Federal Energy Regulatory Commission, which is the Federal agency that would approve project construction and operations. The lease and supporting documentation, including required environmental compliance documentation and the notices that solicited competitive interest, can be found online at: https://www.boem.gov/renewable-energy/state-activities/pacwave-south-project.

Authority: 43 U.S.C. 1337(p); 30 CFR 585.238(f) and 30 CFR 585.206(a).

Amanda Lefton,
Director, Bureau of Ocean Energy Management.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Care Point Pharmacy, Inc.; Decision and Order

On November 20, 2019, the Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause (hereinafter, OSC) to Care Point Pharmacy, Inc. (hereinafter, Registrant). Government’s Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 1 (OSC). The OSC proposed to revoke Registrant’s DEA Certificate of Registration Number BH9966904 (hereinafter, registration) and to deny any pending applications for renewal or modification of the registration, pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Registrant’s “continued registration is inconsistent with the public interest.” Id. (citing 21 U.S.C. 824(a)(4) and 823(f)).

The OSC alleged that Registrant is licensed as a community pharmacy in the State of Florida. Id. at 2. It further alleged that Ekaette Isemin is Registrant’s sole corporate officer, and that she is licensed as a pharmacist in Florida. Id.

The OSC alleged that “[o]n six occasions, [Registrant] dispensed controlled substances to a DEA confidential source pursuant to fraudulent prescriptions, despite clear evidence of diversion.” Id. at 2. The OSC further alleged that “[Registrant’s] dispensing of controlled substances in the face of clear evidence of diversion violated federal and state law.” Id. at 5 (citing 21 CFR 1306.06, 1306.04(a); Fla. Stat. §§893.04(2)(a), 465.016(1)(f), 456.072(1)(m); Fla. Admin. Code. Ann. r. 64B16–27.831, 64B16–27.810).

The OSC notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. Id. at 5–6 (citing 21 CFR 1301.43).

In response to the OSC, Ekaette Isemin filed a timely request for an administrative hearing on Registrant’s behalf, and requested that all future notices and mailings be mailed to her. RFAAX 2 (Request for Hearing). On December 26, 2019, the Chief Administrative Law Judge (hereinafter, Chief ALJ) established a schedule for the filing of prehearing statements. RFAAX 3 (Order for Prehearing Statements). The Government filed a timely prehearing statement on January 6, 2020, but Registrant failed to file any prehearing statement by the deadline. RFAAX 4 (Order Terminating Proceedings), at 1–2.

On January 21, 2020, the Chief ALJ issued an Order Directing Compliance and Postponing Prehearing Conference, which afforded Registrant until February 6, 2020, to file its prehearing statement and to show good cause for the delay. Id. at 2. The Order Directing Compliance and the Order for Prehearing Statements were sent to Ms. Isemin via first class mail, and neither document was returned as undeliverable. Id. Neither Registrant nor Ms. Isemin filed a showing of good cause for the delay or a prehearing statement by the deadline set forth in the Order Directing Compliance. Id. Therefore, the Chief ALJ determined that Registrant had “effectively waived its right to a hearing,” and he terminated the proceedings on February 6, 2020. Id. I agree with the Chief ALJ that Registrant waived its right to a hearing by failing to comply with the Chief ALJ’s order.

On February 19, 2020, the Government forwarded an RFAA, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering its continued registration inconsistent with the public interest. Additionally, I find that Registrant lacks authority to handle controlled substances in the State of Florida, the state where it is registered with DEA.

Accordingly, I conclude that the appropriate sanction is for Registrant’s DEA registration to be revoked.

I. Findings of Fact

A. Registrant’s DEA Registration

Registrant is registered with DEA as a retail pharmacy in Schedules II through V under DEA registration number BH9966904, at the registered address of 1400 Hand Avenue, Suite 0, Ormond Beach, Florida 32174. RFAAX 5 (DEA Certificate of Registration). This registration expires on August 31, 2021.

B. The Status of Registrant’s State Authority

Registrant was previously licensed as a community pharmacy in the State of Florida under license number PH22190. RFAAX 6 Appendix (hereinafter, App’x) B (Division of Corporations Printout), at 1. Registrant’s sole corporate officer was Ekaette Isemin, id., who was previously registered as a pharmacist in Florida under license number PS28851. App’x A, at 1.

