



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)(i), 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, 2020,¹ 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 5, 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.² *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.*³ I agree with the Chief ALJ that Registrant waived its right to a hearing by failing to comply with the Chief ALJ’s order.⁴

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

¹ The Government notified Registrant in its prehearing statement that Registrant’s DEA registration was subject to revocation on the additional ground that Registrant lacked authority to handle controlled substances in Florida, the state in which it is registered with the DEA. *See* 21 U.S.C. 824(a)(3). The Prehearing Statement was mailed to Ms. Isemin at the address that Ms. Isemin designated for future filings in her December 20, 2019 request for hearing. *See* RFAAX 2, at 2.

² The Order Terminating Proceedings noted that Registrant was not currently represented by counsel and “it appear[ed] that Ms. Isemin [was] appearing on the [Registrant’s] behalf.” RFAAX 4, at 1 (citing 21 CFR 1316.50).

³ In the Order Terminating Proceedings, the Chief ALJ stated that “Agency precedent is clear that the unwillingness or inability of a party to comply with the directives of the [ALJ] may support an implied waiver of that party’s right to a hearing.” *Id.* (citing *Robert M Brodtkin, D.P.M.*, 77 FR 73,678, 73,679 (2012); *Kamir Garces-Mejias, M.D.*, 72 FR 54,931, 54,932 (2007); *Andrew Desonia, M.D.*, 72 FR 54,293, 54,294 (2007); *Alan R. Schankman, M.D.*, 63 FR 45,260, 45,260 (1998)).

⁴ *See* 21 CFR 1301.43(d) (“If any person entitled to a hearing or to participate in a hearing pursuant to § 1301.32 or §§ 1301.34-1301.36 . . . files [a request for a hearing] and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure”); *see also* RFAAX 3, at 3-4 (notifying Registrant that “[f]ailure to timely file a prehearing statement that complies with the directions provided [therein] may result in a sanction, including (but not limited to) a waiver of hearing and an implied withdrawal of a request for hearing”).

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. *Id.*

B. The Status of Registrant's State Authority

Registrant was previously licensed as a community pharmacy in the State of Florida under license number PH22199. 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,⁵ 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. RFAAX 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,

⁵ Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the Office of the Administrator, Drug Enforcement Administration, at dea.addo.attorneys@dea.usdoj.gov.

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, 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. RFAAX 6, at 2. At each visit, the DEA CS sought to fill a prescription for controlled substances that had been issued to D.S.⁶ or to A.D., the fake identity of the CS’s girlfriend. *Id.* at 2-8. DI’s declaration states that each prescription that D.S. sought to fill at Registrant was “fraudulent and [] not valid.”⁷ *Id.* 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. *Id.* at 3. The DEA CS sought to fill a controlled substance prescription that had been issued to his girlfriend’s fake identity, A.D., for one hundred eight-milligram tablets of hydromorphone.⁸ *Id.* at 3; App’x E (May 19, 2017 Prescription).⁹ Prior to this visit, D.S. had filled hydromorphone prescriptions at Registrant, while acting in an undercover capacity.¹⁰ 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

⁶ The DEA CS and D.S. are used interchangeably herein.

⁷ DI’s declaration does not provide factual support for the conclusion that the prescriptions were fraudulent and not valid. Presumably, these prescriptions were fraudulent and not valid because they were issued to fake identities. However, I do not find that it is necessary for me to determine whether the prescriptions were fraudulent or invalid, because Registrant clearly violated federal and state law by repeatedly dispensing controlled substances to D.S. with actual knowledge that D.S. intended to divert the controlled substances that Registrant dispensed, based on the recorded conversations. *See infra* II.A.2.

⁸ Hydromorphone is a Schedule II controlled substance. *See* 21 CFR 1308.12(b)(1)(vii) (2017).

⁹ The photocopy of the May 19, 2017 prescription is difficult to read. *See* App’x E, at 1. However, the fill sticker that was generated during this 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.

¹⁰ *See* App’x A, at 3 (stating that D.S. first filled a prescription at Registrant on December 12, 2016).

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.¹¹ 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.*¹² 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.”¹³ *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 Registrant 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.

¹¹ 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.

¹² 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.

