must ''avoid or resolve the problem including consultation with the prescribing practitioner.'' 22 Tex. Admin. Code sections 291.33(c)(2)(A)(i)–(ii); RFAAX 1, at 2–3. A pharmacist must resolve all problems raised by a prescription before dispensing it and must document how the problem was resolved. *Id.* section 291.33(c)(2)(A)(iv); RFAAX 1, at 3; *see also* section 291.33(c)(2)(C) (outlining the information that such documentation must include).

II. Findings of Fact

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

The Agency finds that, in light of Applicant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Applicant is deemed to have admitted and the Agency finds that Applicant repeatedly dispensed prescriptions in violation of the minimum practice standards that govern pharmacy practice in Texas. RFAAX 1, at 4–8. Specifically, from at least March 2021 through August 2022, Applicant repeatedly filled prescriptions for controlled substances that raised multiple red flags of abuse and/or diversion without addressing or resolving the red flags.[6] *Id.*

A. Pattern Prescribing

As discussed above, *see supra* Section I, Texas regulations identify the following prescribing patterns as red flag factors: ''the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances . . . ,'', and ''the Texas Prescription Monitoring Program indicates the person presenting the prescriptions is obtaining similar drugs from multiple practitioners, and/or that the persons [sic] is being dispensed similar drugs at multiple pharmacies.'' 22 Tex. Admin. Code sections 291.29(f)(1), (f)(10). RFAAX 1, at 5.

Applicant is deemed to have admitted that Applicant failed to identify and resolve the red flag of pattern prescribing which is indicative of a lack of individualized care for patients. RFAAX 1, at 3, 5. Applicant admits that ''prescriptions dispensed for seven patients were essentially identical prescriptions issued by the same prescriber and/or similar drugs from multiple practitioners.'' *Id.* at 5. Specifically, Applicant admits that he dispensed the following: six essentially identical prescriptions to J.F. for hydrocodone-acetaminophen 10/325 mg (a Schedule II opioid) and carisoprodol 350 mg (a Schedule IV muscle relaxant) issued by Drs. B.N. and A.N.; three essentially identical prescriptions to P.R. for oxycodone 30 mg (a Schedule II opioid) issued by Drs. B.N. and A.N.; five essentially identical prescriptions to M.R.S. for oxycodone 30 mg issued

[6] Applicant's misconduct which forms the basis of the OSC, and which Applicant is deemed to have admitted, occurred under Applicant's prior DEA registration, which Applicant surrendered for cause on August 25, 2022. *Id.*

by Drs. B.N., A.P., and D.F.; seven essentially identical prescriptions for hydrocodone-acetaminophen 10/325 mg and five essentially identical prescriptions for carisoprodol 350 mg to M.S. issued by Drs. A.P., J.A., M.A., and E.P.; seven essentially identical prescriptions to J.V. for oxycodone 30 mg issued by Drs. A.N., B.N., A.P., and D.F.; and nine essentially identical prescriptions to C.W. for oxycodone 30 mg issued by Drs. A.N., B.N., A.P., and D.F. *Id.*

Accordingly, the Agency finds substantial record evidence that Applicant filled 42 prescriptions to six individuals without first resolving the prescriptions' red flag of pattern prescribing. *Id.*

B. Cash Payments

Texas regulations identify the following prescribing pattern as a red flag factor: ''[P]ersons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.'' 22 Tex. Admin. Code section 291.29(f)(12); RFAAX 1, at 5–6.

Applicant is deemed to have admitted that it failed to identify and resolve the red flag of cash payments for controlled substances, which is a common red flag because it allows a patient to avoid the scrutiny associated with the use of insurance. RFAAX 1, at 5–6. Specifically, from at least March 9, 2021, to June 22, 2022, Applicant accepted cash payments for 492 out of 575 total controlled substance prescriptions (85% of controlled substance prescriptions). *Id.* at 6.

