Accordingly, the Agency will order the revocation of Registrant's registration.

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 No. FO4353188 issued to Ndubuisi J. Okafor, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Ndubuisi J. Okafor, M.D., to renew or modify this registration, as well as any other pending application of Ndubuisi J. Okafor, M.D., for additional registration in Washington, DC. This Order is effective September 18, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 14, 2023, by Administrator Anne Milgram. 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. 2023–17794 Filed 8–17–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–27]

William Tuong, M.D.; Decision and Order

On July 2, 2021, the Drug Enforcement Administration (DEA) issued an Order to Show Cause (OSC) to William Tuong, M.D. (Respondent), of Wilmington, Delaware. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 9, at 1, 7. The OSC proposed the revocation of Respondent's DEA Certificate of Registration, Control No. BT1102653, alleging that Respondent has ''committed such acts as would render [his] registration inconsistent with the public interest.'' *Id.* at 1–2 (citing 21 U.S.C. 824(a)(4) and 823(g)(1) [1]).[2]

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA, which was received by the Agency on January 30, 2023.

I. Findings of Fact

A. Investigation of Respondent

DEA's investigation of Respondent found that between August 30, 2017, and August 28, 2019, Respondent issued seven prescriptions for 56–84 tablets of methadone 10 mg, eight prescriptions for 168 tablets of oxycodone [3] 30 mg, and four prescriptions for 56 tablets of oxymorphone 30 mg to a patient identified as Patient C.D. Declaration, at 1–2; RFAAX 2. Further, DEA's investigation found that between March 30, 2017, and July 18, 2019, Respondent issued thirteen prescriptions for 54–56 tablets of morphine sulfate [4] 100 mg and fourteen prescriptions for 135–168 tablets of oxycodone 30 mg to a patient identified as Patient K.G. Declaration, at 1–2; RFAAX 3. Finally, DEA's investigation found that between May 31, 2017, and August 22, 2018, Respondent issued eighteen prescriptions for 168–174 tablets of methadone 10 mg and eighteen prescriptions for 112–168 tablets of oxycodone 30 mg to a patient identified as Patient J.W. Declaration, at 1–2; RFAAX 4.[5]

B. The Government Expert's Review of Respondent's Prescriptions

The DEA hired Dr. Aviva Fohrer, M.D., to opine on Respondent's controlled substance prescribing based on, among other things, the patient files described above (RFAAX 2–4) and medical records for the patients in question that predated Respondent's treatment of the patients. Declaration, at 1. The Agency finds that Dr. Fohrer is an expert in the standard of care for prescribing controlled substances in Delaware and gives her Declaration full credit in this Decision. *See* RFAAX 5.

Prior to opining on each patient individually, Dr. Fohrer reviewed the relevant prescriptions and described the standard of care for prescribing controlled substances in Delaware. Declaration, at 2–4; *see also* RFAAX 2–4; RFAAX 8. Regarding the standard of care, Dr. Fohrer explained that ''[i]n addition to carefully justifying high-dose opioid prescriptions, practitioners must also ensure that their patients give valid informed consent prior to receiving these dangerous prescriptions.'' Declaration, at 3. Dr. Fohrer noted that ''[o]f special concern is methadone . . . [and] practitioners who prescribe methadone should generally not combine it with other opioids, outside of limited circumstances.'' *Id.* at 3–4. Dr. Fohrer also explained that practitioners must monitor patients who receive high-dose opioids ''to ensure they are not abusing or diverting controlled substances'' and that such monitoring ''should involve checking the prescription drug monitoring program (PDMP) reports and conducting urine drug screens.'' *Id.* at 3. Dr. Fohrer added that ''[w]here there are aberrant urine screen results, practitioners must adequately address the results.'' *Id.* Finally, Dr. Fohrer explained that practitioners should ''periodically attempt to wean patients off high-dose opioid prescriptions and discuss nonpharmacological and nonopioid pharmacological alternatives.'' *Id.*

1. Patient C.D.

On August 30, 2017, Respondent began treatment of Patient C.D., who was a pre-existing patient of Respondent's medical practice, and continued Patient C.D.'s prescriptions, issuing prescriptions to Patient C.D. for 56 tablets of methadone 10 mg and 168 tablets of oxycodone 30 mg. Declaration, at 4; *see also* RFAAX 2, at 156. According to Dr. Fohrer, ''[t]here was no justification in the medical record for this high-dose opioid prescription'' nor was there ''any justification for combining methadone with oxycodone.'' *Id.* Dr. Fohrer also noted that Respondent ''did not obtain Patient C.D.'s informed consent prior to issuing these dangerous prescriptions.'' *Id.*

Through at least August 28, 2019, Respondent continued to treat Patient

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[2] The Government represents that Respondent made a timely hearing request. RFAA, at 1. Subsequently on October 28, 2021, Respondent withdrew his hearing request and the proceedings were terminated. RFAAX 10, at 1.