¹³ Presumably, Ms. Isemin was referring to enforcement efforts by the state or federal government.

c. 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 P, at 2. Ms. Isemin warned D.S. not to get caught, and D.S. assured her that he would not. *Id.* D.S. told 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 Q at 3, 5. D.S. paid Registrant \$3,200, explaining that the extra \$200 was a “Christmas bonus.” App’x T, at 2-3. D.S. said that he had fired the guy who had purchased the hydromorphone from him last time, but he found somebody else to buy the hydromorphone at higher prices. *Id.* at 2. Ms. Isemin asked D.S. if he was sure he wanted to give her a bonus, and he replied, “I’m positive, Christmas bonus. . . . I’m making pretty good now, so we good.” *Id.* at 3.

e. January 23, 2018 Undercover Visit

The DEA CS visited Registrant again in an undercover capacity on January 23, 2018, posing as D.S. RFAAX 6, at 6. The DEA CS presented Registrant with a controlled substance prescription issued to D.S. for one hundred and fifty eight-milligram tablets of hydromorphone. *Id.*; App’x U (January 22, 2018 Prescription). Ms. Isemin told D.S. that she did not have enough eight-milligram tablets to fill the prescription, so D.S. asked if she could provide four-milligram tablets. App’x X, at 1-2. Ms. Isemin agreed, and dispensed two bottles of hydromorphone to D.S.—each containing a mixture of four and eight-milligram tablets. RFAAX 6, at 6. One bottle contained one hundred tablets and the other contained eighty-eight tablets. *Id.* The fill sticker generated by Registrant for this transaction falsely shows that Registrant dispensed one hundred and fifty eight-milligram tablets of hydromorphone to D.S. App’x U, at 3.

Ms. Isemin again warned D.S. not to get caught by the police. App’x X, at 7. D.S. assured her that he is “pretty good, all safe,” when he sells the hydromorphone. *Id.* Ms. Isemin told D.S. that “if they catch [the purchaser] they’ll find out where he’s getting it from.” *Id.* D.S. laughed and told Ms. Isemin that they would not find out if he does not tell the purchaser where the tablets come from. *Id.* Ms. Isemin charged D.S. \$1,410 for the prescription, but D.S. paid Ms. Isemin \$1,500, explaining that “[t]hat way [he] can just pick them up” the next time, and joking that the extra money was so that Ms. Isemin did not “forget [him].” *Id.* at 8. Ms. Isemin told D.S. that she would owe him nine tablets at the next visit. *Id.* at 6.

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.¹⁴ *Id.*; App’x Y (March 5, 2018 Prescription). D.S. asked Ms. Isemin if she was going to get more tablets in stock, because the lack of stock was “killing [his] business.” App’x ZC, at 1-2. Ms. Isemin explained that she was trying to get more tablets in stock. *Id.* at 2. Registrant dispensed one

¹⁴ Oxycodone is a Schedule II controlled substance. See 21 CFR 1308.12(b)(1)(xiii) (2017).

hundred thirty-milligram tablets of oxycodone to D.S. and charged him \$1,100 for the prescription, which D.S. paid in cash. RFAAX 6, at 7; App'x Y at 3.

Registrant also dispensed nine twenty-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* I.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.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003).

According to Agency decisions, I “may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether” to revoke a registration. *Id.*; *see also Jones Total Health Care Pharm., 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); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. 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 I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); *see also Hoxie*, 419 F.3d at 482. “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has

met its *prima facie* case, the burden then shifts to the registrant to show that revoking its registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough*, 73 FR 364, 387 (2008).

In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is most appropriately considered under Factors One, Two, and Four.¹⁵ 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

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* App'x 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(f)(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 a conviction).

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.¹⁶

2. Factors Two and Four – The Registrant’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

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, officers, managing pharmacist, or other key employee.” *Perry Cty. Food & Drug*, 80 FR 70,084, 70,109 (2015) (citing *EZR X, LLC*, 69 FR 63,178, 63,181 (1988); *Plaza Pharmacy*, 53 FR 36,910, 36,911 (1988)).

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 under the laws of the State in which [it] practices.” *See infra* II.B (citing 21 U.S.C. 823(f)); *see also Kenneth Harold Bull*, 78 FR at 62,672 (noting in its Factor 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.”).

