DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lawrence Michael Willis, D.D.S.; Decision and Order

On November 20, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Lawrence Michael Willis, D.D.S., of Commerce City, Colorado (Registrant). OSC, at 1, 6; Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 6. The OSC proposed the revocation of Registrant's DEA Certificate of Registration No. AW1335822, alleging that Registrant has committed acts that are inconsistent with the public interest. OSC, at 1 (citing 21 U.S.C. 823(g)(1); 824(a)(4)).[1] More specifically, the OSC alleged that Registrant repeatedly violated Colorado law by failing to register for and query the Colorado Prescription Drug Monitoring Program, in violation of Colo. Rev. Stat. §§ 12–30–109(1)(b), 12–280–403(2)(a), 12–280–404(4)(a), 12–280–404(4)(a.5). OSC, at 2–4.

On February 4, 2025, the Government submitted an RFAA requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 4–5. 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.

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] . . . 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 notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. RFAAX 1, at 4–5 (citing 21 CFR 1301.43). According to the Government's unrebutted RFAA, Registrant failed to request a hearing and the Agency so finds. RFAA, at 2. Thus, the Agency finds that Registrant is in default and therefore is deemed to have admitted to the factual allegations in the OSC. 21 CFR 1301.43(e).

II. 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'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.

A. Allegation That Registrant Failed To Register for and Query the Colorado Prescription Drug Monitoring Program

Colorado regulations require that every practitioner licensed in the state register for and maintain an account with the Colorado Prescription Drug Monitoring Program (PDMP) and query the Colorado PDMP prior to prescribing any opioid or benzodiazepine. Colo. Rev. Stat. §§ 12–30–109(1)(b), 12–280–403(2)(a), 12–280–404(4)(a), 12–280–404(4)(a.5).

III. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted.[2] 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted to each of the following facts and the Agency finds unrebutted evidence thereof.

Registrant admits that as a licensed practitioner in Colorado, he was required to registered with the Colorado PDMP. RFAAX 1, at 2. Despite this requirement, he failed to timely register for the Colorado PDMP, and on December 16, 2022, the Colorado Dental Board issued a disciplinary order against him for his failure to register for the Colorado PDMP. *Id.* at 3. Registrant admits that from at least July 2018 through at least June 2023, he failed to register for the Colorado PDMP. *Id.* at 3–4.

Registrant further admits that as a licensed practitioner in Colorado, he was required to query the Colorado PDMP prior to issuing prescriptions for opioids and benzodiazepines. *Id.* at 3. Registrant admits that from at least July 2018 through at least June 2023, he failed to query the Colorado PDMP prior to issuing numerous opioid and benzodiazepine prescriptions to his patients. *Id.* at 3–4.

Specifically, Registrant admits that between July 2018 and June 2023, he issued the following prescriptions without querying the PDMP:[3] approximately three prescriptions for hydrocodone-acetaminophen 7.5–325 mg (a Schedule II opiate) and 67 prescriptions for hydrocodone-acetaminophen 10–325 mg to M.G; approximately 27 prescriptions for

[1] Based on the Government's submissions in its RFAA dated February 4, 2025, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on December 3, 2024, the DI, along with a second Diversion Investigator, traveled to Registrant's registered address and personally served the OSC on Registrant. RFAAX 2, at 1.

[2] According to the Controlled Substances Act (CSA), ''[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.'' 21 U.S.C. 877. Here, where Applicant is found to be in default, all the factual allegations in the OSC are deemed to be admitted. These uncontested and deemed admitted facts constitute evidence that exceeds the ''substantial evidence'' standard of 21 U.S.C. 877; it is unrebutted evidence.

[3] These prescriptions were all issued by Registrant's receptionist and patient, M.G., using Registrant's prescription pad. *Id.* at 3–4. Registrant admits that he permitted M.G. to sign and authorize prescriptions on his behalf. *Id.* at 3. Although the Government alleges that Registrant's delegation of his prescribing authority is evidence that Registrant ''failed to take appropriate measures to safeguard against potential misuse, abuse, and/or diversion of controlled substances,'' the Government does not cite any specific violations of state or federal law or explain the nexus to public interest factors B and D (*see infra* IV.A). *Id.* at 3–4. Although the Agency notes that this conduct is clearly unlawful, *see, e.g., Neeraj B. Shah, M.D.,* 89 FR 84195, 84197 n.11 (2024) (''[W]here a registrant's actions allow an unregistered person to prescribe controlled substances, as Respondent did here, the registrant can be found in violation of 21 CFR 1306.04(a)''), the Agency need not adjudicate these allegations because there is other substantial evidence on the record demonstrating that Registrant's registration is inconsistent with the public interest.

hydrocodone-acetaminophen 10–325 mg to R.H.; approximately one prescription for diazepam 5 mg (a Schedule IV benzodiazepine), three prescriptions for hydrocodone-acetaminophen 7.5–325 mg, and 40 prescriptions for hydrocodone-acetaminophen 10–325 mg to A.M.; approximately 26 prescriptions for hydrocodone-acetaminophen 10–325 mg to J.M.; and approximately 28 prescriptions for hydrocodone-acetaminophen 10–325 mg to L.W. *Id.* at 3–4.

