. . . .''). Thus, evaluating an applicant's or registrant's compliance with the Federal laws that govern registration and renewal, including DEA's fee schedule and fee exemptions, is appropriately considered under factor D.[5] 21 U.S.C. 823(g)(1)(D).

Accordingly, making a false statement regarding entitlement to fee exemption has a natural tendency to influence the Agency's decision regarding whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45234, 45238; RFAAX 1, Attach. F, at 1–2. Therefore, the falsities in Registrant's application were ''predictably capable of affecting'' DEA's decision to renew her registration, and therefore the Agency finds that they were material. *Kungys,* 485 U.S. at 771–72.

In sum, the Agency finds clear, unequivocal, and convincing record evidence, based on Registrant's admissions, that she submitted a materially false renewal application for registration. 21 U.S.C. 824(a)(1); 21 CFR 1301.43(e).

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is clear, unequivocal, and convincing record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 824(a)(1).

C. Sanction

Where, as here, the Government has presented a *prima facie* case showing that Registrant submitted a materially false application for registration renewal, the burden shifts to Registrant to show why she can be trusted with a registration. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (D.C. Cir. 2005); *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 a fact-dependent determination based on the circumstances presented by the individual practitioner. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Historically, the Agency has considered acceptance of responsibility, egregiousness, and deterrence when making this assessment.

Specifically, the Agency requires the practitioner to accept responsibility for his or her violation. *Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). Acceptance of responsibility must be unequivocal. *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, the Agency considers the egregiousness and extent of the misconduct in determining the appropriate sanction. *Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by Registrant, by current registrants, and by future applicants for registration. *Stein,* 84 FR at 46972–73.

Here, Registrant did not timely request a hearing, or timely or properly answer the allegations, and was therefore deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–3. 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 herself of the opportunity to refute the Government's case. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding her future compliance with the CSA, and has not made any demonstration that she can be trusted with registration.

Moreover, the evidence presented by the Government shows that Registrant provided false information regarding her fee exempt status. Providing false information as part of an application process for controlled substance privileges governed by Federal law calls into question Registrant's honesty, trustworthiness, and ability or willingness to comply with the laws governing controlled substances. To permit Registrant to maintain a registration under these circumstances would send a dangerous message that DEA does not expect compliance with its registration requirements and that the registration fees required by statute and regulation can be circumvented without consequence by making false statements. Registrant and the regulated community must be on notice that DEA's registration and renewal process, to include the required fees, is governed by Federal law, that DEA will strictly enforce those Federal laws, and that DEA expects applicants and registrants to adhere to those Federal laws.

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), I hereby revoke DEA Certificate of Registration No. MJ5209677 issued to Grace S. Joanita, 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 Grace S. Joanita, N.P., to renew or modify this registration, as well as any other pending application of Grace S. Joanita, N.P., for additional registration in Ohio. This Order is effective November 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 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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BILLING CODE 4410–09–P

[5] To be clear, the Agency is not finding that Registrant violated the above-referenced portions of the CSA or its implementing regulations. This information is presented to give context to the materiality of Registrant's falsification. The Agency's only finding against Registrant is that she materially falsified a renewal application which is grounds for revocation under 21 U.S.C. 824(a)(1).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hovic Pharmacy; Decision and Order

I. Introduction

On October 20, 2021, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Hovic Pharmacy of Houston, Texas (Respondent). Request for Final Agency Action (RFAA), at 1801.[1] The OSC proposes the revocation of Respondent's DEA registration No. FH5569112 (registration), pursuant to 21 U.S.C. 824(a)(4) ''because . . .

[1] The Chief Administrative Law Judge (ALJ) granted the Government's unopposed motion to amend the OSC by Order dated January 10, 2022. RFAA, at 1799–1800. This Decision adjudicates the amended OSC.

[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.* According to the OSC, ''Respondent's pharmacists filled many controlled substance prescriptions outside the usual course of pharmacy practice . . . and in contravention of their 'corresponding responsibility.' '' *Id.* at 1802, citing 21 CFR 1306.06 and 1306.04(a).

The OSC more specifically alleges that, according to an ''independent pharmacy expert'' retained by DEA who ''reviewed . . . prescription data'' referenced in the OSC, the ''data present[ ] multiple red flags that were highly indicative of abuse and diversion.'' *Id.* at 1806. With respect to the ''controlled substances purchased by and distributed to'' a recruiter (Recruiter), the expert opined that the ''red flags inherent in those prescriptions could not have been resolved by a pharmacist acting in the usual course of professional practice, and, therefore, each prescription was filled outside the standard of care of pharmacy practice in Texas.''[3] *Id.* As for the prescriptions whose red flags ''could potentially be resolved, the expert concluded that, based on documentation provided by . . . [Respondent, Respondent] made no effort to resolve the red flags and therefore, those prescriptions were also filled outside the standard of care of pharmacy practice in Texas.'' *Id.*

Respondent initially requested a hearing, but submitted a Waiver of Hearing on February 10, 2022, days before the hearing scheduled for February 14 through February 17 was to begin.[4] *Id.* at 1807–08; *infra* section III.A. The Chief ALJ issued his Order Terminating Proceedings on February 11, 2022. RFAA, at 1809. The Government filed its RFAA, and served Respondent, on October 30, 2023. *Id.* at 21.

