DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22-54]

Michael Gore, P.A.; Decision and Order

On August 26, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Michael Gore, P.A., (Respondent) of Staten Island, New York. OSC, at 1, 8. The OSC proposed the revocation of Respondent's DEA Certificate of Registration, Control No. MG1185277, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1), 1824(a)(4)), 2.

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (ALJ), who, on September 8, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 45. Respondent did not file Exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,2 findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD.

I. Findings of Fact

New York Standard of Care

Dr. Brian Durkin, D.O., testified for the Government as an expert in the area of pain management and the standard of care for prescribing controlled substances in the state of New York. RD, at 9; Tr. 367.3 Dr. Durkin practices as an anesthesiologist and pain management specialist and testified that his expert opinion regarding the standard of care in this case is informed by his experiences, the experiences of his colleagues (including physicians and advanced practice providers), and the medical societies that he participates in or leads. RD, at 8, 13; Tr. 363, 499.4 Dr. Durkin also testified that New York has codified the standards for the prescribing of opioids. RD, at 13; Tr. 500.

According to Dr. Durkin, under the standard of care in New York, a practitioner must establish a patient and provider relationship to prescribe controlled substances and must have a legitimate medical reason to prescribe opioids. RD, at 9; Tr. 368, 383. Further, the practitioner must form a diagnosis and treatment plan after reviewing the patient's full medical history,5 conducting a physical examination, and ordering any necessary tests or referring the patient to a specialist. RD, at 9; Tr. 368, 370-71. Dr. Durkin explained that a proper physical examination requires an initial observation of the patient's

presentation and functionality, followed by a targeted physical examination related to the patient's pain complaint, including tests aimed at diagnosing specific causes of pain. RD, at 10; Tr. 377-78, 494-95, 550. According to Dr. Durkin, a physical examination should be conducted during every encounter, including initial visits, follow-up visits, telehealth visits, and in-person visits. RD, at 10; Tr. 384. Dr. Durkin testified that an in-person physical examination is more involved than a virtual examination, but the physician can still examine the patient virtually, for example, by listening to the patient's voice to see if his words are slurred and observing the patient's state of mind. RD, at 10, 20; Tr. 383-84, 419-20.

Regarding documentation, Dr. Durkin testified that the standard of care requires that practitioners document history and physical examinations in patient records to: 1) guide the diagnosis, treatment plan, and any decisions about diagnostic testing; 2) make the patient's care more efficient and cost-effective; and 3) generate a robust record for future providers. RD, at 11; Tr. 378–81. Dr. Durkin also noted that the standard of care requires that practitioners not falsify patient records. RD, at 9–10; Tr. 549–50.

Regarding the prescribing of opioids to treat pain, Dr. Durkin testified that opioids may be the first line of treatment for acute or severe pain, such as pain following surgery, provided that they are prescribed for no more than three to seven days. RD, at 11; Tr. 368. In contrast, with chronic pain lasting three months or more, there are other modalities that are safer and more effective than opioid therapy. Id. These modalities should be assessed based on their level of invasiveness and risk. RD, at 11; Tr. 369. Dr. Durkin explained that if less-invasive options, such as surgery and physical therapy, have failed, the practitioner should begin medication management with the less risky medications, such as anti-inflammatory drugs and muscle relaxants. RD, at 11; Tr. 369, 371-72, 405. If all of these options fail, then a practitioner may consider opioid therapy, but the practitioner needs to weigh the risks (ranging from mild issues to death) and benefits to the patient. Id.

Dr. Durkin testified that prior to beginning opioid therapy, the physician must obtain informed consent by discussing the risks and benefits of treatment. RD, at 12; Tr. 374–75, 405. Informed consent typically involves a written agreement, signed by the patient (and a witness), that outlines the risks, benefits, rules, and guidelines of opioid treatment, as well as compliance

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 Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALI's assessment of each of the witnesses' credibility. See RD, at 2-22. The Agency agrees with the ALJ that the testimony from the DEA Diversion Investigator (DI), which was primarily focused on the introduction of the Government's documentary evidence, was generally consistent, without indication of any animosity towards Respondent. and thus was fully credible and warranted substantial weight. Id. at 4-5. The Agency also agrees with the ALJ that the testimony from the DEA Special Agent (SA), which was primarily focused on the introduction of the Government's documentary evidence and how the undercover visits were conducted, was generally consistent, without indication of any animosity towards Respondent, and thus was fully credible and warranted substantial weight. Id. at 8. Finally, the Agency agrees with the ALJ that the testimony from the Government's expert witness, Dr. Brian Durkin, D.O., which was focused on the New York standard of care and Respondent's prescribing to the Undercover Officer, presented an objective analysis that was internally consistent, logically persuasive, credible, reliable, and warranted significant weight. Id. at 22.