Accordingly, the Agency finds substantial record evidence that Applicant filled 492 prescriptions without resolving the red flag of cash payments for controlled substance prescriptions. *Id.*

C. Long Distances

Applicant is deemed to have admitted that it repeatedly filled controlled substance prescriptions without identifying and resolving the red flag of patients traveling long distances to obtain or fill the prescriptions.[7] *Id.* at 6–7. Specifically, Applicant is deemed to have admitted that it filled prescriptions for at least four individuals, B.H. (two prescriptions), B.M. (two prescriptions), P.R. (three prescriptions), and C.Y. (three prescriptions), who each traveled over 100 miles one way from their listed address to Applicant's location to purchase controlled substances prescriptions with cash. *Id.* at 7.

Accordingly, the Agency finds substantial record evidence that Applicant filled these ten controlled substance prescriptions without first resolving the red flag of patients traveling long distance to obtain their prescriptions. *Id.* Additionally, Applicant is deemed to have admitted, and the Agency finds substantial record evidence, that Applicant filled these prescriptions outside the usual course of professional practice. *Id.*

D. Drug Cocktails

Texas regulations identify the following prescribing pattern as a red flag factor: ''[P]rescriptions 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.'' 22 Tex. Admin. Code section 291.29(f)(3); RFAAX 1, at 7.

Applicant is deemed to have admitted that it repeatedly filled controlled substance prescriptions without identifying and resolving the red flag of drug cocktails. RFAAX 1, at 7. Specifically, Applicant is deemed to have admitted that on approximately nine occasions, Applicant dispensed a drug cocktail containing an opioid (hydrocodone-acetaminophen) and a muscle relaxant (carisoprodol) to seven patients: J.F., B.H., B.M., P.R., L.S., M.S., and C.Y. *Id.*

Accordingly, the Agency finds substantial record evidence that Applicant filled these nine prescriptions without first resolving the red flag of drug cocktails. *Id.*

E. Other Red Flags[8]

A Texas pharmacist may not fill a prescription when the pharmacist has reason to believe that a prescription is inaccurate, inauthentic, or not issued for a legitimate medical purpose. *See* 22 Tex. Admin. Code section 291.29(a), (b); RFAAX 1, at 7–8. Applicant is deemed to have admitted that it repeatedly filled controlled substance prescriptions when it had reason to doubt the accuracy or legitimacy of multiple prescriptions. RFAAX 1, at 7.

Specifically, Applicant admits that it ''had reason to doubt the accuracy or legitimacy of several prescriptions when the patients who were receiving controlled substances for chronic pain had several late fills.'' *Id.* On six occasions from September 23, 2021, to January 25, 2022, Applicant filled for J.F. multiple controlled substances prescriptions 35 or more days after the prescriptions were written. *Id.* at 8. On multiple occasions from May 12, 2021, to May 5, 2022, Applicant filled for L.S. multiple controlled substances prescriptions 30 or more days after the prescriptions were written. *Id.* Finally, on multiple occasions from October 15, 2021, to August 4, 2022, Applicant filled for J.V. multiple controlled substances prescriptions 30 or more days after the prescriptions were written. *Id.*

Accordingly, the Agency finds substantial record evidence that Applicant filled multiple prescriptions for three patients even though it had reason to doubt their accuracy or legitimacy. *Id.* at 7–8.

F. Expert Review

DEA retained an independent pharmacy expert who concluded that the above prescription data presented multiple red flags that were highly indicative of abuse and diversion. *Id.* at 8. Applicant is deemed to have admitted that ''these red flags were not resolved by a pharmacist acting in the usual course of professional practice prior to dispensing, and, therefore, that each prescription was filled outside the standard of care of pharmacy practice in Texas.'' *Id.*

Accordingly the Agency finds substantial record evidence that Applicant dispensed the above-referenced prescriptions without first resolving the red flags of pattern prescribing, cash payments, long distances, and/or drug cocktails, or when it had reason to doubt the accuracy or legitimacy of the prescriptions. The Agency further finds substantial record evidence that Applicant's dispensing of these prescriptions was outside the usual course of professional practice.

III. Discussion

A. The Five Public Interest Factors

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such

[7] Though long distances are not specifically mentioned in the Texas regulations as a red flag factor, the OSC notes that ''DEA has found that traveling long distances to obtain or fill controlled substance prescriptions is a well-known red flag of abuse or diversion.'' RFAAX 1, at 6 (citing, *e.g., E. Main St. Pharmacy,* 75 FR 66149, 66164 (2010) (finding that ''the fact that the patients were driving so far to get their prescriptions filled 'would be a major red flag to any pharmacist' '').