Having thoroughly analyzed the record and applicable law, the Agency summarizes its findings and conclusions: (1) the OSC includes multiple, specific allegations that Respondent violated the Controlled Substances Act (CSA), the CSA's implementing rules, and Texas law, (2) Respondent requested a hearing, participated during most of the pre-hearing stage, and simply withdrew its hearing request, without explanation or elaboration of any kind, days before the four-day scheduled hearing was to begin, (3) the Government's RFAA presents a *prima facie* case as to all but three of the apparent OSC allegations, and (4) the record includes substantial record evidence, indeed unequivocal and uncontroverted record evidence, that Respondent violated federal and Texas law, thus unlawfully releasing about 13,135 controlled substance tablets, and about a 3,478 days' supply of promethazine with codeine (Schedule V), into the community in a period of about eighteen months.[5] [6] Accordingly, the Agency will revoke Respondent's registration. *Infra,* Order.

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, ''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.''[8] *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

[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, 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] Recruiter pled guilty to ''conspiracy to dispense and distribute hydrocodone,'' and executed a declaration while serving a sentence of sixty months. RFAA, at 1806.

[4] It is not clear, from the record, that Respondent's emailed hearing request was submitted timely. Given that this matter is now before the Agency on the Government's request for final Agency action, however, there is no need for the Agency to try to clear up this matter.

[5] 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, as Respondent withdrew its hearing request before the first day of the hearing, when the Agency finds that the evidence that the Government submitted with its RFAA constitutes substantial record evidence of an OSC allegation, that evidence is also unequivocal and uncontroverted evidence of that OSC allegation. 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'' of 21 U.S.C. 877; it is unrebutted evidence.

[6] The fills are alleged to have spanned the time period of December 17, 2018, through March 15, 2021. RFAA, at 1804.

If the OSC includes an allegation based on Texas Health and Safety Code 481.074(a)(5), ''a pharmacist may not . . . permit the delivery of a controlled substance to any person not known to the pharmacist . . . without first requiring identification of the person taking possession of the controlled substance,'' except in stated circumstances, it is not sustained because the Agency finds unequivocal and uncontroverted record evidence that Recruiter is ''known'' to at least one of Respondent's pharmacists. *Infra* section III.A.2.; RFAA, at 1803, para. 12; RFAA, at 1804, para. 15.

Further, given that the Agency finds unequivocal and uncontroverted record evidence of multiple other OSC allegations, each, alone, being a sufficient basis for revoking Respondent's registration, the Agency need not, and does not, address two OSC allegations: first, allegations concerning the use of cash and cash equivalents to pay Respondent for filling controlled substance prescriptions and, second, allegations concerning Respondent's filling controlled substance prescriptions issued by a physician assistant who, at the time, was allegedly subject to a Texas Physician Assistant Board Order's restrictions and was allegedly not under the supervision of a licensed physician. RFAA, at 1805–06, paras. 16.f. and 16.g.

[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 . . . by, or pursuant to the lawful order of, a practitioner.'' 21 U.S.C. 802(10). It defines ''distribute'' to mean ''to deliver (other than by administering or dispensing) a controlled substance.'' *Id.* 802(11). Thus, according to these CSA definitions, when a pharmacy fills an illegitimate controlled substance prescription, it is ''distributing,'' not ''dispensing,'' controlled substances.

[8] The context of this Supreme Court statement is the Act's requirement that Schedule II controlled substances be dispensed only by written prescription.

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 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, 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) (2017, 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 law 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 circumstances rather than any single factor.'' *Id.* Several of those red flag factors are relevant to the adjudication of the OSC.

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).

The Texas Administrative Code 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.'' [9] *Id.* § 291.33(c)(2)(A)(iv) (2018–2023). 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 [10]

In sum, the Government charges Respondent with filling controlled substance prescriptions outside the usual course of Texas pharmacy practice in contravention of its corresponding responsibility over the course of many years: (1) Respondent filled controlled substance prescriptions for Recruiter and Recruiter's recruits, knowing that the controlled substances were destined for resale on the street, a clearly illegitimate purpose, and (2) Respondent filled controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. RFAA, at 1802, 1804–1806.

The RFAA is more than 1,800 pages, mostly documentary evidence, and includes three sworn, under penalty of perjury, Declarations: one by a (now-retired) Diversion Investigator (DI), one by Recruiter, and one by the Government's expert, Dr. Diane Ginsburg, a Registered Pharmacist. *Id.* at 1810–50.

1. DI's Declaration

The DI's Declaration states that its content is based on ''personal knowledge and/or information gained in the course of . . . official duties.'' *Id.* at 1813. Its content includes background about DEA's investigation of Respondent and others, information supporting the OSC's allegations, and material that is consistent with portions of Recruiter's Declaration.[11] *Id.* at 1813–20. The Agency finds that DI's Declaration is internally consistent and supports the Government's request to revoke Respondent's registration. *Id.* The Agency affords DI's Declaration full credibility, due to its internal consistency and its having been sworn to under penalty of perjury.

