revocation. Registrant's conduct in this matter concerns the CSA's strict requirements regarding registration and recordkeeping and, therefore, goes 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.'' *Gonzales* v. *Raich,* 545 U.S. at 12–14. Permitting Registrant to maintain a registration under these circumstances would send a dangerous message that compliance with the law is not essential to maintaining a registration.

In sum, Registrant has not offered any credible evidence on the record that rebuts the Government's case for revocation of her registration, and Registrant has not demonstrated that she can be entrusted with the responsibility of 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. ME1730870 issued to Dawn Evert, N.P. 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 Dawn Evert, N.P., to renew or modify this registration, as well as any other pending application of Dawn Evert, N.P., for 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.

[FR Doc. 2025–19707 Filed 10–29–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Pharmacy Place, Llc; Decision and Order

I. Introduction

On November 17, 2021, the United States Department of Justice, Drug Enforcement Administration (Agency) issued an Order to Show Cause and Immediate Suspension of Registration (collectively, OSC/ISO) to Pharmacy Place, LLC, of Houston, Texas (Respondent).[1] OSC/ISO, at 1, 10–11. The OSC/ISO immediately suspended, and proposed the revocation of, Respondent's Drug Enforcement Administration (DEA or Government) certificate of registration, No. FP8885785 (registration), pursuant to 21 U.S.C. 824(d) and (a)(4), respectively, ''because . . . [Respondent's] continued registration constitutes 'an imminent danger to the public health or safety''' and ''because . . . [Respondent's] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. . . . [823(g)(1)].''[2] *Id.* at 1.

The OSC/ISO more specifically alleges that, according to an ''independent pharmacy expert retained by the DEA'' who ''reviewed patient profile data, Texas Prescription Monitoring Program data, and prescriptions reported as filled by Respondent,'' Respondent ''filled many controlled substance prescriptions outside the usual course of pharmacy practice'' and ''in contravention of . . . [its] 'corresponding responsibility' under 21 CFR 1306.04(a)'' from March 16, 2020, through August 19, 2021. *Id.* at 2. The OSC/ISO also alleges that Respondent violated recordkeeping requirements.[3]

A DEA Administrative Law Judge (ALJ) determined that Respondent filed a written statement, dated January 20, 2022 (Written Statement), in lieu of requesting a hearing and, accordingly, issued an Order Terminating the Proceedings on January 25, 2022.[4] 21 CFR 1316.49 (2022) (replaced by current rule in effect Nov. 2022).[5] The Government filed its RFAA on September 20, 2023.[6]

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[1] According to GX 3, Attachment B, DEA–82, Notice of Inspection of Controlled Premises, ''Rita Okafor'' is the Pharmacist-in-Charge (PIC) and Chief Executive Officer (CEO) of Respondent, and she signed the DEA–82. *See also* GX 3 (Declaration of First Houston Diversion Investigator (DI)), at 2–3, GX 4 (Declaration of Second Houston DI), at 1–2.

[2] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC/ISO, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[3] The OSC/ISO's recordkeeping violation allegations are:

a. Failure to provide complete and accurate records as required by 21 CFR 1304.21(a);

b. Failure to maintain dispensing records for controlled substances as required by 21 CFR 1304.22(c);

c. Failure to maintain records readily retrievable as required by 21 CFR 1304.04(f)(2);

d. Failure to separate DEA–222 order forms from all other records as required [by] 21 CFR 1305.17(c); and

e. Failure to affix to the package a label showing the date the prescription was filled, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law as required by 21 CFR 1306.14(a).

OSC/ISO, at 10.

[4] Respondent's thirteen-page Written Statement is not included in the Request for Final Agency Action (RFAA), although the Agency accessed it and considered it during this adjudication. *Infra* section III. The Agency obtained the Written Statement from the Office of ALJs' file.

The ALJ's Order Terminating the Proceedings was served on two lawyers for Respondent. Order Terminating the Proceedings, at 3.

[5] The version of 21 CFR 1316.49 in effect during the relevant time period stated: ''Any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, [file a] waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.''

The Rule contemplated that a person who did not want to request a hearing could submit in writing his position on the ''matters of fact and law'' that would be involved in a hearing. An admissible written statement is made a part of the record and the weight attached to its asserted facts is to be determined in light of the lack of opportunity for cross-examination.

The Agency notes that the Written Statement is signed by Respondent's counsels, and that it does not attach any documentary evidence or declaration, let alone a declaration sworn to by a competent fact witness. In other words, the Written Statement is counsel argument untethered to evidence. As such, while the Written Statement provides the Agency with insight into Respondent's position concerning the OSC/ISO, it does not include any facts that the Agency may weigh against the evidence the Government submitted with its RFAA. *Infra* sections III, IV, and V.

[6] The Agency conducted a ''mootness'' analysis. The OSC/ISO was issued on November 17, 2021. The expiration date assigned to Respondent's registration is March 31, 2022. The RFAA is dated September 20, 2023. Respondent's Written Statement contests the OSC/ISO allegations and suggests that they are borne of a misperceived relationship between Respondent and Dr. Rita's Pharmacy and ''whatever shortcomings (if any) remained unaddressed in that matter.'' Respondent's Written Statement, at 12–13 (''Respondent consistently engaged in measures to resolve red flags, acted in the usual course of

Having thoroughly analyzed the record and applicable law, the Agency summarizes its findings and conclusions. First, the OSC/ISO includes specific and detailed factual allegations that Respondent violated Texas law and the CSA. *Infra* section III. Second, Respondent timely filed its Written Statement, and its Written Statement explicitly and implicitly acknowledges its receipt of the OSC/ISO. *Supra.* Third, Respondent's Written Statement, other than explicitly and unambiguously admitting the statement, not the allegation, portion of OSC/ISO paragraph 28 about ''shared addresses'' red flags, is ambiguous about whether Respondent admits unlawfully filling controlled substance prescriptions for individuals sharing the same address, does not respond directly or specifically to any of the OSC/ISO's factual allegations, does not include documentary evidence disproving, or even disputing, any of the OSC/ISO's factual allegations, and does not take responsibility, let alone unequivocal responsibility, for any violation alleged in the OSC/ISO. *Infra* sections III and V; *supra* n.5. Fourth, the RFAA presents a *prima facie* case of the OSC/ISO's general allegations, except for the third through fifth recordkeeping allegations. *Infra* section III. Fifth, the record includes substantial evidence, indeed unequivocal and uncontroverted evidence, that Respondent's controlled substance fills during the period covered by the OSC/ISO violated Texas law and, thus, its CSA corresponding responsibility, and that Respondent violated two recordkeeping rules. 21 CFR 1304.21(a), 1304.22(c); *infra* section III; *infra* n.11. Finally, the Agency concludes that Respondent's continued registration would be inconsistent with the public interest and that it did not unequivocally accept responsibility for its legal violations. 21 U.S.C. 824(a)(4); *infra* sections IV and V. Accordingly, the Agency will revoke Respondent's registration.

II. The CSA and Texas Pharmacists' Professional Responsibility

The main objectives of the CSA, according to the Supreme Court, are to ''conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. 1, at 12 (2005). Given these objectives, the Supreme Court states, particular congressional concerns included ''the need to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–13. Further, according to the Supreme Court, to accomplish the CSA's objectives, ''Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by'' the statute.[7] *Id.* at 13.

According to the CSA's implementing rules, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). As the Supreme Court explained in the context of the Act's requirement that Schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006), *see also United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979) (pharmacist's failed challenge to his federal corresponding responsibility).

While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a).

An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. [§] 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. Accordingly, a pharmacy's registration authorizes it to ''dispense,'' or ''deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, . . . a practitioner.'' 21 U.S.C. 802(10).

The OSC/ISO is addressed to Respondent at its registered address in Texas. Therefore, the Agency also evaluates Respondent's actions according to Texas law, including the applicable Texas pharmacist professional responsibilities. *Gonzales* v. *Oregon,* 546 U.S. at 269–71.

During the period alleged in the OSC/ISO, Texas law specifically addressed pharmacists' professional responsibilities. First, according to Texas law, ''[a] pharmacist may not dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice).'' Tex. Health & Safety Code § 481.074(a) (2019). Second, pharmacists ''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 § 291.29(b) (2018). Further, according to Texas law, 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.'' *Id.* § 291.29(f). Texas specifically identifies ''red flag factors'' that are ''relevant to preventing the non-therapeutic dispensing of controlled substances'' that ''shall be considered by evaluating the totality of the

professional practice prior to dispensing, and continued to fill prescriptions under Respondent's thorough prescription verification and practice measures''), *id.* at 3 (''Disconcertedly, . . . [Respondent] received an email from the DEA Registration Authority (*@deaecom.gov*) purporting to indicate that Rita Okafor had requested revocation of all CSOS certificates asserting DEA Registration number:FP8885785 [sic]. Such a request was never made.''

The Agency notes that Respondent's Written Statement does not explicitly address Rita Okafor's relationship to itself. That relationship, according to the record before the Agency, is 60% owner (with her husband owning the remaining 40%), CEO, and PIC. GX 3, at 2–3, GX 4, at 1–2; *supra* n.1. Further, Respondent's Written Statement does not state that Respondent or its owner/PIC intends to stop dispensing controlled substances; it implicitly indicates its intention to continue dispensing controlled substances. *E.g.* Written Statement, at 6 (stating, regarding a closed-matter letter from the Texas State Board of Pharmacy that ''also served as a reminder of guidelines and expectations it was to follow,'' that Respondent ''has been following those exact guidelines''), *id.* at 9 (stating, regarding a February 2021 interaction with DEA when DEA ''brought [to its] attention'' an incident of its dispensing controlled substances to individuals sharing the same residential address, that Respondent ''took it to heart and thereby immediately implemented *an additional policy* that no other prescriptions were to be dispensed to patients who share the same residential addresses and also implemented additional measures to identify patients from [the] same address . . . [and Respondent] has held to that policy since'' [emphasis in original]). Under these circumstances, the Agency affords Respondent a full adjudication of the OSC/ISO allegations and its Written Statement, as well as the opportunity to seek Circuit Court review of that final adjudication. *See, e.g., id.* at 2–6. The Agency, based on its prior decisions, such as *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68475–79 (2019), adjudicates this matter and issues its final Decision. *See also Abdul Naushad, M.D.,* 89 FR 54059, 54059–60 (2024); *Steven Kotsonis, M.D.,* 85 FR 85667, 85668–69 (2020).

[7] 21 U.S.C. 841(a)(1) (''[I]t shall be unlawful for any person knowingly or intentionally . . . to . . . distribute[ ] or dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance . . . [e]xcept as authorized by'' the CSA.). The CSA defines ''dispense'' to include ''deliver[ing] a controlled substance to an ultimate user.'' 21 U.S.C. 802(10).

circumstances rather than any single factor.'' *Id.* Several of those red flag factors are relevant to the adjudication of the OSC/ISO.

According to Texas law, 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'' is a red flag factor. *Id.* § 291.29(f)(1). Likewise, under Texas law, ''prescriptions by a prescriber . . . [that] are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants containing codeine, or any combination of these drugs'' is a red flag factor. *Id.* § 291.29(f)(3). Another red flag factor is ''prescriptions for controlled substances . . . [that] are commonly for the highest strength of the drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner.'' *Id.* § 291.29(f)(5). Two other red flag factors are ''multiple persons with the same address [who] present substantially similar controlled substance prescriptions from the same practitioner,'' and ''persons [who] consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.'' *Id.* §§ 291.29(f)(11) and (12).

Texas law clearly sets out the operational standard for a pharmacy to follow when it is presented with a controlled substance prescription exhibiting a ''red flag factor'': ''Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.'' [8] *Id.* § 291.33(c)(2)(A)(iv) (2019–2020). This Texas documentation requirement preludes a *post hoc* oral statement that identification and resolution of a ''red flag factor'' actually took place absent the existence of documentation compliant with Section 291.33(c)(2)(C).

III. Findings of Fact

A. The Government's Case

The RFAA includes three sworn, under penalty of perjury, Declarations, one each by two Houston DIs and one by the Government's proposed expert, Registered Pharmacist Katherine Salinas. GX 3, GX 4, and GX 5, respectively.

The content of the DIs' sworn Declarations is internally consistent and consistent with each other. Accordingly, the Agency affords both DIs' Declarations full credibility.

The sworn Declaration of the Government's proposed expert states that she is a former Compliance Officer with the Texas State Board of Pharmacy.[9] The content of the Government's proposed expert's Declaration, setting out the standard of practice of Texas pharmacies and of Texas pharmacists' professional responsibilities, is accurate. *Supra* section II. The Agency, therefore, finds that the Government's proposed expert qualifies as an expert in pharmacy compliance with Texas laws and rules, and accepts her as such in this adjudication. Accordingly, the Agency affords the Government's expert's Declaration full credibility. As such, the Agency affords full credibility to the Government's expert's analyses of the record evidence, including her Declaration statements that (1) ''between at least March 5, 2020[,] to September 23, 2021, the . . . Respondent repeatedly filled prescriptions for controlled substances without addressing or resolving red flags of abuse or diversion, in violation of the minimum standard of care that governs the practice of pharmacy in the State of Texas,'' (2) these, Respondent's repeated fills in violation of the minimum standard of care in Texas, are a violation of Respondent's ''corresponding responsibility to only dispense legitimate prescriptions,'' and (3) Respondent ''filled prescriptions for L.N.W., R.B., J.P., M.F., T.J.P., J.F., M.R., L.H., L.D.W., A.H.G., P.A.T., M.L.P., N.J., J.W.W., J.J.W., J.W., [and] C.R.M. . . . outside the usual course of professional practice.'' [10] GX 5, at 6, 25; *infra.*

Regarding service of the OSC/ISO, the second Houston DI's Declaration states that ''[o]n or about November 22, 2021, . . . [she] personally served the . . . [Respondent] with a copy of the signed OTSC/ISO.'' GX 4, at 3; *see also* Written Statement, at 1, 6, 8, 9, 12, 13, 14 (explicit and implicit references to the OSC/ISO and its content in the Written Statement). Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent received the OSC/ISO before it submitted its Written Statement dated January 20, 2022.[11]

Moreover, the documentary evidence submitted with the RFAA concerning the alleged illegal controlled substance fills corresponds precisely with the unlawful dispensing allegations in the OSC/ISO. Among other things, this means, and the Agency finds unequivocal and uncontroverted record evidence, that Respondent had notice of every dispensing allegation, and data points supporting each allegation, before it submitted its Written Statement. Regardless, Respondent did not include evidence in its Written Statement countering the Government's evidence of specific dispensing violations.

The Agency finds substantial record evidence that the documentation submitted with the RFAA does not fully support OSC/ISO paragraph allegations 31.c, 31.d, and 31.e., but that it does support the rest of the OSC/ISO's recordkeeping allegations. OSC/ISO, at 10.

In sum, the Agency finds substantial record evidence that the RFAA presents a *prima facie* case for the OSC/ISO's dispensing allegations as to Drs. A.N., G.K., and M.K., and for the first two

[8] Subparagraph (C) states: ''Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information: (i) date the prescriber was consulted; (ii) name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' *Id.* § 291.33(c)(2)(C).

[9] Ms. Salinas's *curriculum vitae* states that her responsibilities during her more than nine years serving as a Texas Board of Pharmacy Compliance Officer included performing ''advanced, complex inspections of all classes of pharmacies to ensure compliance with laws and rules.'' GX 5, Attachment A, at 1.

[10] The Government's expert found these red flags of abuse or diversion exhibited among the prescriptions that Respondent filled, and the expert found no evidence either on the prescriptions or in the patient profiles that Respondent identified, addressed, and resolved the red flags: pattern prescribing (the same controlled substances in identical or substantially similar quantities to multiple patients, thus indicating a lack of individualized care), controlled substances known to be abused (such as oxycodone), combinations of controlled substances (such as hydrocodone-acetaminophen 10/325 mg and carisoprodol 350 mg), controlled substances prescribed in the highest strength and/or large quantities, multiple persons with the same address, and cash payments. GX 5, at 6–25.

[11] According to the CSA, ''[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.'' 21 U.S.C. 877. Here, Respondent's Written Statement is not evidence, nor does it attach evidence, such as documents or sworn declarations, that the Agency may consider along with the evidence the Government submitted with its RFAA. Throughout this Decision, therefore, when the Agency finds evidence to be unequivocal and uncontroverted record evidence, the Agency is finding the evidence to be more than the ''substantial evidence'' required by 21 U.S.C. 877; it is unrebutted evidence.

OSC/ISO recordkeeping allegations (paragraphs 31.a and 31.b.). RFAA, at 44–229.