 $^{^{\}rm 3}\, \rm On$ cross-examination, Dr. Durkin testified that the standard of care varies geographically based on the specialists available to patients that live in a given locality; nonetheless, all practitioners in New York are required to complete an opioid prescribing course every two years that establishes guidelines for prescribing opioids in New York. RD, at 12–13; Tr. 497-98, 501-02. When asked to clarify his testimony regarding a regional standard of care, Dr. Durkin testified that the regional aspect was confined to the availability of specialists, and provided as an example that a general practitioner could be competent to deliver a baby in a rural community without obstetricians but is likely not competent and should not offer obstetric services in an urban environment with many local obstetricians. RD, at 13 n.21; Tr. 554-56. Regarding the current matter, Dr. Durkin opined that Respondent's care fell below the standard of care in every New York region and community "because nothing was ever done to address the problem or make a correct diagnosis," as required throughout the state. RD, at 13 n.21; Tr. 556-57.

⁴ For Dr. Durkin's full qualifications, *see* Government Exhibit (GX) 19; RD, at 8–9.

⁵Dr. Durkin testified that a full medical history includes past medical history, past surgical history, a social history, and family history; a full medical history also sometimes focuses on a particular part of the body depending on the complaint of pain, but is always aimed at assessing a patient's overall health. RD, at 9; Tr. 369–70. Dr. Durkin also testified that a practitioner needs records from previous treating providers to make sure that the treatment is not repetitive and to make sure that the patient is treated safely, effectively, and cost effectively. RD, at 9 n.18; Tr. 370.

measures that will be utilized to prevent diversion and abuse, such as urinalysis and pill counts. RD, at 12, 13; Tr. 374–76, 405, 469–71. Dr. Durkin testified that a prescriber must also review a patient's I–STOP ⁶ data, history of addiction and substance abuse, and family history of addiction before prescribing opioids. RD, at 12; Tr. 372–74. Finally, practitioners must address any red flags of abuse or diversion to ensure that the medications that they prescribe are being used safely and legitimately. RD, at 19; Tr. 413–14.

Regarding follow-up visits, Dr. Durkin testified that a provider must assess the effectiveness of the treatment plan, including, (1) whether the patient has tried alternative therapies such as physical therapy, (2) how the patient is progressing in the treatment plan, and (3) the efficacy of any prescribed medications as well as any side effects. RD, at 19–20; Tr. 418–19. For opioid medications in particular, the provider must also conduct an ongoing risk assessment, document functional improvements, and determine whether weaning off or increasing the medication is needed. Id.

Respondent's Treatment of the Undercover Officer

March 11, 2021 Visit

Dr. Durkin reviewed audiovisual recordings of the interactions between Respondent and an Undercover Officer (UC), transcripts of the recordings, the UC's medical records, and the prescription history for the UC. RD, at 13; Tr. 387, 469. The UC first visited Respondent on March 11, 2021, complaining of shoulder pain. RD, at 15; Tr. 388–89, 493; GX 2; GX 3, at 4. The UC reported having pain for ten years, that he had not had any diagnostic imaging done, and that he took his girlfriend's oxycodone because she had insurance. RD, at 15; Tr. 389; GX 1, at 1; GX 2; GX 3, at 4.