2. Recruiter's Declaration

Recruiter's declaration, dated February 17, 2022, is sworn to and signed by Recruiter. *Id.* at 1810–12. According to the Declaration, Recruiter is ''currently incarcerated'' in federal prison ''serving a 60-month sentence as a result of pleading guilty to the charge of conspiracy to dispense and distribute hydrocodone.'' *Id.* at 1810. Recruiter's Declaration describes a conspiracy in which Recruiter and Recruiter's recruits unlawfully obtained controlled substance prescriptions. Recruiter then presented the prescriptions to Respondent, and Respondent's pharmacists filled them even though the pharmacists knew or had reason to

[9] 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.'' 22 Tex. Admin. Code § 291.33(c)(2)(C).

[10] As already explained, Respondent waived its right to a hearing just before the hearing was scheduled to begin and, as such, the record before the Agency does not include evidence or legal analysis from Respondent. RFAA, at 1807–08 (Respondent's Waiver of Hearing); *supra* section I. Accordingly, this Decision contains no material for a section, comparable to this one, about Respondent's case.

[11] While ''consistent'' with portions of Recruiter's Declaration, there is insufficient information in DI's Declaration about the source(s) of all of those consistencies for the Agency to conclude that DI's Declaration ''corroborates'' the entirety of Recruiter's Declaration. In other words, if the source of the consistent material in DI's Declaration is Recruiter, then DI's Declaration simply repeats Recruiter's information, not independently corroborates it. DI's Declaration does, however, explicitly corroborate portions of Recruiter's Declaration. *Infra.* section III.A.2.

know that the prescriptions were unlawfully obtained. Recruiter then sold the unlawfully obtained controlled substances on the street. *Id.* at 1810–12.

Based on the admissions in Recruiter's Declaration, the Agency finds that Recruiter, ''[f]rom at least 2017 through 2020 . . .[,] participated in a scheme to obtain prescriptions for controlled substances from practitioners and those prescriptions were filled at . . . [Respondent].'' [12] *Id.* The Agency further finds unequivocal and uncontroverted record evidence that Recruiter ''recruit[ed] individuals to pose as patients (recruits) who would obtain prescriptions for controlled substances from two different practitioners,'' that Respondent would fill the controlled substance prescriptions, including prescriptions for hydrocodone-acetaminophen 10-325 (Schedule II), promethazine with codeine, carisoprodol (Schedule IV), and alprazolam (Schedule IV), and that Recruiter ''would then purchase these prescriptions with cash, pick up the drugs[,] and sell the drugs to street level customers.'' [13] *Id.* at 1810. In sum, given the self-incriminating nature of Recruiter's Declaration, the corroboration of its content by DI's Declaration, its internal consistency, and its having been sworn to under penalty of perjury, the Agency affords Recruiter's Declaration credibility.[14]

The Agency finds unequivocal and uncontroverted record evidence that Recruiter ''developed a relationship with the employees'' of Respondent who ''rarely questioned'' the controlled substance prescriptions that Recruiter dropped off for about eleven individuals approximately three times a week for several years.'' [15] *Id.* at 1810–11; *see also id.* at 1812 (''Though I firmly believe . . . [Respondent Pharmacist Two] knew or had reason to know that the prescriptions I purchased and picked up from . . . [Respondent] were not issued for a legitimate medical purpose, . . . [Respondent Pharmacist One] was also aware that I was regularly picking up prescriptions for controlled substances that had been prescribed to others.'').

The Agency also finds unequivocal and uncontroverted record evidence that Respondent Pharmacist Two ''instructed'' Recruiter about how to do business with Respondent. *Id.* at 1811. For example, Respondent Pharmacist Two told Recruiter not to bring the recruits to the store to pick up and purchase the controlled substances. *Id.* Instead, she instructed Recruiter ''to come in and pick up the prescriptions,'' and either to forge the recruits' names on the signature log or to sign Recruiter's own name. *Id.; id.* at 31–89 (Respondent's signature logs, GX 4, that Recruiter annotated with a circle or a circle with a check mark to signify when Recruiter forged the recruit's name (circle only) and when Recruiter signed Recruiter's own name (circle and check mark)); *id.* at 171–237 (Respondent's Dispensed Drug Report for the Period of January 3, 2020, through March 29, 2021, GX 8, showing about twenty-seven prescription number matches between the signature log prescription numbers that Recruiter signed, forging the recruit's name, and controlled substances, such as promethazine with codeine, hydrocodone-acetaminophen 10-325, and carisoprodol 350, that Respondent filled and sold to Recruiter from January 23, 2020, to March 23, 2020).[16]

In sum, the Agency finds unequivocal and uncontroverted record evidence that Respondent did not question, address, prevent, or otherwise take any action when Recruiter asked for, signed the signature log for, paid for, and left Respondent's store with filled controlled substance prescriptions issued for persons other than Recruiter. *Id.* at 1811 (''At no time did anyone at . . . [Respondent] question the fact that I was picking up controlled substances for others. At no time did anyone at . . . [Respondent] refuse to provide me with a prescription that was issued to someone else even though I signed the person's name instead of my own. I was also never asked to provide any proof that I had authority to pick up prescriptions for anyone other than myself.'').