B. Respondent's Case

As already discussed, the only input from Respondent in the Agency record is the Written Statement signed by Respondent's Counsel. *Supra,* section I. Nothing, whether documentary evidence or a sworn-to declaration, is attached to the Written Statement. *Id., infra* section III.C. While the Written Statement does not include evidence, it provides the Agency with insight into Respondent's position concerning the OSC/ISO. *Supra* n.5. In this case, the Written Statement disputes most, and possibly all, of the OSC/ISO's allegations.[12] Written Statement, at 4–13. Yet, had Respondent complied fully with applicable federal and Texas law, it would possess documentary evidence disputing the OSC/ISO's dispensing allegations and the first two recordkeeping allegations. *Infra,* sections III.C and III.D. For example, this documentary evidence would include the legally required, under Texas law, documentation that it identified and resolved red flags before filling the associated controlled substance and, under the CSA, the required records that it avers it provided to the DIs and that the DIs returned to it ''two weeks later.'' Written Statement, at 10 (''The DEA found everything to be in order, and two weeks later, returned all the records and information they requested.''); *see also, e.g., id.* at 4–5; *supra* section II. Accordingly, the Agency concludes that no weight may be attached to the matters asserted in the Written Statement because the matters asserted in it are argument, not admissible evidence. *Supra* n.5.

C. The Unlawful Dispensing Allegations: Dispensing Controlled Substances Without Identifying and Resolving the Red Flag Factors of Pattern Prescribing, Prescribing Controlled Substances Commonly Known To Be Abused, Prescribing the Highest Strength and/or Large Quantities of Controlled Substances, a Practitioner's Prescribing the Same or Similar Controlled Substances to Individuals Who Share the Same Address, and Payment by Cash or Cash Equivalents

The Agency finds that the evidence the Government submitted with the RFAA, in conjunction with Respondent's not having submitted any evidence, is unequivocal and uncontroverted record evidence that Respondent filled controlled substance prescriptions issued by Drs. A.N., G.K., and M.K. without identifying, resolving, and documenting the resolution of red flag factors, as alleged in the OSC/ISO, and in violation of the CSA and Texas law. GX 5, at 1–25, GX 3E–3U. The red flag factors that, according to the unequivocal and uncontroverted record evidence, Respondent failed to identify, resolve, and create and maintain written red flag resolution documentation for are pattern prescribing, prescribing of controlled substances commonly known to be abused, prescribing the highest strengths and/or large quantities of controlled substances indicating a lack of individual drug therapy, multiple persons with the same address presenting substantially similar controlled substance prescriptions from the same practitioner, and consistently paying for the controlled substances with cash more often than through insurance. GX 5, at 1–4. The unequivocal and uncontroverted record evidence also includes that ''All State of Texas pharmacists have access to these [Texas dispensing legal] requirements, and are required to pass a jurisprudence examination in order to become a licensed pharmacist,'' and that ''All State of Texas licensed pharmacists know he/she is required to exercise reasonable caution in practice to prevent diversion by following common sense and proper dispensing practices.'' *Id.* at 3. Accordingly, there is unequivocal and uncontroverted record evidence that Respondent ''knowingly'' filled controlled substance prescriptions that were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.[13] 21 CFR 1306.04(a), Tex. Health & Safety Code § 481.074(a) (2019), 22 Tex. Admin. Code § 291.29 (2018), 22 Tex. Admin. Code § 291.33 (2019–2020); GX 3E–3U, GX 5, at 1–25; *supra* sections II, III.A., and III.B.[14]

For example, the Agency finds unequivocal and uncontroverted record evidence that, during the approximate thirteen-month period between June 12, 2020, and July 13, 2021, Respondent unlawfully released into the community about 5,463 tablets of hydrocodone-acetaminophen 10–325 mg and carisoprodol 350 mg for nine individuals based on controlled substance prescriptions issued by the same practitioner. GX 5, at 9–17 and GX 3H, 3I, 3K, 3L, 3M, 3N, 3O, 3P, and 3Q. Each of the nine individuals paid cash for all of these Schedule II and Schedule IV controlled substance tablets. GX 5, at 9–10, 12–16 and GX 3H, at 1, GX 3I, at 1, GX 3J, at 1, GX 3K, at 1, GX 3L, at 1, GX 3M, at 1, GX 3N, at 1, GX 3O, at 1, GX 3P, at 1, and GX 3Q, at 1. All of these prescriptions were written for large quantities and the highest available dosages of hydrocodone-acetaminophen 10–325 mg and carisoprodol 350, controlled substances commonly known to be abused. GX 5, at 9–10, 12–16.

By way of further example, the Agency finds unequivocal and uncontroverted record evidence that, during the approximate eleven-month period between March 16, 2020, and February 19, 2021, Respondent unlawfully released into the community a total of about 4,642 tablets of hydrocodone-acetaminophen 10–325 mg and carisoprodol 350 mg for three individuals who share the same address and based on prescriptions issued by the same practitioner. GX 5, at 17–19 and GX 3R, 3S, and 3T.