In consideration of the above, the Agency finds unrebutted record evidence that Registrant failed to register for the Colorado PDMP and that Registrant issued at least 195 prescriptions for opioids and benzodiazepines without first querying the Colorado PDMP.

IV. Public Interest Determination

A. Legal Background on Public Interest Determinations

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,'' Congress directed the Attorney General to consider five factors in making the public interest determination. *Id.;* 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 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.,* 58 FR 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* v. *Drug Enf't Admin.,* 412 F.3d. 165, 185 n.2 (D.C. Cir. 2005) (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.,* 70 FR 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 FR 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),[5] the Government's evidence in support of its *prima facie* case is confined to Factor D.[6] OSC, at 2–4. Evidence is considered under Factor D when it reflects compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022).

Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant failed to register for the Colorado PDMP and that Registrant issued at least 195 prescriptions for opioids and benzodiazepines without first querying the Colorado PDMP. Accordingly, the Agency finds substantial record evidence that Registrant violated Colo. Rev. Stat. §§ 12–30–109(1)(b), 12–280–403(2)(a), 12–280–404(4)(a), and 12–280–404(4)(a.5). 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 Registrant has presented no mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of Registrant's misconduct, he can be trusted with a registration.

V. 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 he 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 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that he 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.,*

[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).

[5] As to Factor A, there is no record evidence of disciplinary action against Registrant's state medical license. 21 U.S.C. 823(g)(1)(A). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of any federal or state law offense ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay, M.D.,* 75 FR at 49973. As to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

[6] The OSC also alleges that Factor B weighs against Registrant's continued registration, but it does not specify what factual or legal allegations are relevant to the Agency's Factor B analysis. *See supra* n.3.

54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.,* 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (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 FR at 46972–73.

Here, Registrant did not request a hearing or answer the allegations in the OSC, and was therefore deemed to be in default. *See supra* I. 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 himself of the opportunity to refute the Government's case.[7] As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding his future compliance with the CSA, and has not demonstrated that he can be trusted with registration. 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. AW1335822 issued to Lawrence Michael Willis, D.D.S. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Lawrence Michael Willis, D.D.S., to renew or modify this registration, as well as any other pending application of Lawrence Michael Willis, D.D.S., for additional registration in Colorado. This Order is effective December 1, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 9, 2025, by Administrator Terrance 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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[7] Notably, and as described *supra* III, Registrant failed to register for the Colorado PDMP even after he was disciplined by the Colorado Dental Board for his failure to register. RFAAX 1, at 3–4.

DEPARTMENT OF JUSTICE

[OMB 1140–0011]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Title: Application To Make and Register NFA Firearm, ATF Form 5320.1 ("Form 1")

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments for 30 days, until midnight on December 1, 2025.

ADDRESSES: Submit written comments and recommendations for this information collection to the following website: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB control number: 1140–0015.

FOR FURTHER INFORMATION CONTACT: If you have questions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Meghan Tisserand, Division Staff, National Firearms Act Division, either by mail at National Firearms Act Division; Division Staff Office; 244 Needy Road, Martinsburg, WV 25405, by email at *Meghan.tisserand@atf.gov,* or by telephone at 304–616–3219.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, 90 FR 38508, on Friday, August 8, 2025, allowing a 60-day comment period. We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

—Evaluate whether the proposed information collection is necessary to properly perform ATF's functions, including whether the information will have practical utility;

—Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including validity of the methodology and assumptions used;

—Evaluate whether, and if so, how, the quality, utility, and clarity of the collected information can be enhanced; and

—Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting people to submit electronic responses.

You may view this information collection request at *www.reginfo.gov.* Follow the instructions to view Department of Justice information collections currently under review by OMB and look for 1140–0015.

DOJ seeks PRA authorization for this information collection for three years. OMB authorization for an ICR cannot be for more than three years without renewal. DOJ notes that information collection requirements submitted to OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of information collection:* revising a previously approved collection.

2. *Title of the form/collection:* Application to Make and Register NFA Firearm.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* ATF Form 5320.1.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief*