[4410-09-P]

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

De Novo Services, LLC; Decision and Order

I. INTRODUCTION

On June 6, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to De Novo Services, LLC, of Salt Lake City, Utah (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 5. The OSC proposed the revocation of Registrant's DEA Certificate of Registration No. RD0424515, alleging that Registrant has committed such acts as would render its registration inconsistent with the public interest. *Id*. at 1, 2 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

Specifically, the OSC alleged that between 2013 and 2023, Registrant lacked effective controls and procedures to guard against the diversion of controlled substances, as well as committed numerous recordkeeping violations, in violation of the Controlled Substances Act's (CSA) implementing regulations and Utah state law.[1] *Id*. at 2.

The OSC notified Registrant of its right to file with DEA a written request for hearing and an answer, and that if it failed to file such a request, it would be deemed to have waived its right to a hearing and be in default. *Id*. at 4 (citing 21 CFR 1301.43). Here, Registrant 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]." 21 CFR 1301.43(e); *see also* RFAAX 1, at 4 (providing notice to Registrant).

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[1] The Utah state law cited by the Government in the OSC pertains to pharmacists. The applicability of these Utah laws to Registrant is not clear from the OSC and was not addressed in the RFAA. Accordingly, the Agency declines to find any violations of Utah law in this matter. *See id.* at 3. However, the Agency finds that the founded allegations in this decision are more than sufficient to support the Government's requested sanction of revocation under these circumstances.

[2] Based on the Government's submissions in its RFAA dated July 16, 2024, the Agency finds that service of the OSC on Registrant was adequate. Specifically, on June 10, 2024, a DEA Diversion Investigator personally served the OSC on J.C., the signatory and contact person associated with Registrant's DEA Certificate of Registration No. RD0424515. RFAA, at 1; RFAAX 2-3.

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 C.F.R.] § 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c)(1), (f)(1), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.[3]

II. APPLICABLE LAW

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC alleges that Registrant violated 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's allegations concern the CSA's "strict requirements regarding registration . . . drug security, and recordkeeping" and, therefore, go to the heart of the CSA's

[3] On October 7, 2024, Registrant signed a DEA Form 104, Surrender for Cause of DEA Certificate of Registration. *See* 21 CFR 1301.52(a). Even when a registration is terminated, the Agency has discretion to adjudicate the OSC to finality. *See Jeffrey D. Olsen, M.D.*, 84 Fed. Reg. 68,474, 68,479 (2019) (declining to dismiss an immediate suspension order when the registrant allowed the registration to expire before final adjudication); *Steven M. Kotsonis, M.D.*, 85 Fed. Reg. 85,667, 85,668-85,669 (2020) (concluding that termination of a registration under 21 CFR 1301.52 does not preclude DEA from issuing a final decision and that the Agency would assess such matters on a case-by-case basis to determine if a final adjudication is warranted); *The Pharmacy Place*, 86 Fed. Reg. 21,008, 21,008-21,009 (2021) ("Adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrant[s] . . . under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices."); *Creekbend Community Pharmacy*, 86 Fed. Reg. 40,627, 40,628 n.4 (2021) ("Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with [the registrant] . . . or other persons who were associated with [the registrant]."). As in these cases, the Agency has evaluated the circumstances of this matter and determined that the matter should be adjudicated to finality for the purpose of creating an official record of the allegations and evidence, and educating the registrant community, the public, and stakeholders about the responsibilities associated with holding a DEA registration and the Agency's enforcement priorities.

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

B. Failure to Guard Against Diversion and Recordkeeping Violations (21 CFR 1301.74(h), 1304.11(e)(1)(iii), (e)(6), 1304.21(a), (e), 1305.05(d), 1305.12(b), 1305.13(e), 1317.30.)

The OSC alleges that between 2013 and 2023, Registrant lacked effective controls and procedures to guard against the diversion of controlled substances, as well as committed numerous recordkeeping violations. RFAAX 1, at 1. CSA regulations require the following.