In sum, the Agency finds unequivocal and uncontroverted record evidence that the Government presented a *prima*

[12] The Written Statement contains ambiguous statements about whether Respondent disputes the OSC/ISO allegations that it filled prescriptions for the same or substantially similar controlled substances, based on prescriptions written by the same practitioner, to individuals at the ''same address.'' Written Statement, at 8–9. The Agency finds no evidence that Respondent takes responsibility, let alone unequivocal responsibility, for committing the ''same address'' violation, or for committing any violation, whether dispensing or recordkeeping, alleged in the OSC/ISO. *Id.* at 1–13.

[13] Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Morning Star Pharmacy and Medical Supply 1,* 85 FR 51045, 51061 (2020) (pattern prescribing; distance; cash payments; high doses/quantities of high-alert controlled substances); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10898 (2018), *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; cash payments); *Hills Pharmacy,* 81 FR 49816, 49836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances); *The Medicine Shoppe,* 79 FR 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing).

[14] GX 3AA appears immediately after GX 3A in the RFAA.

facie case that Respondent filled controlled substance prescriptions outside the usual course of pharmacy practice and in violation of its corresponding responsibility. 21 CFR 1306.04(a), Tex. Health & Safety Code § 481.074(a) (2019), 22 Tex. Admin. Code § 291.29 (2018), 22 Tex. Admin. Code § 291.33 (2019–2020).[15]

D. The Recordkeeping Allegations

The Agency finds that the evidence the Government submitted is unequivocal and uncontroverted record evidence that Respondent violated recordkeeping requirements.[16] OSC/ISO, at 10 (paragraphs 31.a. and 31.b.), *supra* sections III.A. and III.B. Specifically, the two DIs' credible, sworn Declarations state that Respondent did not have the dispensing records, biennial inventory, and most recent inventory records that the DIs requested, constituting substantial record evidence of Respondent's recordkeeping violations. GX 3, at 2, GX 4, at 2.

According to the Written Statement, Respondent ''denies'' the recordkeeping allegations, and claims that it ''willingly provided the DEA with all the documentation they requested.'' Written Statement, at 2, 10. Respondent further states that ''DEA found everything to be in order, and two weeks later, returned all the records and information they requested.'' *Id.* at 2, 10. If, as the Written Statement states, Respondent received back the records and information that DEA found to be in order, then Respondent could have attached those records and information to the Written Statement to prove its unsworn claims that it complied with the DIs' records request. In fact, Respondent did not submit any evidence, let alone this specific evidence, to support its claims of its compliance with recordkeeping requirements.

Under such circumstances, this Agency has applied, and it also applies here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''[s]imply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent's decision not to provide records gives rise to an inference that any such evidence is unfavorable to Respondent.

In sum, Respondent's unsworn and unsupported claims that it provided the requested records to the DIs are insufficient to rebut the *prima facie* recordkeeping violation case that the Government presented as to OSC/ISO subparagraphs 31.a. and 31.b. *Supra.* Accordingly, the Agency finds substantial record evidence that Respondent violated federal recordkeeping requirements.[17] 21 CFR 1304.21(a) and 1304.22(c).[18]

IV. Discussion

A. The CSA and the Public Interest Factors

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[19]

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). The Agency may give each factor the weight it deems appropriate. *Gonzales* v. *Oregon,* 546 U.S. at 293 (Scalia, J., dissenting) (quoting *In re Arora,* 60 FR 4447, 4448 (1995)), *e.g., Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007) (importer); *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 174 (D.C. Cir. 2005) (practitioner), *quoting Henry J. Schwarz, Jr., Denial of Application,* 54 FR 16422, 16424 (1989).

The Agency ''may properly rely on any one or a combination of factors.'' *Gonzales* v. *Oregon,* 546 U.S. at 293 (Scalia, J. dissenting) (quoting *In re Arora,* 60 FR 4447, 4448 (1995)); *Morall,* 412 F.3d at 185 n.2 (Henderson, J. concurring and referring to pages 173–74 of the majority opinion); *see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (*citing Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). 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) (the Agency ''must consider each of these factors'' but ''need not make explicit findings as to each one'') (quoting *Volkman,* quoting *Hoxie,* and citing *Morall*). ''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) (on remand). Accordingly, as the Tenth Circuit has recognized, 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); *see also Morall,* 412 F.3d at 174.