On August 20, 2018, the Florida Department of Health (hereinafter, Florida DOH) ordered the emergency suspension of Ms. Isemin’s pharmacy license, based on its determination that “Ms. Isemin’s continued practice as a pharmacist constitutes an immediate, serious danger to the health, safety, and welfare of the public . . . .” Id. at 18. The order concluded that Ms. Isemin repeatedly violated state law over the course of approximately sixteen months by dispensing controlled substances to a...
DEA Confidential Source (hereinafter, DEA CS), despite the DEA CS’s repeated statements that he was diverting the controlled substances that Registrant dispensed. *Id.* at 14–18.

Approximately sixteen months later, on December 12, 2019, the Florida DOH ordered the emergency suspension of Registrant’s license to operate as a community pharmacy in Florida. *App’x D* (Order of Emergency Suspension of Permit). The suspension was primarily based on the fact that Registrant had continued to order and dispense controlled substances for approximately one year while Ms. Isemin’s license was suspended. *Id.* at 9–10. The Florida DOH concluded that “[Registrant’s] continued operation as a community pharmacy presents an immediate, serious danger to the health, safety, and welfare of the public, and that this danger is likely to continue.” *Id.* at 9. The Florida DOH noted that “[r]estricting [Registrant’s] permit would not adequately protect the public because any operation as a pharmacy would allow [Registrant] to continue engaging in the same illegal and dangerous conduct set forth above.” *Id.*

According to Florida’s online records, of which I take official notice,]

Registrant’s Florida pharmacy license is “revoked.” Therefore, I find that Registrant does not possess authority to handle controlled substances in Florida, the state in which Registrant is registered with DEA.

C. Government’s Allegation That Registrant Dispensed Controlled Substances Unlawfully

In its RFAA, the Government alleged that Registrant violated federal and state law by dispensing controlled substances to a DEA CS on six occasions in the face of clear evidence of diversion. OSC, at 2, 5. To support this allegation, the Government submitted a declaration of the DEA Diversion Investigator (hereinafter, DI), who was assigned to the investigation of Registrant.

6 (Declaration of DI). DI has been a DI for approximately 30 years and is currently assigned to the Orlando District Office of the Miami Field Division. *Id.* at 1. DI’s declaration summarizes DEA’s investigation, including the details of six undercover visits conducted by the DEA CS at Registrant between June 8, 2017, and March 6, 2018. In addition to DI’s declaration, the Government submitted copies of controlled substance prescriptions that the DEA CS sought to fill at Registrant, along with the corresponding fill stickers. *App’x E, I, M, Q, U, Y.* The Government also submitted audio and video recordings of each undercover visit, as well as transcripts of the recordings. *App’x F, G, J, K, N, O, R, S, V, W, ZA, AB* (recordings); *App’x H, I, L, P, T, X, ZC* (transcripts).

1. The Undercover Visits

The DEA CS visited Registrant in an undercover capacity on six separate occasions using the fake identity D.S. and to A.D., the fake identity of the CS’s girlfriend. *Id.* at 2–8. DI’s declaration states that prescription that D.S. sought to fill at Registrant was “fraudulent and [I] not valid.” *Id.* at 3. At each recorded undercover visit, D.S. admitted that he had diverted, or intended to divert, the controlled substances that Registrant dispensed to him.

a. June 8, 2017 Undercover Visit

On June 8, 2017, the DEA CS visited Registrant in an undercover capacity, posing as D.S. and A.D., the fake identities of the DEA CS’s boyfriend and girlfriend. *Id.* at 3; *App’x E* (May 19, 2017 Prescription). Prior to this visit, D.S. had filled hydromorphone prescriptions at Registrant, while acting in an undercover capacity. *Id.* At this visit, D.S. told Ms. Isemin that he had given half of the hydromorphone prescription that he had previously filled at Registrant to his girlfriend, and some to a friend, so that he could afford Registrant’s high prices. *App’x H, at 1.* D.S. told Ms. Isemin that he would be “splitting these again,” so that he could “get ready for the next time [he] come[s].” *Id.* at 2. Registrant dispensed one hundred eight-milligram tablets of hydromorphone to D.S. in exchange for $1,000 in cash. *Id.* *App’x E, at 2–4; RFAAX 6, at 3.