Registrants receiving controlled substances must maintain complete and accurate records of all controlled substances received. 21 CFR 1304.21(a). Only a licensed practitioner employed at the facility or another authorized individual, authorized in writing, may accept delivery of controlled substances used in a narcotic treatment program, and such delivery acceptance must be documented by signature of the licensed practitioner or authorized individual. 21 CFR 1301.74(h). Specific authorization is required for an individual or entity to collect controlled substances from ultimate users and other non-registrants for destruction, and destruction of controlled substances generally must be documented on a DEA Form 41. 21 CFR 1304.21(e), 1317.30. When executing a power of attorney, a registrant must provide two witnesses. 21 CFR 1305.05(d). When completing a DEA Form 222, purchasers must note the number of lines completed at the bottom of the form, with each line completed containing an item consisting of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same controlled substance. 21 CFR 1305.12(b). Purchasers must also note on each item of the DEA Form 222 the number of commercial or bulk containers furnished and the dates on which the containers are received by the purchaser. 21 CFR 1305.13(e). Finally, regarding inventories of dispensers and researchers, for each controlled substance in finished form, the inventory must document the specific finished form of the substance (for example, a 10 mg tablet). 21 CFR 1304.11(e)(1)(iii), (e)(6).

III. FINDINGS OF FACT

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted.

A. Letters of Admonition

A registrant who is authorized to maintain and/or detoxify controlled substance users in a treatment program is required to keep records for each controlled substance utilized in such a program. 21 CFR 1304.24(a). Registrant is deemed to have admitted that following an on-site inspection by DEA in August 2013, Registrant was mailed a Letter of Admonition specifying Registrant's violation of 21 CFR 1304.24(a) regarding records for maintenance and detoxification treatment programs. RFAAX 1, at 2. Registrant is also deemed to have admitted that it responded to the letter identifying corrective actions it had taken to become compliant. *Id*.

21 CFR 1304.11 details the inventory requirements for registrants, while 21 CFR 1304.21 details the general requirements for continuing records for registrants. Registrant is deemed to have admitted that following an on-site inspection by DEA in March 2022, Registrant was mailed a Letter of Admonition specifying Registrant's violations of 21 CFR 1304.11(e)(6), 1304.21(d) and other federal regulations. RFAAX 1, at 2. Registrant is also deemed to have admitted that it again responded to the letter identifying corrective actions it had taken to become compliant. *Id*.

B. Failure to Guard Against Diversion and Recordkeeping Violations

Registrant is deemed to have admitted that DEA conducted another on-site inspection on November 27-30, 2023, which revealed a lack of effective controls and procedures to guard against diversion. More specifically, Registrant admits that between March 2022 and June 2023, it allowed two unauthorized persons to accept delivery of Schedule III controlled substances. *Id*. The individuals were unauthorized because Registrant failed to produce the required written documentation authorizing the two individuals to accept the deliveries. *Id*. Further, Registrant is deemed to have admitted that on six occasions between July 2023 and November 2023, it

accepted delivery of Schedule III controlled substances without any signature documenting who accepted delivery. *Id*.

Registrant is deemed to have admitted that between March 2022 and November 2023, thirty-one of its Schedule III controlled substance invoices were incomplete. *Id*. Specifically, these thirty-one invoices were missing either the date the controlled substances were received, the specific amount of controlled substances that were delivered, or the signature and title of the authorized receiving individual. *Id*. at 2-3. Registrant is also deemed to have admitted that one of its biennial controlled substance inventory forms dated August 4, 2023, failed to document the finished form for the specified Schedule II controlled substances. *Id*. at 3.

Registrant is deemed to have admitted that, despite its registration not authorizing the collection of controlled substances, on at least five occasions between March 2022 and November 2023, it collected Schedule I, II, and III controlled substances. *Id*. Registrant is also deemed to have admitted that on at least twenty-three occasions between March 2022 and November 2023, it destroyed controlled substances without maintaining a DEA Form 41. *Id*.

Registrant is deemed to have admitted that on its dispensing logs for Schedule III controlled substances, it consistently failed to record the names of the substances, the strengths of the substances, the dosage forms of the substances, and the amount and dosage of the substances taken home by the patients. *Id*. Registrant is also deemed to have admitted that the power of attorney that it executed on November 1, 2021, failed to provide two witnesses. *Id*.