[15] Any one of these distribution violations is sufficient to deny an application for a registration or revoke a registration. 21 U.S.C. 823(g)(1), 824(a)(4).

[16] As already discussed, the Agency finds that the Government did not submit sufficient evidence to prove the recordkeeping allegations in OSC/ISO paragraphs 31.c, 31.d, and 31.e. OSC/ISO, at 10.

[17] Any one of these recordkeeping violations is sufficient to deny an application for a registration. 21 U.S.C. 823(g)(1).

[18] As for the unproven recordkeeping allegation in OSC/ISO paragraph 31.c., regarding 21 CFR 1304.04(f)(2), the Agency notes that neither the OSC/ISO or the RFAA alleges, let alone proves, that Respondent is one of the entities to which 21 CFR 1304.04(f)(2) applies. The Agency also notes, however, that the Written Statement does not claim that 21 CFR 1304.04(f)(2) does not apply to Respondent. As the Government has the burden of proof in these proceedings, this recordkeeping allegation is not sustained.

[19] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

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

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

B. Factors B and/or D—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Relating to Controlled Substances

Allegation That Respondent's Continued Registration Would Be Inconsistent With the Public Interest

While the Agency considered all of the 21 U.S.C. 823(g)(1) factors in this matter, the Agency finds that the Government's *prima facie* case is confined to factors B and D. The Agency finds that the Agency-found facts regarding Respondent's conduct with respect to factors B and D, its unlawful conduct under applicable federal and Texas law, constitute a *prima facie* showing that Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1306.04(a), 1304.21(a), 1304.22(c); Tex. Health & Safety Code § 481.074(a) (2019); 22 Tex. Admin. Code § 291.29 (2018), § 291.33 (2019–2020); *supra* sections III.C. and III.D.

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) in conjunction with 823(g)(1); *supra* sections III.C. and III.D. Respondent, who chose not to submit any evidence for the Agency's consideration, also did not attempt to rebut the Government's *prima facie* case.

V. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration would be inconsistent with the public interest due to its experience dispensing controlled substances and its failure to comply with applicable laws relating to controlled substances, the burden shifts to Respondent to show why the Agency should continue to entrust it with a registration. *Morall,* 412 F.3d at 174; *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *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 respondent. *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 (citing authority including *Alra Labs., Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995) (''An agency rationally may conclude that past performance is the best predictor of future performance.''). ''[T]hat consideration is vital to whether continued registration is in the public interest.'' *MacKay,* 664 F.3d at 820. A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy,* 881 F.3d at 830–31.

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 respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, Respondent chose to submit a written statement in lieu of requesting a hearing. As already discussed, the Written Statement is signed by Respondent's counsels and, as such, is not evidence. *Supra* section I, n.5. Nor does it attach evidence. *Id.* Instead, it denies, without offering proof, the existence of any legal violation. As such, the Written Statement does not offer evidence to refute the Government's *prima facie* case. Respondent has not convinced the Agency that it understands that its filling of controlled substance prescriptions fell short of the applicable legal standards and that this substandard controlled substance prescription filling has serious negative ramifications for the health, safety, and medical care of individuals who come to it with controlled substance prescriptions to be filled. *E.g., Jones Total Health Care Pharmacy,* 881 F.3d at 834 and n.4; *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases) (''The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.''). As such, it is not reasonable to believe that Respondent's future controlled substance prescription filling or recordkeeping will comply with legal requirements.

The unequivocal and uncontroverted record evidence is that Respondent's founded violations resulted in the unlawful release of over 10,000 controlled substance tablets over a sixteen-month period. *Supra* section III.C. The tablets unlawfully released into the community were hydrocodone-acetaminophen and carisoprodol, controlled substances known to be abused and diverted. *Id.*

The Written Statement does not evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations. There is no record evidence from which the Agency may reasonably conclude that Respondent's future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that it should continue to entrust Respondent with a registration.

The interests of specific and general deterrence weigh in favor of revocation. Further, given the foundational nature and vast number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not essential to maintaining a registration.

Accordingly, I shall order the sanction the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FP8885785 issued to Pharmacy Place, LLC. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending application of Pharmacy Place, LLC, to renew or modify this registration, as well as any other pending application of Pharmacy Place, LLC, for registration in Texas. 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.

[FR Doc. 2025–19708 Filed 10–29–25; 8:45 am]

BILLING CODE 4410–09–P