

SUPPLEMENTARY INFORMATION:

Background: The Commission had instituted Investigation No. 332–599 under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)). See 88 FR 45922 (July 18, 2023).

By order of the Commission.

Issued: February 11, 2025.

Lisa Barton,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No. 23–1]

Robert L. Carter, D.D.S.; Decision and Order

On September 29, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Robert L. Carter, D.D.S., of Camden Wyoming, Delaware (Respondent). Request for Final Agency Action (RFAA), Appendix (RFAAX) A, at 1, 9. The OSC proposes the revocation of Respondent's DEA registration in Delaware, Number BC5574048 (Registration), and the denial of Respondent's application for a DEA registration in New Jersey, Application Number W20128194C (Application), pursuant to 21 U.S.C. 824(a)(1), (a)(3), and (a)(4), and 823(g)(1), because Respondent materially falsified multiple renewal applications and his registration is inconsistent with the public interest.¹ OSC, at 1.

I. Procedural Background

The OSC notified Respondent of the right to request a hearing. OSC, at 7–8 (citing 21 CFR 1301.43). On October 25, 2022, Respondent timely requested a hearing in this matter. RFAAX B. The matter was placed on the docket of DEA Chief Administrative Law Judge John J. Mulrooney, II (the Chief ALJ), who, on October 26, 2022, issued an Order for

¹ The OSC also proposes an additional ground for denial of Respondent's application for a DEA registration in New Jersey on the basis that he lacks authority to handle controlled substances in New Jersey. The record contains no evidence showing that Respondent has regained authority to handle controlled substances in New Jersey in the time since his New Jersey controlled dangerous substance license expired, but that evidence dates back to 2022. RFAA, GX 6. Even without considering Respondent's state authority to handle controlled substances in New Jersey, the Agency has ample grounds to deny Respondent's 2020 application due to the substantial record evidence that Respondent materially falsified multiple applications and that granting the application would be inconsistent with the public interest.

Prehearing Statements. RFAAX C. The Order for Prehearing Statements directed the parties to submit prehearing statements and explained the criteria these statements must meet to be considered adequate. *Id.* at 2. Consistent with Agency practice, the Order for Prehearing Statements explained that an adequate prehearing statement must include the names of witnesses expected to testify at the hearing, a summary of their expected testimony, and a list of evidentiary exhibits expected to be offered at the hearing. *Id.*; see also 21 CFR 1316.52(c), 1316.58. The Order for Prehearing Statements further notified the parties that failure to submit a compliant prehearing statement may incur a sanction, to include “a waiver of hearing and an implied withdrawal of a request for hearing,” RFAAX C, at 4. The Order for Prehearing Statements also set the date for the prehearing conference. *Id.* at 3; see also 21 CFR 1316.54.

Both parties submitted timely prehearing statements. RFAAX D & E. The Chief ALJ, however, found Respondent's prehearing statement to be deficient. RFAAX F, at 1. Specifically, the Chief ALJ noted that instead of providing names of witnesses, summaries of testimony, and proposed exhibits as directed, Respondent's prehearing statement stated that Respondent could not comply with the Order for Prehearing Statements because the Government had not turned over documents supporting the OSC. *Id.* at 2. The Chief ALJ found that Respondent's noncompliant prehearing statement amounted to “a refusal to follow the issued directions.” *Id.* The Chief ALJ issued an Order Directing Compliance (Compliance Order) in which he provided Respondent another opportunity to submit a compliant prehearing statement and again informed Respondent that failure to do so could result in “dismissal of his request for hearing.” *Id.* The Compliance Order further explained the tribunal's “[l]ongstanding practice” of requiring parties to identify proposed evidentiary exhibits in their prehearing statements before being directed to exchange evidence. *Id.* at 2 n.3. The Compliance Order additionally informed Respondent that he would be provided the opportunity to file a supplemental prehearing statement at a later time. *Id.*

Instead of submitting a compliant prehearing statement in response to the Compliance Order as directed, Respondent submitted a letter in which he reiterated his position that he cannot comply with the Order for Prehearing Statements or the Compliance Order

until he receives the Government's “supporting documents.” RFAAX G, at 1. Specifically, Respondent stated that he “simply cannot respond without reviewing the documents the Government has referenced” and it is “impossible” to identify witnesses and proposed testimony “without the documents the Government references.”² *Id.* at 2. Respondent concludes by stating that “once [he] receives the requested documents, [he] will provide an appropriate response,” but until then, he “cannot provide an appropriate response . . . without the documents supporting the Government's case.”³ *Id.* Attached to this letter were emails between Respondent's counsel and DEA counsel in which it was explained that the Government would supply its evidentiary exhibits to Respondent according to the deadline established by the Chief ALJ at the prehearing conference. *Id.* at 3–11.