Further, the Agency finds unequivocal and uncontroverted record evidence that at least one of Respondent's pharmacists knew, and even conversed ''often'' with Recruiter, about Recruiter's street resale of the controlled substances that Respondent filled for Recruiter and Recruiter's recruits. *Id.* at 1811–12. For example, Recruiter and at least Respondent Pharmacist Two ''often'' discussed Recruiter's specific controlled substance brand preferences, the brands with a

[12] In addition to the RFAA's documentary evidence that corroborates Recruiter's Declaration, *infra.,* DI's Declaration references a court-authorized Title III wiretap that corroborates Recruiter's Declaration. RFAA, at 1815 (DI Declaration stating that Recruiter's ''role in the enterprise was confirmed by a court-authorized Title III wiretap undertaken on phones utilized by recruiters and clinic staff members'').

The Agency makes the decision that Recruiter's Declaration is credible after evaluating paragraph 20 of DI's Declaration, paragraph 14 of Recruiter's Declaration, and the report of Respondent Pharmacist One. *Id.* at 1817, 1812, and 105, respectively. According to DI's Declaration, DI ''attempted to confirm . . . [Recruiter's] statement regarding an incident'' that Recruiter described involving Respondent Pharmacist One's ''mistakenly'' filling a recruit's carisoprodol (Schedule IV) prescription with hydrocodone-acetaminophen 10-325 tablets (Schedule II). *Id.* at 1817. According to Recruiter, Respondent Pharmacist One contacted Recruiter and asked Recruiter to return the mistakenly issued hydrocodone-acetaminophen 10-325. *Id.* at 1812. According to the report of Respondent Pharmacist One, he ''reached out to'' the recruit, not Recruiter, to ''swap'' those tablets for an equal number of carisoprodol tablets. *Id.* at 105. According to the report of Respondent Pharmacist One, the ''customer'' ''would not come around'' for such a swap. *Id.* at 105.

The Agency concludes that Recruiter's statement is consistent with the report of Respondent Pharmacist One on all salient points, and that the difference between Recruiter's recollection and the report of Respondent Pharmacist One about whom he contacted regarding the matter is not essential. Further, Recruiter's basis for knowing about the incident could very well be from receiving the request of Respondent Pharmacist One to return the hydrocodone-acetaminophen 10-325. After all, Respondent Pharmacist Two instructed Recruiter to transact business with Respondent alone, without bringing the recruits. *Id.* at 1811. Second, had Respondent Pharmacist One only contacted the recruit, as his report states, and had the recruit not returned the hydrocodone-acetaminophen 10-325 as his report also states, Recruiter would not necessarily know about the wrongful hydrocodone-acetaminophen 10-325 dispensing. Third, it is not realistic to expect Respondent Pharmacist One to report that he contacted the ''patient's'' ''recruiter'' about the wrongly issued hydrocodone-acetaminophen 10-325. Regardless, the Agency finds that whether Respondent Pharmacist One contacted Recruiter or the recruit is insignificant, and that this discrepancy between Recruiter's Declaration and the report of Respondent Pharmacist One does not impugn the credibility of Recruiter's Declaration.

[13] The Agency notes that ''hydrocodone'' is used in the RFAA when the actual controlled substance named in the RFAA's documentary evidence is hydrocodone-acetaminophen 10-325. The RFAA brief does not address this abbreviated usage of ''hydrocodone'' for hydrocodone-acetaminophen 10-325. While the Agency prefers precision, including explicit explanations in parties' submissions, it also recognizes that the controlled portion of hydrocodone-acetaminophen 10-325 is hydrocodone. The Agency further notes that the Diversion Control Division issued a public fact sheet in 2019 titled ''Hydrocodone'' that includes Vicodin and Lortab, trade names for hydrocodone with acetaminophen, in its subtitle. Hydrocodone (Trade Names: Vicodin®, Lortab®, Lorcet-HD®, Hycodan®, Vicoprofen®), *https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf* (last visited date of signature of this Order).

[14] The Agency also finds unequivocal and uncontroverted record evidence in the Declaration of Dr. Diane Ginsburg that further corroborates the self-incriminating content of Recruiter's Declaration. RFAA, at 1847–48; *infra.* section III.A.3. The Declaration of Dr. Ginsburg also contains unequivocal and uncontroverted record evidence of Respondent's unlawful controlled substance distribution to Recruiter. *Infra.* section III.A.3.

[15] Recruiter's Declaration includes the names of two such pharmacist employees of Respondent and states that Recruiter identified them both from photographs that DI displayed.

[16] The Agency is considering Respondent's actions during the time frame alleged in the OSC: December 17, 2018, through March 15, 2021. RFAA, at 1804.