[8] Although the OSC refers to the following alleged conduct as ''Other Red Flags,'' these forms of alleged conduct are not specifically listed in the Texas regulations as red flags under 22 Texas Administrative Code section 291.29(f). Instead, the following alleged conduct constitutes violations of 22 Texas Administrative Code section 291.29(a)–(b).

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).[9] 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.[10] *See* RFAAX 1, at 4. 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 Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(g)(1).

B. Allegation That Applicant's Registration Is Inconsistent With the Public Interest

Factors B and/or D—Applicant'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, Applicant is deemed to have admitted and the Agency finds that Applicant 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 4–8. DEA's independent pharmacy expert concluded that these red flags were highly indicative of abuse and diversion. *Id.* at 8. Applicant has further admitted 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 the Government established a *prima facie* case that Applicant violated 21 CFR 1306.04, 1306.06; 22 Texas Administrative Code sections 291.29, 291.33; and Texas Health & Safety Code sections 481.074, 481.128. The Agency further finds that Factors B and D weigh in favor of denial of Applicant's application and that Applicant'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 Applicant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the denial of Applicant's application. 21 U.S.C. 823(g)(1).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Applicant's registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Applicant 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 resgistrant. *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, Applicant 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, Applicant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Applicant 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, Applicant 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 Applicant violated the CSA, further indicating that Applicant cannot be entrusted.

Accordingly, the Agency will order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the pending application for a DEA Certificate of Registration, Control No. W22147152A, submitted by Baijes Bissonnet Pharmacy, as well as any other pending application of Baijes Bissonnet Pharmacy for additional registration in Texas. This Order is effective May 1, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 25, 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

[9] 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.

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

electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mary Massullo, D.O.; Decision and Order

On April 8, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Mary Massullo, D.O. of Brookfield, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 4. The OSC proposed the revocation of Registrant's Certification of Registration No. BM0548238,[1] alleging that Registrant's registration should be revoked because Registrant is ''currently without authority to handle controlled substances in the State of Ohio, the state in which [she is] registered with DEA.'' RFAAX 2, at 2 (citing 21 U.S.C. 824(a)(3)).[2]

The OSC notified Registrant of her right to file a written request for hearing, and that if she had failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. RFAAX 2, at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.[3] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 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(e), (f), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective January 31, 2024, Registrant's Ohio medical license was permanently revoked. RFAAX 2, at 2. According to Ohio online records, of which the Agency takes official notice, Registrant's Ohio medical license remains under a ''Permanent Revocation'' status.[4] eLicense Ohio Professional Licensure License Look-Up, *https://elicense.ohio.gov/oh_verifylicense* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Ohio, the state in which she is registered with DEA.[5]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[6]

According to Ohio statute, ''[n]o person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog,'' except pursuant to a ''prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical

[1] According to Agency records, Registrant's registration expired on January 31, 2025. The fact that a registrant allows her registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68476–79 (2019).

[2] The OSC also proposed the revocation of Registrant's registration because Registrant was mandatorily excluded from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* In its RFAA, the Government referenced this mandatory exclusion allegation in the introductory paragraph, the procedural background, and the proposed findings of fact. RFAA, at 1–3. However, in the ''Proposed Conclusions of Law and Argument'' section of the RFAA through the remainder of the document, the Government only discussed the aforementioned loss of state authority allegation. *Id.* at 3–5. As such, the Government appears to have dropped the mandatory exclusion allegation and the Agency does not consider it in this decision.

[3] Based on the Government's submissions in its RFAA dated June 25, 2024, the Agency finds that service of the OSC on Registrant was sufficient. Specifically, the included Declaration from a DEA Diversion Investigator (DI) indicates that on May 2, 2024, a copy of the OSC was left in the mailbox of Registrant's registered address following an attempt of personal service on the Registrant. RFAAX 3, at 3. The DI had made a previous unsuccessful attempt to serve Registrant with the OSC via certified mail to Registrant's registered address on May 1, 2024. *Id.* at 2–3; *see also id.,* Appendix D.

[4] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[5] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this decision, is not licensed to practice medicine in Ohio. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[6] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* M.D., 76 FR 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton, M.D.,* 43 FR 27617.