Following receipt of Respondent's letter and prior to the deadline set by the Compliance Order, the Chief ALJ issued an Order Terminating Proceedings (Termination Order) in which he found that Respondent had “effectively waived his right to a hearing” by failing to comply with the Order for Prehearing Statements and Compliance Order, and by informing the tribunal that he did not intend to

² Respondent's argument that he does “not know what is contained in” the Government's documents underlying the OSC is disingenuous. RFAAX G, at 2. The Government's Prehearing Statement noticed proposed exhibits of Respondent's Delaware registration history, his New Jersey application history, his Delaware dental license and controlled substances registration, his New Jersey dental license, a letter showing the current status of his New Jersey controlled dangerous substances registration, documents from Respondent's New Jersey state administrative case, emails to Respondent, and prescriptions he wrote. RFAAX D, at 14–17. Respondent received a clear description of the exhibits, most of which were publicly available records concerning Respondent, and seven pages of detailed testimony in the Government's Prehearing Statement. It is difficult to believe that Respondent truly felt that he could not prepare a prehearing statement, which he was informed could be supplemented after receiving the Government's evidence.

³ In his letter to the Chief ALJ, Respondent stated that the Government's documents supporting the OSC “must be produced.” RFAAX G, at 2. The question is not, however, whether the Government's evidence “must be produced”; the issues are whether Respondent is entitled to receive the evidence prior to filing a prehearing statement and whether the prehearing filing schedule should be handled differently in this case than all other matters that come before the tribunal. Respondent provided no authority to support his claim that the evidence “must be produced” on demand at the specific time that he requested it. *Id.* Likewise, he provided no authority to support his expectation that this case be handled differently than how the tribunal typically handles prehearing procedures. *Id.*

comply. RFAAX H, at 3. The Termination Order dismissed the request for hearing, cancelled the scheduled prehearing conference, and terminated the proceedings. *Id.* The Chief ALJ found that Respondent had failed to show good cause for not submitting a compliant prehearing statement, and that the sole basis for his continued noncompliance was his claim that he could not comply until he received the Government's evidence. *Id.* The Chief ALJ further found that Respondent's basis for not complying did not constitute good cause to handle this case's prehearing procedures "in any manner that varie[d] from the multitudes of cases that have been litigated in this forum in the past." *Id.*

After issuance of the Termination Order but shortly before the deadline set by the Compliance Order,⁴ Respondent submitted an amended prehearing statement. RFAAX I. In response, the Chief ALJ issued a letter informing Respondent that because the matter had been terminated, no action would be taken on the amended prehearing statement⁵ and the matter would be returned to the Office of Chief Counsel for any action it deemed appropriate. RFAAX J. In the month following the Termination Order, Respondent submitted a letter addressed to the DEA Administrator. RFAAX K.

In this letter, Respondent reiterated the same arguments that he advanced before the tribunal; specifically, that he was "deprived of the ability to defend himself," and that he was (and still is) entitled to receive evidence from the Government prior to the normally scheduled deadline for the exchange of evidence. *Id.* In support, Respondent cited *Transportation Leasing Co. v. Department of Employment Services*,

690 A.2d 487 (DC App. 1997). But that case stood for the proposition that "an individual is entitled to fair and adequate notice of administrative proceedings that will affect his or her rights, in order that he or she may have an opportunity to defend his or her position." *Id.* at 489 (internal quotations and brackets omitted). The Agency finds that Respondent received adequate notice of the issues to be litigated and was given an opportunity to defend himself. Respondent was notified of the allegations against him in the OSC, afforded the right to request a hearing, received the Government's Prehearing Statement which contained a detailed description of the testimony that would be elicited to support the Government's allegations, was put on notice of the evidence to be offered, and was afforded the opportunity to submit his own prehearing statement and propose his own evidence after reviewing the Government's submission. Respondent was simply unwilling to proceed pursuant to the normal prehearing process.

