



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Empire Pharmacy Inc.; Skyline Pharmacy Inc.; Decision and Order

I. Introduction

On October 31, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registrations (OSC/ISO) to Empire Pharmacy, Inc., and Skyline Pharmacy, Inc., of Philadelphia, Pennsylvania (collectively, Registrants). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 18. The OSC/ISO informed Registrants of the immediate suspension of their DEA Certificates of Registration, Nos. FE8167733 and FS0903840, pursuant to 21 U.S.C. 824(d), alleging that Registrants' continued registration constitutes "an imminent danger to the public health or safety." *Id.* at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrants' registrations, alleging that Registrants' continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).¹

Specifically, the OSC/ISO alleged that between February 20, 2019, and August 30, 2023, Registrants failed to maintain accurate records of their purchasing, dispensing, and physical inventory of controlled substances, in violation of federal and Pennsylvania state law. RFAAX 2, at 4-6 (citing 21 CFR 1304.04(a), 1304.11(a)-(c), 1304.21(a); 35 Pa. Cons. Stat. Ann. sections 780-112(a)-(c), and 780-113(a)(21)).

The OSC/ISO notified Registrants of their right to file with DEA a written request for hearing and that if they failed to file such a request, they would be deemed to have waived their right to a hearing and be in default. RFAAX 2, at 7 (citing 21 CFR 1301.43). Here, Registrants

¹ According to Agency records, Empire Pharmacy's registration expired on August 31, 2024, and Skyline Pharmacy's registration expired on February 29, 2024. The fact that a registrant allows its registration to expire during the pendency of an administrative enforcement proceeding does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC/ISO to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68474, 68476-79 (2019).

did not request a hearing. RFAA, at 2.² “A default, unless excused, shall be deemed to constitute a waiver of the registrant’s/applicant’s right to a hearing and an admission of the factual allegations of the [OSC/ISO].” 21 CFR 1301.43(e).

Further, “[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.” *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrants’ default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

II. Applicable Law

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC/ISO alleges that Registrants violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales v. Raich*, “the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to . . . dispense[] or possess any controlled substance except in a manner authorized by the CSA.” 545 U.S. 1, at 12-13 (2005). In maintaining this closed regulatory system, “[t]he CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping.” *Id.* at 14.

Here, the OSC/ISO’s allegations concern the CSA’s “strict requirements regarding registration[,] . . . drug security, and recordkeeping” and, therefore, go to the heart of the CSA’s

² Based on the Government’s submissions in its RFAA dated February 9, 2024, the Agency finds that service of the OSC/ISO on Registrants was adequate. Specifically, the included Declaration from a DEA Special Agent asserts that on November 1, 2023, the OSC/ISO was personally served at both of Registrants’ registered addresses during the execution of simultaneous search warrants at both locations. RFAAX 3, at 1-2. The Special Agent noted in the Declaration that an individual who serves as the owner and/or controlling officer at both Empire Pharmacy and Skyline Pharmacy was physically present at the location of Empire Pharmacy during the execution of the search warrant and service of the OSC/ISO. *Id.* at 2. This individual received a copy of the OSC/ISO as well as instructions from DEA personnel. *Id.*

“closed regulatory system” specifically designed “to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.” *Id.*

B. Improper Dispensing, Recordkeeping, and Unaccounted For Controlled Substances

According to DEA’s implementing regulations, pharmacies must maintain “a complete and accurate record of each controlled substance . . . sold” 21 CFR 1304.21(a). This includes conducting and maintaining an “initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,” as well as a “biennial inventory . . . of all stocks of controlled substances on hand.” 21 CFR 1304.11(a)-(c). Pharmacies must retain these inventories “for at least 2 years from the date of such inventory or records, for inspection and copying.” 21 CFR 1304.04.

Pennsylvania law also requires pharmacies to keep accurate records and maintain proper inventories regarding the purchase, sale, or dispensing of any controlled substances. 35 Pa. Cons. Stat. Ann. section 780-112(a)-(c). In Pennsylvania, it is unlawful for a pharmacy to fail to “make, keep or furnish any record, notification, order form, statement, invoice or information” relating to the purchasing or dispensing of a controlled substance. *Id.* section 780-113(a)(21).

III. Findings of Fact

The Agency finds that, in light of Registrants’ default, the factual allegations in the OSC/ISO are deemed admitted.³ Registrants are deemed to have admitted that from February 20, 2019, until at least August 30, 2023, Empire Pharmacy failed to maintain accurate records of its purchasing and dispensing of controlled substances. RFAAX 2, at 6. For example, Registrants admit that there were significant discrepancies between the dispensing/order data that

³ Registrants are deemed to have admitted and the Agency finds that Registrants share common management and control. RFAAX 2, at 3. Registrants admit that S.O. is the owner and/or controlling officer of both Empire Pharmacy and Skyline Pharmacy. Given the fact that the same individual exercises management and control over the entities, the misconduct of any entity is relevant to the determination of whether the others can be entrusted with a DEA registration. *See Morning Star Pharmacy & Med. Supply*, 85 FR 51045, 51062 (2020) (“Due to the commonality of . . . management, and key employees between Respondent Pharmacy and Cedar Hill [Pharmacy], any misconduct related to controlled substances at Cedar Hill is relevant to the determination of whether Respondent pharmacy can be entrusted with a registration.”).