b. July 28, 2017 Undercover Visit

The DEA CS visited Registrant again in an undercover capacity on July 28, 2017, posing as D.S. *RFAAX 6, at 3–4.* The DEA CS presented Registrant with a controlled substance prescription that had been issued to D.S. for one hundred eight-milligram tablets of hydromorphone. *Id.* At this visit, D.S. again admitted to Ms. Isemin that he was diverting some of the hydromorphone that Registrant dispensed to him. *App’x L, at 5–6.* He said that he only takes a few tablets himself, because they make him “woozy,” and he sells the rest to his employee. *Id.* at 6. D.S. told Ms. Isemin that he was going back to the doctor in a couple of weeks and he was “gonna try to get him to up ‘em, so [he] [could] sell a few more.” *Id.* at 6. Ms. Isemin advised D.S. not to obtain more than one hundred and thirty or one hundred and fifty tablets, because “they are checking.” *Id.*

Registrant dispensed one hundred eight-milligram tablets of hydromorphone to D.S. at this visit and charged D.S. $1,000.84. *App’x I; RFAAX 6, at 4.* D.S. paid Registrant $1,020, and explained to Ms. Isemin that the extra money could cover what D.S owed transaction shows the strength and quantity of hydromorphone that was dispensed, and it is consistent with DI’s representation of the prescription that D.S. presented to Registrant at this visit. *Compare App’x E, at 4 with GX 6, at 3.*

See *App’x A, at 3* (stating that D.S. first filled a prescription at Registrant on December 12, 2016).

The receipt from the transaction shows that Registrant charged D.S. $1,000.84. *App’x E, at 2, 4,* but D.S. paid Registrant $1,000 in cash. *RFAAX 6, at 3.*

The Government did not include a copy of the prescription that D.S. presented to Registrant on this date, but the Government provided a copy of the fill sticker, which is consistent with DI’s representation of the prescription that D.S. presented to Registrant at this visit. *Compare App’x I with RFAAX 6, at 3.*

Presumably, Ms. Isemin was referring to enforcement efforts by the state or federal government.
Register for the other prescriptions that Registrant had filled. RFAAX 6, at 4; App’x L, at 6. D.S. said, “That way I don’t owe you anything, cuz I don’t want you to one day be like, Hey, this guy owes me, so I’m not going to fill you, I’ll fill somebody else’s.” App’x L, at 6; App’x K, at 11:12:11–20.

October 17, 2017 Undercover Visit

The DEA CS visited Registrant again in an undercover capacity on October 17, 2017, posing as D.S. RFAAX 6, at 4. The DEA CS presented Registrant with two controlled substance prescriptions—one that was issued to D.S. and one that was issued to A.D. Id. Each prescription was for one hundred and fifty eight-milligram tablets of hydromorphone. App’x M, at 1 (October 12, 2017 Prescriptions). At this visit, D.S. again admitted to Ms. Isemin that he was diverting some of the hydromorphone that Registrant dispensed to him. App’x F, at 2. Ms. Isemin warned D.S. not to get caught, and D.S. assured her that he would not. App’x M, at 2. Ms. Isemin again warned D.S. not to get caught, explaining that “[t]hey’ll be gone as fast as [he] get[s] them from [her], except for [him],” because “[t]hey’ll be gone as fast and D.S. assured her that he would not.

Isemin warned D.S. not to get caught, dispensed to him. App’x P, at 2. Ms. Isemin had purchased the hydromorphone from D.S. again admitted to Ms. Isemin that they have “a very short window of catching [him],” because “[t]hey’ll be gone as fast as [he] get[s] them from [her], except for the ones [he] take[s].” Id. Registrant dispensed three hundred eight-milligram tablets of hydromorphone to D.S. and charged D.S. $3,000. App’x M, at 3, 5. D.S. paid Registrant $3,020 in cash. RFAAX 6, at 5.

d. December 18, 2017 Undercover Visit

The DEA CS visited Registrant in an undercover capacity again on December 18, 2017, posing as D.S. RFAAX 6, at 5. The DEA CS sought to fill two controlled substance prescriptions—one that was issued to D.S. and one that was issued to A.D. Id. Each prescription was for one hundred and fifty eight-milligram tablets of hydromorphone. App’x Q (December 15, 2017 Prescriptions). At this visit, Registrant dispensed three hundred eight-milligram tablets of hydromorphone to D.S. and charged D.S. $3,000. App’x M, at 3, 5. D.S. paid Registrant $3,020 in cash. RFAAX 6, at 5.