Dr. Durkin testified that a physician acting within the standard of care would have made a diagnosis and developed a treatment plan (as described above), after conducting a focused physical examination of the UC's cervical spine, shoulders, and upper extremities, and ordering imaging of those areas. RD, at 15; Tr. 390–91.7 Respondent

documented a very thorough physical examination of the UC-including a full vascular, muscular, and neurological examination and range of motion testing—but Dr. Durkin's review of the video recording revealed that the actual physical examination that Respondent performed was "[not] anywhere close to what [was] documented in the medical record." RD, at 17; Tr. 400; GX 1, at 2-4. According to Dr. Durkin, Respondent's examination of the UC appeared to take about twelve seconds, whereas the examination documented in the medical file would have taken a neurologist ten or fifteen minutes to complete. RD, at 17; Tr. 400-01; GX 2; GX 3, at 6. Moreover, while there was a documented pain score in the record, Dr. Durkin saw "no indication that there was a pain score asked [about] during the audio visual or in the transcripts. Tr. 402; see also RD, at 17; GX 1, at 2; GX 2; GX 3, at 3-11. As such, Dr. Durkin concluded that the notes in the UC's patient file do not accurately reflect what happened during the March 11, 2021 visit. RD, at 17; Tr. 401.

Regarding Respondent's patient notes from this visit, Dr. Durkin testified that the "Past Medical/Surgical History" section should have detailed any chronic medical problems and past surgeries; however, this section in the UC's medical file is blank. RD, at 16; Tr. 391. Further, based on the recording of this visit, Respondent did not ask the UC about his medical or surgical history, did not request any medical files or imaging studies from previous providers, and did not order any diagnostic imaging. RD, at 16; Tr. 391-93; GX 1; GX 2; GX 3, at 3-10. Dr. Durkin testified that this is "Medicine 101" and that the "heart and soul of medicine is getting a history, a physical examination, and confirmation with testing." RD, at 16; Tr. 392-93. Regarding a patient's history in particular, providers need to know what treatments the patient has tried, whether they have worked, and whether nonopioid medications have been trialed. RD, at 16; Tr. 392-394, 396.8

As for the "Medications" and "Allergies" sections of Respondent's patient notes from the initial visit, Dr. Durkin noted that these sections are blank in the UC's medical file despite

the UC telling Respondent: (1) that he had been taking oxycodone 20 mg (which was prescribed to his girlfriend) several times a day; and (2) that he is allergic to penicillin and sulfa antibiotics. RD, at 16; Tr. 395-398, 549; GX 1, at 1–2; GX 2; GX 3, at 4–5. As for the "Social History" section, Dr. Durkin testified that Respondent did not ask the UC about his history of smoking or alcohol during the initial visit but Respondent documented that the UC does not use alcohol or tobacco. RD, at 16; Tr. 398; GX 1, at 2; GX 2; GX 3, at 11. Further, despite the UC reporting his use of oxycodone (not prescribed to him) three weeks prior to the visit, the "Social History" section indicates that the UC was not using drugs. RD, at 16; Tr. 399-400; GX 1, at 2; GX 2; GX 3, at

Regarding the "Assessment" section of the UC's patient file, Dr. Durkin testified that this is where the "working diagnosis" should be located. RD, at 17-18; Tr. 403. For a patient complaining of chronic shoulder pain, Dr. Durkin explained that an appropriate diagnosis based solely on a history and physical examination would be chronic shoulder pain or acute shoulder pain. RD, at 18; Tr. 403. However, Respondent documented that the UC had a herniated disc and lumbar radiculopathy, which are diagnoses that cannot be made without imaging, or justified by the limited physical examination that Respondent conducted; Dr. Durkin therefore concluded that these assessments do not make sense. RD, at 18, 20; Tr. 403-04, 423-24; GX 1, at 4. Dr. Durkin further noted that while the UC only complained of shoulder pain, the "Assessment" section references back and leg pain with no mention of shoulder pain or a working diagnosis related to the shoulder pain. RD, at 18; Tr. 404. As such, Dr. Durkin concluded that no steps were taken to hone in on an actual diagnosis. Id.

Overall, Dr. Durkin opined that Respondent's prescribing of 90 tablets of oxycodone 10 mg to the UC on the UC's initial March 11, 2021 visit was "clearly outside the bounds of legitimate prescribing of opioids." RD, at 19; Tr. 408; see GX 1, at 4. Dr. Durkin testified that Respondent's diagnosis of the UC did not resemble the UC's complaint or justify opioid therapy, despite Respondent's attempts to generate inaccurate paperwork to justify the prescribing. Id. Dr. Durkin further testified that issuing an opioid prescription without an established diagnosis is outside the standard of care and that the oxycodone prescription issued to the UC was not issued for a legitimate medical purpose by a

⁶ I–STOP, New York's Prescription Monitoring Program, includes a record of controlled substances prescribed to a patient in New York. RD, at 6 n. 12, 12; Tr. 372–73. This data is analyzed to ensure that patients are not doctor shopping or receiving opioids from multiple providers. RD, at 12; Tr. 383.