[3] The patient files for Patients C.D., K.G., and J.W. indicate that Registrant prescribed Roxicodone, which is a brand name for oxycodone. RFAA, Attachment 2 (hereinafter, Declaration), at 2 n.1; *see also* RFAAX 2–4.

[4] Specifically, Respondent prescribed MS Contin, a brand name of morphine sulfate. Declaration, at 2 n.2.

[5] Oxycodone, methadone, oxymorphone, and morphine are all Schedule II controlled substances. 21 CFR 1308.12(b)(1)(ix), (b)(1)(xiv), (b)(1)(xv), (c)(15).

C.D., and, as Dr. Fohrer stated, ''none of the issues identified with the August 30, 2017, prescriptions were ever addressed.'' *Id.* Additionally, Dr. Fohrer explained that there was ''never any attempt to wean Patient C.D. off the high-dose opioids,'' nor did Respondent ''adequately monitor Patient C.D.'' or check the Delaware PDMP. *Id.*

Based on her expert medical opinion, Dr. Fohrer concluded, and the Agency agrees, that ''all [nineteen] controlled substance prescriptions that [Respondent] issued to Patient C.D. were issued outside the usual course of professional practice for the state of Delaware.'' *Id.*

2. Patient K.G.

On March 30, 2017, Respondent began treatment of Patient K.G., who was a pre-existing patient of Respondent's medical practice, and continued Patient K.G.'s prescriptions, issuing prescriptions to Patient K.G. for 56 tablets of morphine sulfate 100 mg and 168 tablets of oxycodone 30 mg. Declaration, at 5; *see also* RFAAX 3. According to Dr. Fohrer, ''[t]here was no justification in the medical record for this high-dose opioid prescription.'' *Id.* Dr. Fohrer also noted that Respondent ''did not obtain Patient K.G.'s informed consent prior to issuing these dangerous prescriptions.'' *Id.*

Through at least August 15, 2019, Respondent continued to treat Patient K.G., and, as Dr. Fohrer stated, ''none of the issues identified on the March 30, 2017 prescriptions were ever addressed.'' *Id.* Additionally, Dr. Fohrer explained that there was ''never any attempt to wean Patient K.G. off the medication,'' nor did Respondent ''adequately monitor Patient K.G.,'' or check the Delaware PDMP. *Id.*

Further, Dr. Fohrer stated that ''[e]ven more concerning, was [Respondent's] failure to properly address aberrant urine drug screens'' when, ''[o]n both October 12, 2017, and November 8, 2018, Patient K.G. tested positive for methamphetamine, an illicit controlled substance.'' *Id.* As Dr. Fohrer explained, ''[Respondent] fail[ed] to address these signs of diversion.'' *Id.*

Based on her expert medical opinion, Dr. Fohrer concluded, and the Agency agrees, that ''all [twenty-seven] controlled substance prescriptions that [Respondent] issued to Patient K.G. were issued outside the usual course of professional practice for the state of Delaware.'' *Id.*

3. Patient J.W.

On May 31, 2017, Respondent began treatment of Patient J.W., who was a pre-existing patient of Respondent's medical practice, and continued Patient J.W.'s prescriptions, issuing prescriptions to Patient J.W. for 168 tablets of methadone 10 mg and 168 tablets of oxycodone 30 mg. Declaration, at 6; *see also* RFAAX 4. According to Dr. Fohrer, ''[t]here was no justification in the medical record for this high-dose opioid prescription'' nor was there ''any justification for combining [the 'dangerous prescriptions' of] methadone with oxycodone.'' *Id.* Dr. Fohrer also noted that Respondent ''did not obtain Patient J.W.'s informed consent prior to issuing these dangerous prescriptions.'' *Id.*

Through at least July 30, 2019, Respondent continued to treat Patient J.W., and, as Dr. Fohrer stated, ''none of the issues identified on the May 31, 2017 prescriptions were ever addressed.'' *Id.* Dr. Fohrer explained that ''[t]here was also never any attempt to wean Patient J.W. off the medication,'' nor did Respondent ''adequately monitor Patient J.W.,'' or check the Delaware PDMP. *Id.*

Further, Dr. Fohrer stated that Respondent ''failed to adequately address [ ] clear signs of abuse and medication diversion'' present in Patient J.W.'s urine drug screen results. *Id.* Dr. Fohrer explained that ''[o]n June 27, 2018, Patient J.W. tested negative for all prescribed controlled substances, an indication of diversion.'' *Id.* ''This urine test was sent to a lab on June 28, 2018, and was confirmed negative for all prescribed medications as well as positive for methamphetamines, an illicit controlled substance.'' *Id.* Then, ''[o]n June 26, 2019, Patient J.W. again tested positive for methamphetamines.'' *Id.* According to Dr. Fohrer, ''[t]hese urine screens indicate that Patient J.W. was diverting the medication prescribed to him and acquiring illicit controlled substances.'' *Id.*

Based on her expert medical opinion, Dr. Fohrer concluded, and the Agency agrees, that ''all [thirty-six] controlled substance prescriptions that [Respondent] issued to Patient J.W. were issued outside the usual course of professional practice for the state of Delaware.'' *Id.* at 7; *see also* RFAAX 4.