The Agency finds that the Chief ALJ acted within his authority in determining that Respondent failed to cooperate with the tribunal's prehearing procedures after being afforded two opportunities to come into compliance and being cautioned on both occasions that failure to comply would be treated as an implied waiver of his right to a hearing. RFAAX C, at 2, 4; RFAAX F, at 2. The Chief ALJ did not err in using his discretion to find that Respondent's failure to file a compliant prehearing statement amounted to an implied waiver of his hearing request.⁶

II. Findings of Fact

A. Material Falsification Allegation

The Agency finds clear, unequivocal, and convincing record evidence for each of the following facts, which are uncontroverted. On October 31, 1995,

⁶ The Agency distinguishes this case from *Daniel B. Brubaker, D.O.*, 77 FR 19322 (2012). In *Brubaker*, the ALJ found that despite filing several deficient prehearing statements, the respondent's repeated noncompliance did not amount to an implied waiver of his hearing request. *Id.* at 19,322–23. The Agency notes that the present matter is different from that case, in that the respondent in *Brubaker* did not argue that his inability to file a compliant prehearing statement was due to the Government's waiting to provide its evidence until directed by the tribunal, an argument that the Agency finds lacks merit. Moreover, in *Brubaker*, the respondent's supplemental prehearing statement did disclose some details about his defense, such as the identity of several witnesses and a "vague[] outline[] [of] the testimony of his witnesses." *Id.* at 19,322. Furthermore, in both the present matter and *Brubaker*, the Agency deferred to the ALJ's use of discretion in how to handle repeated noncompliant filings.

the New Jersey State Board of Dentistry (State Board) issued an Administrative Action (Complaint) against Respondent. RFAA, GX 7(B). That Complaint alleged that Respondent improperly prescribed chloral hydrate,⁷ to multiple individuals in violation of state law and "accepted dental practices." *Id.* at 1–2, 5–8, 11–12, 17. The Complaint further alleged that Respondent engaged in "the indiscriminate prescribing of [chloral hydrate]," prescribed dosages of chloral hydrate in excessive amounts, recorded inaccurate dosages of chloral hydrate in his medical records compared to the amount actually prescribed, and failed to create accurate patient medical records supporting the issuance of chloral hydrate prescriptions. *Id.* at 6–17. The Complaint alleged that a child who Respondent was treating died as a result of Respondent's improper prescribing of chloral hydrate, and that another child underwent emergency hospitalization due to being "over-sedated" with chloral hydrate prescribed by Respondent. *Id.* at 5–6, 10. The Complaint recommended that Respondent's state license to practice dentistry in New Jersey be *suspended* or *revoked*. *Id.* at 18.

The Agency finds clear, unequivocal, and convincing record evidence that, on September 25, 1996, the State Board and Respondent entered a Consent Order in which they agreed that, based upon the allegations in the Complaint, Respondent's New Jersey dentistry license would be suspended for one year, with 60 days of active suspension followed by probation for the remaining period. RFAA, GX 7(C), at 2.

The Agency finds clear, unequivocal, and convincing record evidence that, on January 19, 2004, and August 28, 2006, Respondent applied to renew DEA registration BC5574048. RFAA, GX 1, at 4–5, 17–22. These renewal applications asked whether "the applicant [has] ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" (Liability Question 3). RFAA, GX 1, at 17.⁸ The Agency finds clear,

⁷ Chloral hydrate is a schedule IV controlled substance sold under the brand name Noctec. RFAAX A, at 4. The generic name (chloral hydrate) is used in this Decision.

⁸ The quoted language appears in the 2006, 2009, 2012, 2015, 2018, and 2021 applications. RFAA, GX 1, at 7, 9, 11, 13, 15. Liability Question 3 was phrased slightly differently on the 2004 renewal application, which asked whether "the applicant ever surrendered or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? Is any such action pending?" RFAA, GX 1, at 21.