''higher resale value'' on the street. *Id.* at 1811 (Recruiter's Declaration identifying specific brands of promethazine with codeine and of hydrocodone products). Further, Respondent ''often required [Recruiter] to pay more than the cash price that was listed on the prescription itself.'' *Id.* at 1812. Regarding promethazine with codeine, for example, Recruiter ''would pay approximately $240 for 8 ounces . . . [t]hough this arrangement seemed unfair, . . . [but Recruiter] accepted it because . . . [Recruiter] was able to sell the controlled substances on the street for more.'' [17] *Id.*

The Agency further finds unequivocal and uncontroverted record evidence that Recruiter was not the only recruiter for whom Respondent filled controlled substance prescriptions. *Id.* at 1811. The record evidence is that Respondent Pharmacist Two interacted with another recruiter, and even catered to him by instructing Recruiter to frequent Respondent ''at approximately 4 p.m. each day to pick up prescriptions, so . . . [Recruiter] would not be seen by'' the other recruiter who did not want Recruiter to ''use'' Respondent ''to fill prescriptions.'' *Id.*

Further, the Agency finds unequivocal and uncontroverted record evidence that one of Respondent's pharmacists even lent Recruiter money to pay for the recruits' doctor visits with the understanding that Recruiter would re-pay the money after selling on the street the controlled substances that Respondent provided. *Id.* at 1811–12. Further, the Agency finds undisputed record evidence that one of Respondent's pharmacists lent Recruiter as much as $800 for this purpose. *Id.* at 1812.

In sum, the Agency finds unequivocal and uncontroverted record evidence that, ''[f]rom at least 2017 through 2020,'' Respondent, by its pharmacists, filled controlled substance prescriptions for Recruiter, and for at least one other recruiter, with knowledge that those controlled substances would be diverted. *E.g., id.* at 1810.

3. The Declaration of the Government's Expert, Dr. Ginsburg

The Agency finds that Dr. Ginsburg qualifies as an expert in pharmaceutical controlled substance dispensing in Texas, and accepts her as such in this adjudication.[18] *Id.* at 1725–84 (sixty-page curriculum vitae of Dr. Ginsburg, a Texas Registered Pharmacist, listing her accomplishments; education; publications on a broad variety of pharmacy-related topics; invited papers and presentations on the national, international, state, and local levels with a primary focus on pharmacy- and pharmacist-related topics; professional affiliations; honors and awards, and her work experience as a pharmacist and educator). The Agency recognizes Dr. Ginsburg as an expert in pharmaceutical controlled substance dispensing in Texas.[19] *Id.* at 1725–84, 1821–50. The Agency, because Dr. Ginsberg is an expert in pharmaceutical controlled substance dispensing in Texas, because her Declaration accurately states Respondent's legal responsibilities according to relevant federal and Texas law, because her Declaration is sworn to under penalty of perjury, and because her Declaration asserts that she reviewed Government exhibits 4 through 36, affords Dr. Ginsburg's Declaration full credibility.[20] *Id.* at 31–1724, 1822–23, 1825.

Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent's ''pharmacists failed to carry out their corresponding responsibility when they dispensed controlled substances to . . . customers, in that they ignored red flags indicating a risk of diversion and failed to ensure that the prescriptions dispensed were issued for a legitimate medical purpose in the usual course of professional practice.'' *Id.* at 1823 (Dr. Ginsburg's Declaration is based on the record evidence she reviewed); *see also id.* (Dr. Ginsburg's Declaration stating that ''all minimally competent pharmacists can and should be able to recognize 'red flags' related to prescriptions, and they are required to do so in the usual course of pharmacy practice in Texas.''); *id.* at 1823–24 (Dr. Ginsburg's Declaration stating that ''a 'red flag' is anything about a prescription that would cause the pharmacist to be concerned that the prescription was not issued for a legitimate medical purpose in the usual course of professional practice.''); *id.* at 1824 (Dr. Ginsburg's Declaration stating that, ''When confronted with a red flag or red flags concerning a prescription for controlled substances, a pharmacist must try to resolve the red flags to determine whether or not the prescription is legitimate. A pharmacist must resolve the red flag(s) prior to filling the prescription. Depending on the type of red flag, there are different steps that the pharmacist can take to determine whether or not the prescription is legitimate. These steps involve obtaining more information from the physician or the patient, or both.''); *id.* at 1825; *infra* (Dr. Ginsberg's Declaration explaining ''unresolvable'' red flags, offering the example of Recruiter's picking up controlled substance prescriptions issued to others, and concluding that both Respondent Pharmacists filled controlled substance prescriptions in the face of unresolvable red flags).

According to the OSC's allegations, controlled substance ''cocktail prescriptions'' are controlled substance prescriptions including ''various combinations of the highly abused hydrocodone, carisoprodol, alprazolam . . . [,] and promethazine with codeine.'' RFAA, at 1804–05. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that ''hydrocodone, promethazine with codeine, carisoprodol, and alprazolam . . . [are] highly abused controlled substances,'' and that these types of combination controlled substance ''cocktail prescriptions have long been recognized as a red flag for abuse and/or diversion in Texas and significantly increase a patient's risk of morbidity and overdose.'' *Id.* at 1832; *see also id.* at 1823 (Dr. Ginsburg's Declaration stating that ''[h]ydrocodone, alprazolam, promethazine with codeine, and carisoprodol are several of the more commonly diverted and abused drugs in Texas.''). Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing in any of the [record] documents [that Dr. Ginsburg reviewed] to show that . . . [Respondent]

[17] The Agency further finds unequivocal and uncontroverted record evidence that at least Respondent Pharmacist Two helped Recruiter buy the specific brand of a controlled substance that brought the higher street resale value. RFAA, at 1811 (Recruiter's Declaration stating that Respondent Pharmacist Two even suggested that Recruiter fill a controlled substance prescription at another pharmacy because Respondent did not have Recruiter's preferred brand in stock).