d. December 18, 2017 Undercover Visit

The DEA CS visited Registrant in an undercover capacity again on December 18, 2017, posing as D.S. RFAAX 6, at 5. The DEA CS sought to fill two controlled substance prescriptions—one that was issued to D.S. and one that was issued to A.D. Id. Each prescription was for one hundred and fifty eight-milligram tablets of hydromorphone. App’x Q (December 15, 2017 Prescriptions). At this visit, Registrant dispensed three hundred eight-milligram tablets of hydromorphone to D.S. and charged D.S. $3,000. App’x M, at 3, 5. D.S. paid Registrant $3,020 in cash. RFAAX 6, at 5.

December 18, 2017 Undercover Visit

The DEA CS visited Registrant in an undercover capacity again on December 18, 2017, posing as D.S. RFAAX 6, at 5. The DEA CS sought to fill two controlled substance prescriptions—one that was issued to D.S. and one that was issued to A.D. Id. Each prescription was for one hundred and fifty eight-milligram tablets of hydromorphone. App’x Q, at 2. Registrant dispensed three hundred eight-milligram tablets of hydromorphone to D.S. and charged D.S. $3,020 in cash. RFAAX 6, at 5.

December 18, 2017 Undercover Visit

The DEA CS visited Registrant in an undercover capacity again on December 18, 2017, posing as D.S. RFAAX 6, at 5. The DEA CS sought to fill two controlled substance prescriptions—one that was issued to D.S. and one that was issued to A.D. Id. Each prescription was for one hundred and fifty eight-milligram tablets of hydromorphone. App’x Q, at 2. Registrant dispensed three hundred eight-milligram tablets of hydromorphone to D.S. and charged D.S. $3,020 in cash. RFAAX 6, at 5.

f. March 6, 2018 Undercover Visit

The DEA CS visited Registrant in an undercover capacity again on March 6, 2018, posing as D.S. RFAAX 6, at 7. The DEA CS presented Registrant with a controlled substance prescription issued to D.S. for one hundred thirty-milligram tablets of oxycodone to D.S., although D.S. did not present a prescription for twenty-milligram tablets. RFAAX 6, at 8; App’x Z. (Photograph of the Oxycodone Dispensed). Ms. Isemin confirmed that Registrant owed D.S. these tablets from a prior visit. App’x ZC, at 2. As discussed above, see supra L.C.1.e, Ms. Isemin had explained to D.S. at the previous visit on January 23, 2018, that she owed him nine tablets of hydromorphone, because she was unable to completely fill D.S.’s prescriptions for one hundred and fifty tablets of hydromorphone on that day. App’x X, at 6. At this visit, Ms. Isemin substituted nine tablets of oxycodone for nine tablets of hydromorphone, even though D.S.’s previous prescription had been for hydromorphone. There was no corresponding prescription for the nine tablets of oxycodone that Ms. Isemin dispensed to D.S.

II. Discussion

A. Registrant’s Registration is Inconsistent With the Public Interest

The Government alleged that Registrant’s DEA registration should be revoked because Registrant committed acts that would render its registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The Government’s case centers on six recorded undercover visits, during which Registrant repeatedly dispensed controlled substances to a DEA CS, notwithstanding the CS’s recurring statements that he was diverting the controlled substances that Registrant dispensed.

Under the Controlled Substances Act (hereinafter, the CSA), “[a] registration . . . to . . . 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 section 823 of this title inconsistent with the public interest as determined under 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 the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(2) The [registrant]’s experience in dispensing . . . controlled substances.
(3) The [registrant]’s conviction record under Federal or State laws relating to the . . . distribution [or dispensing of controlled substances].
eight felony counts of drug trafficking, officer, Ms. Isemin, was arrested and charged with contains evidence that Registrant’s sole corporate distribution, or dispensing of controlled Federal or State laws relating to the manufacture, or dispensing of controlled substances, I find that 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).