Empire submitted to its distributors and the dispensing data that Empire reported to Pennsylvania's PDMP. *Id.* at 4. Registrants admit that a comparison of Empire's PDMP data to Empire's distributor order data from February 20, 2019, through July 14, 2022, revealed discrepancies of: (1) approximately 404,106 dosage units of alprazolam 1 mg, (2) approximately 822,700 dosage units of alprazolam 2 mg, and (3) approximately 1,969 bottles of promethazine with codeine. *Id.* at 5. These discrepancies amounted to an approximately 99% variance between the PDMP data and Empire's distributor order data. *Id.* Registrant admits that there were also significant discrepancies for Skyline Pharmacy,⁴ and that both pharmacies failed to maintain accurate records of their purchasing and dispensing of controlled substances. *Id.* at 4-6. Registrants further admit that Empire Pharmacy failed to adequately maintain an initial and biennial inventory, and that Skyline Pharmacy failed to maintain an initial inventory of controlled substances. *Id.* at 4.

Accordingly, the Agency finds substantial record evidence that each Registrant failed to maintain accurate records of its purchasing and dispensing of controlled substances. The Agency also finds substantial record evidence that each Registrant failed to maintain adequate inventories of all controlled substances on hand.

IV. Discussion

A. The Controlled Substances Act and Implementing Regulations

Under Section 304 of the CSA, “[a] registration . . . to . . . distribute[] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.” 21 U.S.C. 824(a)(4). In the case of a “practitioner,” which is defined in 21 U.S.C. 802(21) to include a

⁴ Registrants admit that when comparing Skyline Pharmacy's PDMP data to Skyline's distributor order data from July 18, 2022, through October 18, 2021, there was a discrepancy of approximately 117,600 dosage units of alprazolam 1 mg, 223,500 dosage units of alprazolam 2 mg, and 789 bottles of promethazine with codeine. *Id.* at 6. These discrepancies amounted to an approximately 100% variance between the PDMP data and Skyline's distributor order data. *Id.*

“pharmacy,” Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A-E).⁵

The five factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. 243, 292-93 (2006) (Scalia, J., dissenting) (“It is well established that these factors are to be considered in the disjunctive,” citing *In re Arora*, 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *Penick Corp. v. Drug Enf’t Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall*, 412 F.3d. at 185 n.2; *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Agency finds that the Government’s evidence in support of its *prima facie* case is confined to Factors B and D.⁶ See RFAAX 1, at 4. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that each Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 823(g)(1).

A. Allegation that Registrants’ Registrations are Inconsistent with the Public Interest

Factors B and/or D – Registrants’ Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Evidence is considered under Public Interest Factors B and D when it reflects compliance or non-compliance with federal and local laws related to controlled substances and experience

⁵ The five factors of 21 U.S.C. 823(g)(1)(A-E) are:

- (A) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (B) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.
- (C) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (D) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (E) Such other conduct which may threaten the public health and safety.

⁶ The Agency has carefully considered the entire transmitted record, and this Decision/Order is the result of its adjudication of that record in its entirety.

dispensing controlled substances. 21 U.S.C. 823(g)(1)(B) and (D); *see also Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). Here, as found above, Registrants are deemed to have admitted and the Agency finds that Registrants failed to maintain accurate records of their purchasing and dispensing of controlled substances. RFAAX 2, at 4-6. Additionally, Registrants are deemed to have admitted and the Agency finds that each pharmacy failed to maintain adequate inventories of all stocks of controlled substances on hand. Therefore, the Agency finds substantial record evidence that Registrants violated federal and state law, namely 21 CFR 1304.04(a), 1304.11(a)-(c), 1304.21(a); and 35 Pa. Cons. Stat. Ann. sections 780-112(a)-(c), 780-113(a)(21).⁷

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Registrants' registrations and thus finds Registrants' continued registration to be inconsistent with the public interest. The Agency further finds that Registrants failed to provide any evidence to rebut the Government's *prima facie* case.

V. Sanction

Here, the Government has met its *prima facie* burden of showing that Registrants' continued registration is inconsistent with the public interest due to their numerous violations pertaining to controlled substance dispensing and recordkeeping. Accordingly, the burden shifts to Registrants to show why they can be entrusted with registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018); *supra* sections III and IV. The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best

⁷ The OSC/ISO alleges that Registrants violated additional state statutes related to their failure to maintain adequate records and their failure to adequately report their dispensing of controlled substances to the Pennsylvania PDMP. *See* RFAAX 2, at 2 (citing 35 Pa. Cons. Stat. Ann. sections 872.7(a), (c), 780-113(a)(12)). Neither the OSC/ISO nor the RFAA contains sufficient analysis to allow the Agency to adjudicate these allegations. However, the found violations in this decision are more than sufficient to support the Government's requested sanction of revocation under these circumstances.

predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy*, 881 F.3d at 830-31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 & n.4. The Agency has also considered the need to deter similar acts by the registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972-73.

Here, Registrants did not timely or properly request a hearing and were deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1-2. To date, Registrants have not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrants have thus failed to answer the allegations contained in the OSC and have not otherwise availed themselves of the opportunity to refute the Government's case. As such, Registrants have made no representations as to their future compliance with the CSA nor made any demonstration that they can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrants violated the CSA, further indicating that Registrants cannot be entrusted.

VI. Conclusion

Accordingly, the Agency will order the revocation of Registrants' registrations.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificates of Registration Nos. FE8167733 and FS0903840 issued to Empire Pharmacy Inc. and Skyline Pharmacy Inc. Further, pursuant to 28

CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Empire Pharmacy Inc. and/or Skyline Pharmacy Inc. to renew or modify the named registrations, as well as any other pending application of Empire Pharmacy Inc. and/or Skyline Pharmacy Inc. for additional registration in Pennsylvania. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2025, by Acting Administrator Derek Maltz. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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