⁴ Respondent has not raised any argument concerning the timing of the Termination Order, specifically, the fact that the proceedings were terminated before the original 2:00 p.m. deadline for filing an amended prehearing statement.

⁵ Respondent's amended prehearing statement was filed after the matter had been terminated by the Chief ALJ. Nevertheless, the Agency has reviewed the submission and finds that the amended prehearing statement remains deficient. The only substantive revisions include identifying Respondent as a witness, providing a two-sentence summary of his proposed testimony, and indicating that Respondent does not anticipate offering any evidence not offered by the Government. RFAAX I, at 3. As for the summary of Respondent's proposed testimony, the amended prehearing statement indicates that he "will testify to his knowledge of his application, license, and application renewals. [Respondent] will testify in opposition to the allegations in the [OSC]." *Id.* This two-sentence summary fails to comply with the Chief ALJ's order that summaries must disclose "each and every matter as to which he intends to introduce evidence in opposition" and "summaries are to state what the testimony will be, rather than merely list the areas to be covered." RFAAX C, at 2.

unequivocal, and convincing record evidence that Respondent accurately answered “yes” to Liability Question 3 on both renewal applications. *Id.* When an applicant answers “yes” to Liability Question 3, the application prompts the applicant to provide additional information explaining the answer. *Id.* On the January 2004 application, Respondent entered the following narrative response explaining his “yes” answer to Liability Question 3: “1996 sixty day suspension for improper record keeping. NJ license.” *Id.* at 21. Respondent did not provide any narrative information on the August 2006 application explaining his “yes” answer to Liability Question 3. *Id.* at 17–20.

The Agency finds clear, unequivocal, and convincing record evidence that, on August 23, 2009, July 24, 2012, August 28, 2015, August 8, 2018, and August 15, 2021, Respondent submitted applications to renew DEA registration BC5574048. RFAA, GX 1, at 2–15. On each of these applications, Respondent falsely answered “no” to Liability Question 3, representing that he had never had a state professional license or controlled substance registration suspended or placed on probation. *Id.* at 7, 9, 11, 13, 15.

The Agency finds clear, unequivocal, and convincing evidence that, on December 11, 2020, Respondent applied for a new DEA registration addressed in New Jersey (Application Number W20128194C). RFAA, GX 2, at 1–3. On this application, Respondent answered “yes” to Liability Question 3. *Id.* at 3. Respondent entered the following narrative response explaining his “yes” answer to Liability Question 3: “My license was suspended in 1992, 22 years ago for failure to keep adequate records. I agreed to a consent order, rather than pay for an investigation at my expense. My license was suspended for 30 days. The license was suspended for 30 days and restored.” *Id.* at 6–7.

B. Prescriptions Issued in Violation of the CSA’s Requirement That Registrant Maintain Separate Registrations at Each Principal Place of Business or Professional Practice Where the Registrant Dispenses Controlled Substances

The Agency finds substantial record evidence for each of the following facts, which are uncontroverted. Respondent is a licensed dentist in both Delaware and New Jersey. RFAA, GX 3–6. Respondent’s DEA registration, BC5574048, was originally registered in the State of New Jersey, but Respondent applied to change the registered address to Delaware. RFAA, GX 1, at 1. On May

23, 2019, Respondent’s change of address application was approved, and the registered address for DEA registration BC5574048 became the State of Delaware. RFAA, GX 1, at 1. DEA registration BC5574048 has been registered to an address in Delaware ever since May 23, 2019. *Id.* Prior to that date, it was registered in New Jersey. *Id.*

The Agency finds substantial record evidence that, from June 19, 2019, to November 28, 2020, Respondent issued eight prescriptions⁹ for controlled substances using a State of New Jersey prescription pad bearing registration number BC5574048 and a place of business address in New Jersey. RFAA, GX 11–18. Respondent issued these New Jersey prescriptions even though he did not have a DEA registration in New Jersey at that time. RFAA, GX 1–2.

III. Discussion

A. The CSA and the OSC Allegations

Pursuant to the CSA, the Attorney General is authorized to suspend or revoke a registration “upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.” 21 U.S.C. 824(a)(1).