1. Factor One—The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

In determining the public interest under Factor One, the “recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.” 21 U.S.C. 823(f)(1). “Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority . . . which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity’s action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.” John O. Dimowo, 85 FR 15,800, 15,809 (2020); see also Kenneth Harold Bull, M.D., 78 FR 62,666, 62,672 (2013) (“DEA . . . thus considers disciplinary actions taken by a state board as relevant in the public interest determination when they result in a loss of state authority, or are based on findings establishing that a registrant diverted controlled substances . . . .”).

Florida, the state in which Registrant is registered with DEA, immediately suspended Ms. Isemin’s pharmacy license on August 20, 2018. See supra I.b. The suspension was primarily based on Registrant’s unlawful dispensing of controlled substances to the DEA CS—the same misconduct that is at issue in this proceeding. Id. According to Florida’s online records, Registrant’s Florida pharmacy license has been “revoked.” Id. Because the “appropriate State licensing board” has revoked Registrant’s state authority based on Registrant’s unlawful dispensing of controlled substances, I find that Factor One weighs strongly in favor of revocation.

In determining the public interest under Factors Two and Four, I am to consider evidence of Registrant’s compliance (or non-compliance) with laws related to controlled substances and Registrant’s experience dispensing controlled substances. The Government’s case relies primarily on the actions of Registrant’s sole corporate owner, Ms. Isemin. “Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy’s owners, majority shareholders, managers, pharmacist, or other key employee.” Perry Cty. Food & Drug, 80 FR 70,084, 70,109 (2015) (citing EZRX, LLC, 69 FR 63,178, 63,181 (1998); Plaza Pharmacy, 53 FR 36,910, 36,911 (1998)). The Government alleged that Registrant violated several federal and state laws related to controlled substances by dispensing controlled substances to a DEA CS in the face of clear evidence of diversion. OSC, at 2, 5 (citing violations of 21 CFR 1306.06 and 1306.04(a); Fla. Stat. §§ 893.04(2)(a) and 465.016(1)(j); and Fla. Admin. Code. Ann. r. 64B16–27.831 and 64B16–27.810). The Government also alleged that Registrant violated federal and state law by dispensing a Schedule II controlled substance without a written prescription. Id. at 5 (citing 21 U.S.C. 829(a); Fla. Stat. § 465.015(2)(c); Fla. Stat. § 465.016(1)(i)).

(a) Violations of Federal Law

According to the CSA’s implementing regulations, a lawful controlled substance order or prescription is one that is “issued for a legitimate medical purpose for a recognized legitimate medical purpose under the laws of the State in which it is practiced.” See infra I.B (citing 21 U.S.C. 823(f)); see also Kenneth Harold Bull, 78 FR at 62,672 (noting in its Fact One analysis that where a state board takes action to restrict a practitioner’s authority to dispense controlled substances, “at a minimum, a practitioner’s [DEA] registration must be limited to authorize the dispensing of only those controlled substances, which he can lawfully dispense under state law”); David W. Bailey, M.D., 81 FR 6045, 6046 n.2 (2016) (“As for Factor One, while the State has not made a recommendation to the Agency, the State has revoked Respondent’s medical license and thus, he no longer meets the CSA’s requirement that he is authorized to dispense controlled substances in the State where he is registered.”).

15 As to Factor Three, although the record contains evidence that Registrant’s sole corporate officer, Ms. Isemin, was arrested and charged with eight felony counts of drug trafficking, see Appx A at 11; RFAAX 6 at 2, there is no evidence that Registrant has had a “conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(i)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. Dewey C. MacKay, M.D., 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. Id.; see also David D. Moon, D.O., 82 FR 19,385, 19,389 n.9 (finding that Factor Three was not dispositive where the registrant had been arrested for controlled substance-related charges, but there was no evidence of conviction).

16 Additionally, because Florida revoked Registrant’s pharmacy license, I must revoke Registrant’s DEA registration because Registrant is not “authorized to dispense . . . controlled substances” 21 U.S.C. 823(i)(3).
purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR1306.04(a). 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.” Id. The regulations establish the parameters of the pharmacy’s corresponding responsibility:

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 . . . 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. “The language in 21 CFR § 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.” Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, 55 FR at 4729, 4730 (1990) (citing United States v. Hayes, 595 F.2d 258 (5th Cir. 1979), cert. denied, 444 U.S. 866 (1979); United States v. Henry, 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA’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] bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006).