⁷ On cross-examination, Dr. Durkin was asked how an uninsured patient can afford diagnostic imaging. RD, at 15 n.26; Tr. 509–15. Dr Durkin testified that Respondent could have helped the UC

find an affordable Medicaid plan that would cover imaging or could have referred the UC to a university hospital for free or low-cost imaging and "charity care." *Id.*

⁸ On cross-examination, when asked about the UC having a fictious identity with no prior medical history or records, Dr. Durkin opined that this lack of history and records should have generated additional red flags of abuse or diversion. RD, at 16 n 27: Tr. 502–04

practitioner acting within the normal course of professional practice. RD, at 19; Tr. 408–09, 415. Dr. Durkin noted that the UC presented himself as a highrisk patient by admitting to using opioids that were not prescribed to him, as well as presenting with other concerning factors such as his age and lack of documented treatment history, yet Respondent failed to conduct a sufficient risk assessment. RD, at 19; Tr. 409-11. Additionally, Respondent completely ignored red flags of abuse and diversion and therefore disregarded the risks associated with prescribing oxycodone to the UC. Id. Dr. Durkin also testified that Respondent failed to obtain informed consent from the UC for prescribing opioids because he failed to discuss the risks of opioids, possible interactions with other substances, and proper storage and disposal, and failed to advise the UC to discontinue the opioids if they were not effective. RD, at 18-19; Tr. 405-406.9

Follow-Up Visits (April 2021–October 2021)

Regarding the UC's follow-up visit to Respondent on April 8, 2021, Dr. Durkin testified that he would expect to see in the "History of Present Illness" section of the medical file an assessment of the UC's functional gains and improvements related to the treatment plan, whether the UC's condition had worsened, and how the UC was doing since the last visit. RD, at 20; Tr. 420-21. However, Dr. Durkin testified that the visit was very brief, lasting approximately one minute, and Respondent's examination of the UC was only "a quick look at the patient as he popped his head in the room." RD, at 20; Tr. 420. Dr. Durkin testified that

despite this, the notes in the "History of Present Illness" section are, again, far more extensive than what actually occurred during the visit and the patient record does not accurately reflect the visit. RD, at 20; Tr. 421-22; GX 1, at 6-9; GX 4, GX 5, at 1–2. According to Dr. Durkin, although the patient file indicates that a thorough examination and pain assessment took place, including notes of symptoms that were not discussed, the actual April 8, 2021 visit only consisted of a "how are you doing, we'll see you next month[,]... I'll send in your prescription refills." RD, at 20; Tr. 421-22; GX 1, at 6-8; GX 4; GX 5, at 1–2. In addition to continuing to include the unsupported diagnoses of herniated discs and lumbar radiculopathy, the medical records also falsely indicate that Respondent checked I-STOP, executed an opioid agreement with the UC, discussed physical therapy, and reviewed the pain management policies of Respondent's practice, as well as the expectations of opioid treatment and treatment goals. RD, at 20-21; Tr. 423-26; GX 1, at 9; GX 4; GX 5, at 1-2.

Dr. Durkin testified that Respondent did not obtain the UC's informed consent for continued opioid treatment and that Respondent could not have adequately examined the UC to justify prescribing opioids during this oneminute visit. RD, at 21; Tr. 424, 426–27. Ultimately, Dr. Durkin opined that the prescription for 90 tablets of oxycodone 10 mg issued by Respondent to the UC on April 8, 2021, was not issued for a legitimate medical purpose by a practitioner acting within the normal course of professional practice. RD, at 21; Tr. 427; see GX 1, at 9.