Also according 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).¹⁰ The five factors are

⁹ The eight prescriptions are: (1) acetaminophen-codeine 300/30 mg, Schedule III, issued to M.J. on June 19, 2019, RFAA, GX 11; (2) hydrocodone-acetaminophen 7.5/325 mg, Schedule II, issued to L.L. on July 13, 2019, RFAA, GX 12; (3) acetaminophen-codeine 300/30 mg, issued to R.J. on December 14, 2019, RFAA, GX 13; (4) tramadol 50 mg, Schedule IV, issued to G.B. on March 7, 2020, RFAA, GX 14; (5) diazepam 10 mg, Schedule IV, issued to T.R. on July 24, 2020, RFAA, GX 15; (6) tramadol 50 mg, issued to G.B. on October 14, 2020, RFAA, GX 16; (7) acetaminophen-codeine 300/30 mg, issued to C.M. on November 28, 2020, RFAA, GX 17; acetaminophen-codeine 300/30 mg, issued to N.F. on November 28, 2020, RFAA, GX 18. See also 21 CFR 1308.12–14.

¹⁰ 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.

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* public interest revocation case is confined to factors B and D.

According to DEA regulations, “[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e); see also *Morall*, 412 F.3d. at 174; 21 CFR U1301.44(d) (same as to the “denial of a registration”).

B. Material Falsification

As already discussed, Respondent submitted registration renewal applications in 2009, 2012, 2015, 2018, and 2021 and falsely answered “yes” to the third liability question regarding whether he ever surrendered (for cause) or had a state professional license revoked, suspended, denied, restricted, or placed on probation, or whether any such action is pending. *Supra* section II.A. Respondent answered “no” to the same liability question in 2004, 2006, and 2020. *Id.* The Agency finds based on clear, unequivocal, convincing, and uncontroverted evidence that these conflicting responses show that Respondent knew that his false answers on certain renewal applications were, in fact, falsities. *Frank Joseph Stirlacci, M.D.*, 85 FR 45237–40 (collecting cases).

Regarding materiality, the Supreme Court explained decades ago that “the ultimate finding of materiality turns on an interpretation of substantive law.” *Kungys v. United States*, 485 U.S. 759, 772 (1988) (citing a Sixth Circuit case involving 18 U.S.C. 1001 and explaining that, even though the instant case

(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.

concerned 8 U.S.C. 1451(a), “we see no reason not to follow what has been done with the materiality requirement under other statutes dealing with misrepresentations to public officers”). The Supreme Court also clarified that a falsity is material if it is “predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision.” 485 U.S. at 771.

Respondent’s false submissions are material under the Supreme Court’s materiality analysis because they are “capable of affecting . . . the [Agency’s] official decision.” *Id.* Indeed, Respondent’s falsifications relate to three of the five factors that the Agency must consider in determining whether an application is consistent with the public interest, and should be granted or denied: Factors A, B, and D. 21 U.S.C. 823(g); *Frank Joseph Stirlacci, M.D.*, 85 FR 45229, 45234–35 (2020). Therefore, Respondent’s falsifications directly implicate the Agency’s CSA mandated analysis and final decision by depriving it of legally relevant facts needed to decide whether to grant Respondent’s application. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 193 (2016) (“Under any understanding of the concept, materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.’”); *Maslenjak v. United States*, 582 U.S. 335, 348 (2017) (concluding that when “there is an obvious causal link between the . . . lie and . . . [the] procurement of citizenship,” the facts “misrepresented are themselves disqualifying” and the fact finder “can make quick work of that inquiry”). In other words, there is no doubt that Respondent’s falsifications were “predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision” the CSA instructs the Agency to make. *Kungys*, 485 U.S. at 771.

Consequently, the Agency must find, based on the CSA and the analysis underlying multiple Supreme Court decisions involving materiality, that Respondent’s false responses on multiple registration renewal applications dated 2009, 2012, 2015, 2018, and 2021 are material.

C. Unlawful Prescribing and Public Interest Analysis

Under the CSA, “[e]very person who dispenses¹¹ . . . any controlled substance, shall obtain from the

¹¹ “The term ‘dispense’ means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance” 21 U.S.C. 802(10).