To prove that a pharmacist violated his corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. See 21 CFR 1306.04(a) (“[T]he person knowingly filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”) (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that “[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.” Bertolino, 55 FR at 4730 (citations omitted); see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp., 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise “common sense and professional judgment” when filling a prescription issued by a physician. Bertolino, 55 FR at 4730.

In this matter, the Government alleges that Registrant engaged in blatant drug dealing by dispensing controlled substances to a DEA CS, who “exhibited clear and unambiguous signs of diversion.” RFAA, at 21. The Government asserts that in cases involving blatant drug dealing, “this Agency has found that a pharmacy’s registration [i]s inconsistent with the public interest under Factors Two and Four, even without the benefit of any expert opinion.” Id. at 20–21 (citing Lincoln Pharmacy, 75 FR 65,667, 65,668 (2010) (revoking respondent’s registration and labeling its dispensing as “blatant drug dealing,” where a cooperating source told respondent’s pharmacist that he was selling the dispensed drugs); S & S Pharmacy, Inc., d/b/a Platinum Pharmacy & Compounding, 78 FR 57,656, 57,660 (2013) (affirming immediate suspension of registration and labeling respondent’s dispensing as a “blatant drug deal,” where respondent’s pharmacist dispensed drugs pursuant to prescriptions that he knew were fictitious).

I agree with the Government that this case involves blatant drug dealing, and I find that the Government has proven by substantial evidence that Registrant filled prescriptions for controlled substances that it knew were illegitimate, in violation of its corresponding responsibility under 21 CFR1306.04(a), and that Registrant filled these prescriptions outside the usual course of the professional practice of pharmacy in Florida, in violation of 21 CFR 1306.06. At each undercover visit, the DEA CS told Ms. Isemin that he was planning to divert, or already had diverted, the controlled substances that Registrant dispensed. See supra l.c.1. Ms. Isemin clearly understood that the DEA CS intended to divert the drugs, because she warned the DEA CS on several occasions not to get caught. Id. Ms. Isemin even accepted a cash tip from D.S. on several occasions, id., which further evidences her knowledge that she was engaging in blatant drug dealing. Respondent’s flagrant violations of federal law weigh strongly against a finding that Registrant’s continued registration is consistent with the public interest.

(b) Violations of State Law

In addition to alleging that Registrant violated 21 CFR 1306.04(a) and 1306.06, the Government alleges that Registrant violated Florida state law by: (1) Failing to “exercis[e] sound professional judgment” and “work with the patient and the prescriber to assist in determining the validity of the prescription”; 20 (2) failing to review each prescription for potential problems, such as “[o]ver utilization or under-utilization” and “[e]clinical abuse/ misuse,” and failing to “take appropriate steps to avoid or resolve the potential problems”; 21 and (3) dispensing Schedule II controlled substances to a patient “without first determining, in the exercise of her or his professional judgment, that the prescription is valid.” 22 The Government also alleges that Registrant violated Florida and federal law on March 6, 2018, when it dispensed a Schedule II controlled substance without a written prescription of a practitioner.23