Regarding the UC's approximately monthly follow-up visits (both inperson and via telehealth) to Respondent through October 2021, Dr. Durkin again observed concerning deficiencies and contradictions between the recordings and the medical records similar to his concerns with the initial visit. RD, at 21-22; Tr. 427-462; GX 1, at 10-26; GX 6; GX 7, at 1-3; GX 8; GX 9, at 1-2; GX 10; GX 11; GX 12; GX 13, at 1-5; GX 14; GX 15; see also GX 17, at 1, 5, 6, 9, 10, 12. Ultimately, Dr. Durkin opined that the prescriptions issued by Respondent to the UC, each for 90 tablets of oxycodone 10 mg, were not issued for a legitimate medical purpose by a practitioner acting within the normal course of professional practice. RD, at 21-22.

In sum, based on his review of the recordings and the related medical records of the UC's visits with Respondent, Dr. Durkin opined that all of the prescriptions issued by

Respondent to the UC for oxycodone were not issued for a legitimate medical purpose by a practitioner acting within the normal course of professional practice. RD, at 22; Tr. 461. Dr. Durkin further opined that Respondent's prescribing of oxycodone to the UC was likely to cause harm to the UC and fell below the standard of care for a practitioner in New York. RD, at 22; Tr. 462.

Respondent offered no testimony or documentary evidence and did not present a case-in-chief. RD, at 22.

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 [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.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a caseby-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).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its prima facie case for revocation of Respondent's registration is confined to Factors B and D. RD, at 25; see also id. at 25 n.32 (finding that Factors A, C, and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ,

⁹On cross-examination, Dr. Durkin was asked whether his opinions would change if the UC had filled out an intake form or pain management agreement that was not included in the files that he reviewed, RD, at 14-15; Tr. 469, 474-76, 479-80. 534-35, 546-49, 551-53, 481-87. Dr. Durkin testified that these documents would not change his opinions. Id. Although intake forms can be a good starting point to initiate a patient visit, they do not absolve a physician of the duty to have the necessary discussions with his patient to establish a diagnosis or treatment plan. RD, at 14-15; Tr. 479–80, 534–35. And if a patient had filled out a pain management agreement prior to the visit that the physician did not discuss with the patient during the visit, it would generate an additional red flag because it would indicate that the practice was prescribing opioids readily. RD, at 15; Tr. 548, 552-53. Moreover, the Agency may infer from Respondent's failure to produce these forms that they would not be supportive of his case. Pharmacy Drs. Enters., 83 FR 10876, 10899 (2018) ("[W]hen a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him."); UAW v. NLRB, 459 F.2d 1329, 1338 (D.C. Cir. 1972); Huthnance v. DC, 722 F.3d 371, 378 (D.C. Cir. 2013).

adopts the ALJ's analysis, and finds that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4); RD, at 22–41.

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). In the current matter, the Government has alleged that Respondent violated numerous Federal and State laws regulating controlled substances. OSC/ ISO, at 1–2. Specifically, Federal law requires that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a).¹⁰ As for state law, New York regulations also provide that a controlled substance may only be prescribed by "[a] practitioner, in good faith, and in the course of his or her professional practice." N.Y. Pub. Health Law section 3331(2); 11 see also N.Y. Comp. Codes R. & Regs. tit. 10, sections 80.62(a) (practitioners "in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment . . . "), 80.65 (prescriptions for controlled substances "shall be issued for legitimate medical purposes only"), 94.2(e)(2) (a physician assistant may only prescribe controlled substances "in good faith and acting within his or her lawful scope of practice"). Further, New York state law provides that a practitioner's license "may be revoked . . in whole or in part upon a finding that the licensee or certificate holder has . . . falsified any [required] application, report, or record" or "failed to maintain effective control against diversion of controlled substances " N.Y. Pub. Health Law section 3390(1), (5).

In the current matter, the Agency agrees with the ALJ's analysis that Respondent repeatedly issued controlled substance prescriptions outside the usual course of professional practice and not for a legitimate medical purpose because, as detailed above, Respondent failed to adequately examine, evaluate, and diagnose the UC to medically justify prescribing him controlled substances, and failed to address red flags of abuse and/or diversion before issuing the prescriptions. RD, at 27-28. Further, Respondent repeatedly and egregiously falsified the UC's medical records, documenting physical examinations, compliance measures, and patientdoctor discussions that did not occur. Id. As Respondent's conduct displays clear violations of the federal and state regulations described above, the Agency agrees with the ALJ and hereby finds that Respondent repeatedly violated federal and state law relating to controlled substances. RD, at 41. Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's continued 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 sufficient 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, 18904 (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). 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 requested a hearing and submitted a prehearing statement, Respondent ultimately offered no testimony or documentary evidence and did not present a case-inchief. Respondent's failure to demonstrate any remorse for his actions or offer any assurances about his future compliance weigh strongly against continued registration because his

conduct did much to diminish his credibility with the Agency.