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)(i); and Fla. Admin. Code. Ann. r. 64B16-27.831 and 64B16-27.810).¹⁷ 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 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 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

¹⁷ The Government also alleged in the OSC that registrant violated Fla. Stat. § 456.072(1)(m), which prevents the use of "trick[s] or scheme[s] in or related to the practice of a profession." OSC, at 3, 5. Because the Government did not reference this statute in the RFAA, or argue its applicability, I will not consider this allegation.

controlled substances may be dispensed only by written prescription, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

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 [is] 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 CFR 1306.04(a),¹⁸ and that Registrant filled these prescriptions outside the usual course of the professional practice of pharmacy in Florida, in violation of 21 CFR 1306.06.¹⁹ 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* I.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

¹⁸ *See Ralph J. Bertolino Pharmacy*, 55 FR at 4730 (noting that a pharmacist's corresponding responsibility requires him "to ensure that controlled substances are not dispensed for non-medical reasons") (internal citations omitted); *S & S Pharmacy, Inc.*, 78 FR at 57,660 (finding that respondent violated 21 U.S.C. 841(a)(1) and 21 CFR 1306.04 by exchanging controlled substances for cash, knowing that the prescriptions provided by the DEA's confidential source were fictitious).

¹⁹ In relevant part, section 1306.06 provides that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." In order to prove a violation of this regulation, the Government 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 Yani*, 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.

validity of the prescription”;²⁰ (2) failing to review each prescription for potential problems, such as “[o]ver utilization or under-utilization” and “[c]linical 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

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

²⁰ *See* Fla. Admin. Code. r. 64B16-27.831 (2015). This rule was amended in 2018, after the relevant misconduct in this case took place; however, there were no relevant, substantive modifications to this regulation in 2018.

²¹ *See* Fla. Admin. Code. r. 64B16-27.810.

²² *See* Fla. Stat. § 893.04(2)(a) (2016). This statute was amended in 2018, after the relevant misconduct in this case took place; however, there were no relevant, substantive modifications to this regulation in 2018.

²³ *See* 21 U.S.C. 829(a); 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 known as prescription or legend drugs which are required by federal or state law to be dispensed only on a prescription”) (internal quotations omitted).

²⁴ In the emergency order suspending Ms. Isemin’s state license, the Florida DOH concluded that Ms. Isemin “lacks the good judgment needed to practice as a pharmacist in the State of Florida,” because of her “repeated failure to require patient identification from D.S. or to verify whether D.S.’ prescriptions were valid prior to dispensing controlled substances; her continued sale of controlled substances to D.S., despite being informed on several occasions that he was selling them to unauthorized individuals; and her acceptance of a ‘bonus’ for assisting D.S. in his illegal sale of controlled substances” App’x A, at 12. The order also concluded that Ms. Isemin violated Fla. Stat. §§ 893.04(1) and (2)(a), in part, because she “[k]nowingly dispens[ed] controlled substances to a patient who stated he was selling the controlled substances to unauthorized persons.” *Id.* at 17.

²⁵ *See also* Fla. Stat. § 893.04(2)(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”).

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 oxycodone, 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 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; *Sheran 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 . . . [w]hich 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 . . . [t]o 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).²⁶ 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.

²⁶ *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 . . . [i]n which a person not licensed as a pharmacist in this state . . . fills, compounds, or dispenses any prescription or dispenses medicinal drugs.”)

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 accept responsibility for [the registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.” *Jayam Krishna-Iyer*, 74 FR at 463 (quoting *Med. Shoppe*, 73 FR 364, 387 (2008)); *see also Samuel S. Jackson*, 72 FR 23,848, 23,853 (2007); *John H. Kennedy, M.D.*, 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency’s interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016).

Here the Registrant did not avail itself of the opportunity to refute the Government’s case. In light of Registrant’s egregious violations, which go to the heart of the CSA’s purpose of “prevent[ing] addiction and recreational abuse” of controlled substances,²⁷ Registrant’s silence

²⁷ *Gonzales v. Oregon*, 546 U.S. at 274.

weighs against the Registrant's continued registration. *Zvi H. Perper, M.D.*, 77 FR at 64,142 (citing *Med. Shoppe*, 73 FR at 387); *see also Jackson*, 72 FR at 23,853.

Accordingly, I find that the factors weigh in favor of revocation, and I shall order the sanctions that 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), I hereby revoke DEA Certificate of Registration BH9966904 issued to Care Point Pharmacy, Inc. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Care Point Pharmacy, Inc. to renew or modify this registration. This order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Anne Milgram,

Administrator.

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