must “establish what the standards of pharmacy practice require, through either expert testimony or by reference to federal or state laws, pharmacy board or Agency regulations, or decisional law (whether of administrative bodies or the courts).” Farmacia Yuni, 80 FR 29,053, 29,062 (2015). I find below that the Government has proven by substantial evidence that Registrant violated several Florida laws related to the proper dispensing of controlled substances. See infra II.A.2.b. 20 See Fla. Admin. Code, r. 64B 9.010(1)(c). 21 See D.S. on several occasions not to get caught. 22 See supra that Registrant dispensed. 23 See supra 1.c.1. Ms. Isemin clearly understood that the DEA CS intended to divert the drugs, because she warned the DEA CS on several occasions not to get caught. 20 See Fla. Stat. § 465.015(2)(c) (prohibiting the dispensing of “drugs as defined in [Fla. Stat. § 465.003(8) without first being furnished with a prescription]); see also Fla. Stat. § 465.003(8) defining “[m]edicinal drugs or drugs” as “those substances or preparations commonly
I find that the Government has provided substantial evidence that Registrant violated these federal and state laws by dispensing controlled substances to the DEA CS on the six occasions outlined above. Ms. Isemin clearly did not “exercise[e] sound professional judgment” 24 or “work with the patient and the prescriber to assist in determining the validity of the prescription,” as required by Fla. Admin. Code. r. 64B16–27.831. 25 The DEA CS told Ms. Isemin that he intended to divert the controlled substances that she dispensed, and she simply warned him not to get caught. See supra I.c.1. Ms. Isemin also failed to identify and respond to factors that indicated a lack of “therapeutic appropriateness” of the drugs dispensed, as outlined in Fla. Admin. Code. r. 64B16–27.810. Rather, Ms. Isemin knew that the controlled substances that Registrant dispensed would not be used for legitimate medical purposes, but she dispensed them anyway. In fact, the DEA CS told Ms. Isemin on one occasion that he does not take many of the pills himself because they make him “woozy.” See supra I.c.1.b. Finally, I found above that Registrant dispensed nine tablets of oxycodeone, a Schedule II controlled substance, on March 6, 2018, without a written prescription of a practitioner. Id. Therefore, Registrant violated federal and state law. See 21 U.S.C. 829(a); Fla. Stat. § 465.015(2)(c) (2016).

In light of Registrant’s egregious conduct that has no resemblance to the professional practice of pharmacy, I conclude that Factors One, Two, and Four overwhelmingly demonstrate that Registrant “has committed such acts as would render [its] registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4). I further conclude that Registrant has not rebutted the Government’s prima facie case.

B. Registrant Lacks Authority To Handle Controlled Substances

The Government alternatively alleged that Registrant’s DEA registration should be revoked because Registrant does not possess the requisite authority to dispense controlled substances in the State of Florida, where it is registered with DEA, RFAA, at 22.

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, the agency has long stated that the possession of authority to dispense controlled substances under the laws of the state in which the practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. See, e.g., James L. Hooper, M.D., 76 FR 71,371 (2011), pet. for rev. denied, 481 F. App’x 826 (4th Cir. 2012); Frederick Marsh Blanton, M.D., 43 FR 27,616, 27,617 (1978).

This rule derives from the text of the two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a pharmacy . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which . . . [it] practices . . . to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the Agency has repeatedly stated that revocation of a practitioner’s registration is the appropriate sanction whenever it is no longer authorized to dispense controlled substances under the laws of the state in which she practices. See, e.g., James L. Hooper, M.D., 76 FR at 71,371–72; Sberan Arden Yeates, M.D., 71 FR 39,130, 39,131 (2006); Dominick A. Ricci, M.D., 58 FR 51,104, 51,105 (1993); Bobby Watts, M.D., 53 FR 11,919, 11,920 (1988); Frederick Marsh Blanton, M.D., 43 FR at 27,617.

According to Florida statute, “It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of . . . a pharmacy . . . [which is not registered under the professions of [Chapter 465].” Fla. Stat. Ann. § 465.015(1)(a) (West, current with chapters from the 2021 First Regular Session of the Twenty-Seventh Legislature in effect through June 22, 2021). Further, “It is unlawful for any person . . . [to] fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in [Florida] . . . .” Fla. Stat. Ann. § 465.015(2)(b). Accordingly, holding a permit issued by the Florida Board of Pharmacy is a prerequisite to operating a pharmacy and dispensing a controlled substance in Florida.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to operate a pharmacy in Florida. As such, Registrant is not qualified to dispense controlled substances in Florida. Accordingly, I will order that Registrant’s DEA registration be revoked.

III. Sanction

Where, as here, the Government has met its prima facie burden of showing that Registrant’s continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why it can be entrusted with a registration. Garrett Howard Smith, M.D., 83 FR 18,882, 18,910 (2018) (collecting cases).

The CSA authorizes the Attorney General to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.” 21 U.S.C. 871(b). This authority specifically relates “to ‘registration’ and ‘control,’ and for the efficient execution of his functions under the statute.” Gonzales, 546 U.S. at 259. “Because ‘past performance is the best predictor of future performance, ALRA Labs, Inc. v. Drug Enf’t Admin., 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must

24 See also Fla. Stat. Ann. § 465.015(1)(b) (“It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of . . . a pharmacy . . . [in which a person not licensed as a pharmacist in this state . . . fills, compounds, or dispenses any prescription or dispenses medicinal drugs.]"