II. Discussion

A. The Five Public Interest Factors

Under the Controlled Substances Act (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). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant'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. 21 U.S.C. 823(g)(1).

The DEA considers these public interest factors in the disjunctive. *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. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),[6] the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D. *See* RFAA, at 7–9. 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 Respondent's continued registration

[6] As to Factor A, there is no record evidence of disciplinary action against Registrant's state medical license. 21 U.S.C. 823(g)(1)(A). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of [a registrant's] DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). 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 49956, 49973 (2010). Agency cases have therefore found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.* As to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a). The Agency further finds that Respondent failed to provide sufficient evidence to rebut the Government's *prima facie* case.

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.,* 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). The Government has alleged that Respondent's prescribing practices violated both federal and Delaware state law. RFAAX 9, at 2–6. 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 CFR 1306.04(a). Moreover, Delaware law requires that ''[a] prescription for a controlled substance must be issued for a legitimate medical purpose by practitioner[s] acting in the usual course of their professional practice.'' 24 Del. Admin. Code CSA section 4.2.1.[7] Delaware law lists the requirements for the safe prescribing of opioid analgesics,[8] including that physicians must: obtain an Informed Consent form signed by the patient that includes information regarding the drugs potential for addiction, abuse, and misuse; query the Delaware Prescription Monitoring Program at least every six months for pain patients; document in a pain patient's medical record ''alternative treatment options that have been tried by the patient, including non-pharmacological treatments, and their adequacy with respect to providing sufficient management of pain.'' *Id.* sections 9.6.4, 9.8.1, 9.8.6. Delaware law also states that ''[s]pecial attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion.'' 24 Del. Admin. Code 1700 section 18.6. Finally, Delaware law defines actions by a practitioner subject to sanction to include the ''fail[ure] to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.'' Del. Code tit. 16, section 4735(b)(1).

Based on the credible and unrebutted opinion of the Government's expert, the Agency found above that Respondent's prescribing of the relevant controlled substance prescriptions to Patients C.D., K.G., and J.W. was outside the usual course of professional practice for the state of Delaware. *See supra* I.B. Specifically, Respondent gave no justification in the patients' medical records for issuing high-dose opioid prescriptions; did not obtain the patients' informed consent prior to issuing such prescriptions; made no attempt to wean the patients off such prescriptions, offer nonpharmacologic therapies, or offer alternative, nonopioid medications; and failed to adequately monitor the patients, with Respondent failing to check the Delaware PDMP. *Id.* Further, with regards to Patients C.D. and J.W., Respondent gave no justification for combining methadone with oxycodone, while with regards to Patients K.G. and J.W., Respondent failed to properly address aberrant urine drug screens that indicated both diversion and use of illicit controlled substances. *Id.*

In sum, the Agency finds that the record contains substantial evidence that Respondent prescribed 82 controlled substances in violation of both federal law, 21 CFR 1306.04, and state law, 24 Del. Admin. Code CSA sections 4.2.1, 9.6.4, 9.8.1, and 9.8.6. The Agency, therefore, finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1).

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

Here, although Respondent initially requested a hearing, he withdrew his hearing request and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Respondent has made no representations as to his future compliance with the CSA nor made any demonstration that he can be trusted with a registration. The evidence presented by the Government clearly shows that Respondent violated the CSA and indicates that he cannot be entrusted. Accordingly, the Agency will order the revocation of Respondent's registration.

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 No. BT1102653 issued to William Tuong, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of William Tuong, M.D., to renew or modify this registration, as well as any other pending application of William Tuong, M.D., for additional registration in Delaware. This Order is effective September 18, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 14, 2023, by Administrator Anne Milgram. 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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[7] Delaware law also provides that ''[a] prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a person engaged in substance abuse or misuse . . . for the purpose of continuing such person's dependence upon such drugs, unless otherwise authorized by law.'' *Id.* section 4.2.3.

[8] Delaware law defines an ''opioid analgesic'' as ''a drug that is used to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (synthetic drugs).'' *Id.* section 9.3. Delaware law includes methadone and morphine as specific examples of opioid analgesics. *Id.*