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. Daniel A. Glick, D.D.S., 80 FR 74800, at 74810 (2015). In this case, the Agency agrees with the ALJ that the interests of specific deterrence weigh in favor of revoking Respondent's registration. RD, at 44; GX 1-17. Further, the Agency agrees with the ALJ that the interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that prescribing controlled substances without conducting and documenting even the most basic treatment-related evaluations and examinations can be overlooked or excused. RD, at 44.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. Id. at 43-44. Not only did Respondent fail to complete all of the necessary components of a proper medical examination to justify the prescribing of opioids, he flagrantly falsified the UC's medical record presumably to evade government scrutiny. Notably, Respondent documented a detailed evaluation and examination of the UC that did not occur. Id. at 44. This indicates that Respondent was well acquainted with his professional and legal obligations, yet chose to disregard them, despite the serious dangers the prescribed controlled substances posed to the UC, an admitted abuser, and the community. Further, Respondent fabricated diagnoses that were neither tied to the UC's initial complaint nor supported by any imaging that would be necessary to reach such diagnoses. In this case, the Agency believes that revocation of Respondent's registration would deter Respondent and encourage the general registrant community to take caution when prescribing controlled substances and ensure that their medical records are thorough and accurate.

In sum, Respondent has not offered any credible evidence on the record to rebut the Government's case for revocation of his registration and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. RD, at 45. Accordingly, the Agency will order that Respondent's registration be revoked.

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. MG1185277 issued

¹⁰ The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. Ruan v. United States, 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

¹¹ A "practitioner" is defined as "[a] physician . . . or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice" N.Y. Pub. Health Law section 3302(27).

to Michael Gore, P.A. 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 Michael Gore, P.A., to renew or modify this registration, as well as any other pending application of Michael Gore, P.A., for additional registration in New York. This Order is effective July 29, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 21, 2024, 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. 2024–14195 Filed 6–27–24; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lisa Jones, N.P.; Decision and Order

On July 18, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Lisa Jones, N.P. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. MJ7465289 in Wilkesboro, NC 28659. Id. at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of North Carolina, the state in which [she is] registered with DEA." Id. at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of her right to file with DEA a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* (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] 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(c), (f), 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 March 13, 2023, the North Carolina Board of Nursing inactivated Respondent's nurse practitioner license. RFAAX 2, at 1. According to North Carolina online records, of which the Agency takes official notice, Registrant's nurse practitioner license is under an 'Inactive'' status.2 North Carolina Board of Nursing License Verification Search, https://portal.ncbon.com/license verification/search.aspx (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed as a nurse practitioner in North Carolina, the state in which she 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. See, e.g., James L. Hooper, D.O., 76 FR 71371, 71372 (2011), pet. for rev. denied, 481 F. App'x 826 (4th Cir. 2012); Frederick Marsh Blanton, D.O., 43 FR 27616, 27617 (1978).3

According to North Carolina statute, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery." N.C. Gen. Stat. Ann. section 90-87(8) (West 2023). Further, a "practitioner" means a "physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State." Id. at section 90-87(22)(a).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice as a nurse practitioner in North Carolina. As discussed above, an individual must be a licensed practitioner to dispense a controlled

¹ Based on the Government's submissions in its RFAA dated September 21, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Government's included Notice of Service of Order to Show Cause asserts that Registrant was personally served with the OSC on July 27, 2023. RFAAX 1, at 1. The Government notes that "[Registrant] did not agree to sign a Form DEA—12 acknowledging receipt of the [OSC]." *Id.*

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.

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, 76 FR 71371–72; Sheran Arden Yeates, D.O., 71 FR 39130, 39131 (2006); Dominick A. Ricci, D.O., 58 FR 51104, 51105 (1993); Bobby Watts, D.O., 53 FR 11919, 11920 (1988); Frederick Marsh Blanton, 43 FR 27617.