25 See also Fla. Admin. Code. r. 64B16–27.841(a) (prohibiting pharmacists from dispensing Schedule II controlled substances to a patient “without first determining, in the exercise of her or his professional judgment, that the prescription is valid”).
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Creekbend Community Pharmacy; Decision and Order

On May 29, 2019, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Creekbend Community Pharmacy (hereinafter, Respondent Pharmacy). Government’s Request for Final Agency Action Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed to revoke Respondent Pharmacy’s DEA Certificate of Registration Number FL4375730 (hereinafter, registration) and to deny any pending applications for renewal or modification of the registration, pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent Pharmacy’s “continued registration is inconsistent with the public interest.” Id. (citing 21 U.S.C. 824(a)(4) and 823(f)).

I. Procedural History

The OSC alleged that Respondent Pharmacy committed a number of record keeping violations. Id. at 2–4. Specifically, the OSC alleged failures in Respondent Pharmacy’s inventory documentation in violation of 21 CFR 1304.11(a) and (c) and 1304.04(h)(1); failures to properly complete and execute DEA Form 222 in violation of 21 CFR 1305.12(a)–(e); failures to record the receipt date on invoices in violation of 21 CFR 1304.21(a), (d), and 1304.22(a)[2](iv) and (c); and failure to maintain complete and accurate records of invoices, returns, and controlled substance transactions in violation of 1304.21(a). Id. The OSC further alleged that Respondent Pharmacy lacked candor by failing to be candid and truthful in the DEA investigation. Id. at 4–6. In particular, the OSC alleged that Respondent Pharmacy lacked candor with regard to its filling of fraudulent prescriptions and its hiding of controlled substances. Id.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. OSC, at 7 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. Id. at 8 (citing 21 U.S.C. 824(c)(2)(C)).

Following service of the OSC, Respondent Pharmacy sent a letter to the Government which appears to be a written response to the OSC, dated June 25, 2019. RFAAX 3. The letter was not signed and the author was not explicitly identified; however, it appears to have been written by or from the perspective of Respondent Pharmacy’s owner, Binta Barry. RFAAX 3; RFAAX 1, at 1; RFAAX 47 (Declaration of Diversion Investigator), at 1–2. The letter did not state that Respondent Pharmacy intended to request an administrative hearing, and the Government did not otherwise receive a hearing request.

RFAAX 3; RFAAX 5 (correspondence from the hearing clerk), at 1. The letter was accompanied by a document titled “Corrective Action Plan,” which the Government submitted into the record. RFAAX 4. The Corrective Action Plan proposed nine changes and improvements to Respondent’s Pharmacy’s policies and practice.2 Then, Respondent Pharmacy’s Owner sent a signed letter dated July 29, 2019, stating that she would not “fight [her] case with the D.E.A.” and that she was planning to “sell [her] business.” RFAAX 5, at 2 (hereinafter, RFAAX 3 and RFAAX 5, at 2 are collectively referred to as the “written response”).

On September 10, 2019, the Government forwarded a Request for Final Agency Action, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Respondent Pharmacy committed acts rendering its continued registration inconsistent with the public interest. Accordingly, I conclude that the appropriate sanction is for Respondent Pharmacy’s DEA registration to be revoked.1

II. Findings of Fact

A. DEA Registration

Respondent Pharmacy is registered with the DEA as a retail pharmacy authorized to handle controlled substances in schedules II–V under DEA Registration number FL4375730 at 8103

1 I find that the Government’s service of the OSC was adequate.

2Respondent Pharmacy’s proposed corrective action plan proposed, among other things, that Respondent Pharmacy put into place three new policies that would reflect requirements that already exist in law, enforce compliance with two existing policies that reflect requirements that already exist in law (without explaining how those policies would be enforced), and would stop working with the Pharmacist-in-charge (hereinafter, PIC) involved in this case. RFAAX 4. Additionally, the corrective action plan explained that the Respondent Pharmacy was trying to move to a “close door pharmacy” model, and proposed putting in place policies saying that it no longer accepted walk-in prescriptions and would only accept “e-scripts” for controlled substances. Id.

1 I find that Respondent waived her right to a hearing in this matter.

2 Gonzales v. Oregon, 546 U.S. at 274.