[18] This decision is consistent with prior Agency decisions accepting Dr. Ginsburg as an expert. *E.g., Lewisville Medical Pharmacy,* 87 FR 59456 (2022) (Texas), *Medical Pharmacy,* 86 FR 72030 (2021) (Louisiana).

[19] Dr. Ginsburg's credentials also include the academic appointment of Clinical Professor in the Division of Pharmacy Practice in the College of Pharmacy at the University of Texas (Austin), and multiple pharmacist positions in Texas. RFAA, at 1725–29; *see also id.* at 1822 (''Based on my training and experience, I am an expert in the practices of a pharmacist in Texas, and in particular, the dispensing of controlled substances by Texas pharmacists.'').

[20] The Agency determines that the statement in paragraph 5 of Dr. Ginsberg's Declaration, that her *curriculum vitae* is included in the RFAA as GX 36, is a typographic error; it is RFAA GX 37. RFAA, at 1821.

recognized these cocktail prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flags prior to dispensing'' them. *Id.* at 1832; *id.* at 1825–32.

Accordingly, based on these expert-based, undisputed findings and opinions, the Agency finds unequivocal and uncontroverted record evidence that, from July 17, 2019, to July 10, 2020, Respondent filled about 138 controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion. *Id.* at 106–237, 425–616, 1824–32. By failing to exercise its corresponding responsibility and filling these controlled substance prescriptions, Respondent released into the community about 3143 hydrocodone-acetaminophen 10-325 mg tablets, about 2680 carisoprodol 350 mg tablets, about 1326 days' supply (or more than three and a half years' supply) of promethazine with codeine, about 190 alprazolam 1 mg tablets, and about 90 alprazolam 2 mg tablets. *Id.* at 106–237, 425–616.

According to the OSC's allegations, Respondent filled monthly prescriptions for promethazine with codeine to three individuals from March 4, 2019, to June 18, 2020. *Id.* at 1804. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent failed to exercise its corresponding responsibility and filled ''[r]epeated and continuous'' prescriptions for promethazine with codeine to three individuals from March 4, 2019, to June 18, 2020, approximately monthly.[21] *Id.* at 1832 (describing the promethazine with codeine prescriptions for the three individuals as ''monthly prescriptions,'' ''continuous prescriptions,'' and ''continuous prescriptions,'' respectively). Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that promethazine with codeine is a ''highly abused cough suppressant normally prescribed for short term use,'' and that its ''repeated prescribing . . . has long been recognized in Texas as a red flag for abuse and/or diversion.'' *Id.* at 1834; *see also id.* at 1824. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that Respondent failed to exercise its corresponding responsibility as ''[t]here is nothing . . . [in the record] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1834.

Accordingly, consistent with the expert's undisputed Declaration, the Agency finds unequivocal and uncontroverted record evidence that, from March 4, 2019, to June 18, 2020, Respondent released about 1,089 days' (or almost 3 years') worth supply of promethazine with codeine into the community by its ''[r]epeated and continuous'' failures to exercise its corresponding responsibility and filling three individuals' almost monthly illegitimate controlled substance prescriptions. *Id.* at 294–324, 425–93, 1610–1714, 1832–34. Taking into account overlap with the promethazine with codeine involved in the cocktail calculations, Respondent, violating its corresponding responsibility, released about an additional 285 days' worth supply of promethazine with codeine into the community by its ''[r]epeated and continuous'' filling of three individuals' prolonged, and almost monthly, promethazine with codeine controlled substance prescriptions. *Id.* at 294–324, 425–93, 1610–1714.

According to the OSC's allegations, ''pattern prescribing'' is ''when a practitioner prescribes the same controlled substances in identical or substantially similar dosages and quantities, thus indicating a lack of individualized care.'' *Id.* at 1805. According to Dr. Ginsburg's Declaration, ''pattern prescribing'' is a prescriber's employment of a '' 'one size fits all' approach to prescribing potentially dangerous narcotics, usually by prescribing the narcotics in identical or nearly identical quantities to each patient regardless of the patient's individualized medical condition.'' *Id.* at 1824. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency finds unequivocal and uncontroverted record evidence that two physicians engaged in ''pattern prescribing,'' that both doctors' pattern prescribing involved their issuing controlled substance prescriptions for hydrocodone-acetaminophen 10-325 mg, carisoprodol 350 mg, and promethazine with codeine, and that they issued these controlled substance prescriptions to at least seven individuals. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing . . . [in the record] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1843, *see also id.* at 1834–43.

In sum, according to evidence that is unequivocal and uncontroverted, from March 8, 2019, to July 3, 2020, Respondent released about 1,456 days' (or almost a 4 years') worth supply of promethazine with codeine 240 mL, about 303 days' (or about two months shy of one year) worth supply of promethazine with codeine 180 mL, about an additional 2,666 tablets of carisoprodol 350 mg, and about an additional 3,328 tablets of hydrocodone-acetaminophen 10-325 into the community by filling controlled substances prescriptions without resolving the red flag of pattern prescribing.[22] *Id.* at 325–424, 617–804, 1610–1714, 1834–43.