Registrant is deemed to have admitted that on both May 3, 2022, and September 6, 2023, J.K. failed to properly fill out a DEA Form 222 (Order Request Form). *Id*. On May 3, 2022, J.K. "failed to report the last line completed section," and on September 6, 2023, J.K. failed to indicate the number of commercial or bulk containers received of the Schedule II controlled substance, as well as the date received. *Id*.

Finally, Registrant is deemed to have admitted that between March 2022 and November 2023, Registrant failed to maintain complete and accurate records and, due to that failure, DEA

Investigators were unable to conduct an accountability audit for controlled substances. *Id*. at 4. Based on the above, the Agency finds substantial record evidence that Registrant failed to maintain effective controls and procedures to safeguard against diversion and failed to maintain complete and accurate records.

IV. DISCUSSION

A. The Controlled Substances Act's Public Interest Factors

Pursuant to 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," Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A-E).[4] 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 Fed. Reg. 4,447, 4,448 (1995)); *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (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 Fed. Reg. 37,507, 37,508 (1993).

According to Agency decisions, the Agency "may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate in determining whether" to revoke a registration. *Id*.; *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't*

[4] 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.

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. U. S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005).

Moreover, while the Agency is required to consider each of the factors, it "need not make explicit findings as to each one." *MacKay*, 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 Fed. Reg. 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

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* public interest revocation case regarding Registrant's violations of the CSA's implementing regulations is confined to Factors B and D. RFAAX 1, at 4. Moreover, the Government has the burden of proof in this proceeding. 5 U.S.C.A. 556(d); 21 CFR 1301.44.

B. Factors B and/or D - Applicant's Registration is Inconsistent with the Public Interest

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 dispensing controlled substances. 21 U.S.C. 823(g)(1)(B) and (D); *see also Kareem Hubbard, M.D.*, 87 Fed. Reg. 21,156, 21,162 (2022). Here, as found above, Registrant is deemed to admit and the Agency finds that between March 2022 and November 2023, Registrant lacked effective controls and procedures to guard against the diversion of controlled substances, as well as committed numerous recordkeeping violations. RFAAX 1, at 2. More specifically, the Agency finds substantial record evidence that Registrant violated 21 CFR 1301.74(h), 1304.11(e)(1)(iii),

(e)(6), 1304.21(a), (e), 1305.12(b), 1305.13(e), and 1317.30. Additionally, the Agency finds substantial evidence that Registrant's power of attorney dated November 1, 2021, violated 1305.05(d).

The Agency further finds that Factors B and D weigh in favor of denial of Registrant's application and that Registrant's registration would be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). Accordingly, the Agency finds that the Government established a *prima facie* case, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 823(g)(1).

V. SANCTION

Here, the Government has met its *prima facie* burden of showing that Registrant's continued registration is inconsistent with the public interest due to its numerous violations pertaining to its handling of controlled substances. Accordingly, the burden shifts to Registrant to show why it can be entrusted with a 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 Fed. Reg. 18,882, 18,904 (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 Fed. Reg. 46,968, 46,972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that 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 Fed. Reg. at 46,972-73.

Here, Registrant failed to answer the allegations contained in the OSC and did not otherwise avail itself of the opportunity to refute the Government's case. As such, there is no record evidence that Registrant takes responsibility, let alone unequivocal responsibility, for the founded violations, meaning, among other things, that it is not reasonable to believe that Registrant's future controlled substance-related actions will comply with legal requirements. Accordingly, Registrant did not convince the Agency that it can be entrusted with a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Given the foundational nature of Registrant's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

VI. CONCLUSION

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

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. RD0424515 issued to De Novo Services, LLC. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of De Novo Services, LLC, to renew or modify this registration, as well as any other pending application of De Novo Services, LLC, for additional registration in Utah. 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 18, 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.

[FR Doc. 2025-07026 Filed: 4/22/2025 8:45 am; Publication Date: 4/23/2025]