Attorney General a registration issued in accordance with the rules and regulations promulgated by him.” 21 U.S.C. 822(a)(2). Moreover, “[a] separate registration [is] required at each principal place of business or professional practice where the [registrant] . . . dispenses controlled substances.” *Id.* § 822(e).

As already discussed, the Agency found substantial record evidence that while Respondent’s registered place of business was in Delaware, he issued multiple controlled substance prescriptions on a New Jersey prescription pad containing a New Jersey place of business. *Supra* section II.B. Because Respondent did not have a DEA registration in New Jersey when the prescriptions for controlled substances were issued, issuance of these prescriptions violated DEA’s separate registration requirement. The Agency finds that Respondent unlawfully issued controlled substance prescriptions, implicating Factors B and D. 21 U.S.C. 823(g); 21 U.S.C. 822(e); *Wedgewood Vill. Pharm., Inc. v. Ashcroft*, 293 F.Supp.2d 462, 467 (D.N.J. 2003). The Agency further finds that Respondent’s continued registration is inconsistent with the public interest. 21 U.S.C. 823(g)(1).

While Respondent initially requested a hearing, his non-compliance with prehearing proceedings resulted in his implied waiver of that right. As such, Respondent also waived the opportunity to present evidence and, therefore, to rebut the Government’s *prima facie* case. The Government’s *prima facie* case was established by substantial record evidence and clear, unequivocal, and convincing record evidence. *Supra* section II. Accordingly, the Agency finds that there is substantial, clear, unequivocal, convincing, and uncontroverted record evidence supporting the revocation of Respondent’s registration and denying his application for registration in New Jersey. 21 U.S.C. 824(a)(1) and (a)(4); 21 U.S.C. 823(g); *supra* section II.

IV. Sanction

Here, the Government has met its *prima facie* burden of showing that Respondent’s existing registration should be revoked and his application for a new registration denied due to his multiple material falsifications, and has shown that Respondent’s continued registration is inconsistent with the public interest due to his numerous violations pertaining to his controlled substance prescribing. Accordingly, the burden shifts to Respondent to show why he 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 FR 18882, 18904 (2018); *supra* sections II and III. The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *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 respondent and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972–73.

Regarding these matters, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations meaning, among other things, that it is not reasonable to believe that Respondent’s future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that he can be entrusted with a registration.

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

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

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C.

824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. BC5574048 issued to Robert Carter, D.D.S. 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 pending application Number W20128194C and any other pending application of Robert Carter, D.D.S., for registration in Delaware or New Jersey. This Order is effective March 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on February 3, 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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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Yogesh Patel, M.D.; Decision and Order

On June 7, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Yogesh Patel, M.D., of Grand Junction, Colorado (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. FP8684931, alleging that Registrant's registration should be revoked because Registrant is "currently without authority to handle controlled substances in Colorado, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a

hearing. RFAA, at 2.¹ "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).

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 Registrant's default pursuant to 21 CFR 1301.43(d), (e), (f)(1), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective on or about January 22, 2024, Registrant entered into a Non-Disciplinary Interim Cessation of Practice Agreement with the Colorado Medical Board that indefinitely prohibited him from "performing any act requiring a license issued by the Colorado Medical Board." RFAAX 1, at 1. According to Colorado online records, of which the Agency takes official notice, Registrant's Colorado medical license is under an "Active—Restricted" status and Registrant is not permitted to practice medicine.² Colorado Division of Professions and Occupations License Search, <https://apps2.colorado.gov/>

¹ Based on the Government's submissions in its RFAA dated August 1, 2024, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the included Declaration from a DEA Diversion Investigator (DI) indicates that on July 1, 2024, Registrant was personally served a copy of the OSC at a residence located in Illinois. RFAAX 2, at 1–2. Registrant also signed a DEA Form 12 acknowledging receipt of the OSC on this date. *Id.* at 2; RFAAX 3.

² 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 the Agency's finding by filing a properly supported motion for reconsideration of findings 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 DEA Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

<dora/licensing/lookup.aspx> (last visited date of signature of this Order).

Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Colorado, the state in which he is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "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, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) ("The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).") The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371, 71,372 (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).³

³ This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he 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(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he 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.