The OSC states that ''pharmacy shopping'' is when an individual ''fill[s] prescriptions for controlled substances at multiple pharmacies.'' *Id.* at 1805. Dr. Ginsburg's Declaration states that ''pharmacy shopping'' may indicate that a customer is trying to avoid being suspected of abuse and/or diversion while obtaining controlled substances. *Id.* at 1847; *see also id.* at 1824, 1843–47. The Ginsburg Declaration further states that ''[p]harmacy shopping has long been recognized as a red flag for abuse and/or diversion in Texas because it may indicate the customer is attempting to obtain prescriptions and avoid suspicion.'' [23] *Id.* at 1847. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds

[21] The Agency finds unequivocal and uncontroverted record evidence that, for the first individual, S.L., Respondent filled monthly prescriptions for promethazine with codeine (240 mL) from March 4, 2019, to December 6, 2019, and then again from March 9, 2020, to May 21, 2020; for the second individual, M.R., Respondent filled twelve prescriptions for promethazine with codeine (180 mL) more frequently than monthly, from March 15, 2019, to November 20, 2019, and five prescriptions, monthly, from February 7, 2020, to June 5, 2020; and for the third individual, C.G., Respondent filled fourteen promethazine with codeine (240 mL) prescriptions from March 29, 2019, to June 18, 2020, almost monthly.

[22] The amount of promethazine with codeine 240 mL that Respondent distributed that has not already been counted in this Decision is about a 1,108 days' worth supply. RFAA, at 325–424, 1610–1714.

[23] According to Recruiter's Declaration, Recruiter obtained controlled substances from pharmacies other than Respondent when, for example, Respondent Pharmacist Two ''suggested . . . [that Recruiter] fill the hydrocodone prescription at another pharmacy'' because Respondent did not have Recruiter's ''preferred brand in stock.'' RFAA, at 1811. Recruiter's Declaration also states that Recruiter ''utilized'' Respondent after ''develop[ing] a relationship with the employees'' and because the ''prescriptions that were submitted were rarely questioned.'' *Id.* at 1810.

unequivocal and uncontroverted record evidence that controlled substance prescriptions for three individuals, including for Recruiter, were filled by ''pharmacy shopping,'' that is, by filling one of three controlled substance prescriptions issued at, or at about, the same time (including hydrocodone-acetaminophen 10-325 in all but one case) at a different pharmacy from where they filled the other two, typically at Respondent. *Id.* at 1843–47. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing . . . [in the record evidence] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion,'' and that there is ''nothing [in the record evidence] to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1847.

Accordingly, based on these expert-based, undisputed findings, the Agency finds unequivocal and uncontroverted evidence that, from December 17, 2018, to May 22, 2020, Respondent released about an additional 1,038 tablets of carisoprodol 350 mg and about an additional 456 days' (or over one year's) worth supply of promethazine with codeine 240 mL into the community by filling controlled substance prescriptions issued to individuals who engaged in ''pharmacy shopping'' without resolving that red flag. *Id.* at 1594–1609, 1843–47.

In sum, based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent's pharmacists failed to recognize and resolve red flags of abuse and/or diversion, ''failed to carry out their corresponding responsibility,'' and ''failed to ensure that the dispensed prescriptions were issued for a legitimate medical purpose in the usual course of professional practice.'' *Id.* at 1823.

B. The Unlawful Distribution Allegations: in 2019 and 2020, Respondent's Employees Knowingly Participated in a Scheme To Distribute Controlled Substances to a Known Street Dealer

As already discussed, 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 Recruiter, ''[f]rom at least 2017 through 2020,'' participated in a scheme to obtain illegitimate controlled substance prescriptions, to present them to Respondent to fill, and to sell the Respondent-filled controlled substances on the street. *Supra* section III.A.2. As already discussed, the Agency also finds unequivocal and uncontroverted record evidence that Respondent Pharmacists One and Two knowingly participated in the scheme by filling the illegitimate controlled substance prescriptions without identifying, let alone resolving, those prescriptions' red flags. *Supra* sections III.A.2, III.A.3. For example, as already discussed, Respondent Pharmacist Two instructed Recruiter on how to carry out parts of the scheme, lent Recruiter money to enable accomplishment of the scheme's goals, and charged inflated costs for fills. *Supra* section III.A.2. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law because, at least in 2019 and 2020, Respondent's employees knowingly participated in a scheme to distribute controlled substances to a known street dealer. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *supra* section II.

C. The Unlawful Distribution Allegations: Between September 16, 2019, and March 23, 2020, Respondent Distributed Controlled Substances to a Recruiter Pursuant to Prescriptions Issued to Other Individuals, and With Reason To Believe That the Recruiter Intended To Resell Them

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Recruiter, ''[f]rom at least 2017 through 2020,'' participated in a scheme to obtain illegitimate controlled substance prescriptions, to present them to Respondent to fill, and to sell the Respondent-filled controlled substances on the street. *Supra* section III.A.2. For example, as the Agency already found, Respondent Pharmacist Two told Recruiter not to bring the recruits to the store to pick up and purchase the controlled substance prescriptions. *Id.* Instead, Respondent Pharmacist Two instructed Recruiter ''to come in and pick up the prescriptions,'' and either to forge the recruits' names on the signature log or to sign Recruiter's own name. *Id.* By way of further examples, as the Agency already found, Respondent Pharmacist Two and Recruiter ''often'' discussed Recruiter's specific controlled substance brand preferences, the brands with a ''higher resale value'' on the street; a Respondent pharmacist helped Recruiter buy the specific brand of a controlled substance that brought the higher street resale value; and one of Respondent's pharmacists even lent Recruiter money to pay for the recruits' doctor visits with the understanding that Recruiter would re-pay the money after selling on the street the controlled substances that Respondent provided. *Id.* Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law between at least September 16, 2019, and March 23, 2020. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *supra* section II.

D. The Unlawful Distribution Allegations: Between March 4, 2019, and June 18, 2020, Respondent Filled Monthly Prescriptions for Promethazine With Codeine to Three Individuals

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that, monthly from March to December of 2019, and from February to June of 2020, Respondent filled prescriptions for promethazine with codeine for two individuals. *Supra* section III.A.3.; n.21. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law, monthly, as to the two individuals' monthly, or more frequently than monthly, prescriptions for promethazine with codeine. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023). *Supra* section II.

E. The Unlawful Distribution Allegations: Between December 27, 2019, and July 10, 2020, Respondent Filled ''Cocktail'' Prescriptions for Five Different Individuals Including Various Combinations of Hydrocodone, Carisoprodol, Alprazolam, and Promethazine With Codeine

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Respondent filled about 138 controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion from July 17, 2019, to July 10, 2020. *Supra* section III.A.3. Also as already discussed, the Agency finds unequivocal and uncontroverted record evidence that these cocktail prescriptions involved various combinations of hydrocodone-acetaminophen 10-325 mg, carisoprodol 350 mg, alprazolam 1 mg, alprazolam 2 mg, and promethazine with codeine.

Supra section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law by filling controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion from July 17, 2019, to July 10, 2020. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

F. The Unlawful Distribution Allegations: Between March 8, 2019, and July 3, 2020, Respondent Distributed Controlled Substances Pursuant to Prescriptions Issued by Practitioners Engaged in ''Pattern Prescribing''

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that, between March 8, 2019, and July 3, 2020, Respondent filled controlled substance prescriptions issued by two practitioners to at least seven individuals without resolving the prescriptions' pattern prescribing red flags. *Supra* section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law, between March 8, 2019, and July 3, 2020, by filling controlled substance prescriptions without identifying and resolving those prescriptions' pattern prescribing red flags of abuse and/or diversion. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

G. The Unlawful Distribution Allegations: Between December 17, 2018, and May 22, 2020, Respondent Filled Controlled Substances for Three Individuals Despite Prescription Histories That Indicated Each Was Engaged in ''Pharmacy Shopping,'' or Filling Prescriptions for Controlled Substances at Multiple Pharmacies

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Respondent filled controlled substance prescriptions for three individuals without identifying and resolving their pharmacy shopping red flags from December 17, 2018, to May 22, 2020. *Supra* section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

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).[24]

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 (Apr. 24, 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.

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); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *MacKay,* 664 F.3d at 819; *supra* section II.

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 II, III.A.1. III.A.2., III.A.3., III.B., III.C., III.D., III.E., III.F., III.G. 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.

[24] 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.

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 withdraw its request for a hearing just days before the hearing was scheduled to begin. *Supra* section I. As such, the record includes no evidence submitted by Respondent. Nor did Respondent attempt to convince the Agency that it understands that its issuance of controlled substances fell short of the applicable legal standards, and that this substandard controlled substance issuance 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 issuance of controlled substances will comply with legal requirements.

The unequivocal and uncontroverted record evidence is the Respondent's founded violations resulted in the release of about 13,135 controlled substance tablets, and about a 3478 days' supply of promethazine with codeine into the community in a period of about eighteen months. *Supra* sections I, III.A.3., III.B., III.C., III.D., III.E., III.F., III.G. The controlled substances unlawfully released into the community were hydrocodone-acetaminophen 10–325 mg tablets, carisoprodol 350 mg tablets, alprazolam tablets, and promethazine with codeine, controlled substances known to be abused and diverted. *Id.*

There is no record 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. FH5569112 issued to Hovic Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending application of Hovic Pharmacy to renew or modify this registration, as well as any other pending application of Hovic Pharmacy for registration in Texas. This Order is effective November 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 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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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24–69]

Shannon Wagner, D.O.; Decision and Order

On August 13, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Shannon Wagner, D.O., of Green Bay, Wisconsin (Respondent). OSC, at 1, 3. The OSC proposed the denial of Respondent's application for a DEA Certificate of Registration (registration), Control No. W23130415C, alleging that Respondent has been mandatorily excluded from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* at 1–2 (citing 21 U.S.C. 824(a)(5)).

A hearing was held before DEA Administrative Law Judge (ALJ) Teresa A. Wallbaum who, on February 21, 2025, issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD). The RD recommended that Respondent's application be granted. RD, at 20. The Government filed exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[1] findings of fact, conclusions

[1] The Agency adopts the ALJ's summary of the witnesses' testimonies as well as the ALJ's assessment of the witnesses' credibility. RD, at 3–