affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The Eastern Washington University has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- There is a connection between the human remains described in this notice and the Suquamish Indian Tribe of the Port Madison Reservation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 22, 2024. If competing requests for repatriation are received, the Eastern Washington University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Eastern Washington University is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 11, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–24417 Filed 10–22–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David Carlos Rodriguez, M.D.; Decision and Order

On September 11, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to David Carlos Rodriguez, M.D. (Registrant), of Lake City, South Carolina. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 7. The OSC proposed the revocation of Registrant's DEA Certificate of Registration (registration) No. BR6910803, alleging that Registrant has committed such acts as would render his registration inconsistent with the public interest. *Id.* at 3 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).[1]

The OSC notified Registrant of his right to file with DEA 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 5–6 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.[2] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

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.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted.[3] Registrant is deemed to have admitted and the Agency finds that from at least January 2018 through at least January 2019, Registrant issued multiple controlled substance prescriptions to five patients that lacked a legitimate medical purpose and were issued outside the usual course of professional practice. RFAAX 1, at 3, 5.

A. Prescribing to C.R.

Registrant is deemed to have admitted that between May 2018 and December 2018, on approximately a monthly basis, Registrant issued prescriptions for various quantities of oxycodone 30 mg (a Schedule II opioid) to C.R. RFAAX 1, at 3. Registrant issued these controlled substance prescriptions without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits, and treatment options with the patient. *Id.* Further, during several of C.R.'s visits to Registrant's office, Registrant engaged in sexual conduct with C.R. prior to issuing C.R. the prescriptions. *Id.*

B. Prescribing to K.D.

Registrant is deemed to have admitted that between January 2018 and December 2018, on an approximately monthly basis, Registrant issued prescriptions for various quantities of alprazolam 2 mg (a Schedule IV benzodiazepine), zolpidem tartrate 10 mg (a Schedule IV sedative), and dextroamphetamine-amphetamine 20 mg (a Schedule II stimulant) to K.D. *Id.* at 4. Registrant issued these controlled substance prescriptions without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits, and treatment options with the patient. *Id.*

C. Prescribing to R.R.

Registrant is deemed to have admitted that between October 2018 and December 2018, on an approximately monthly basis, Registrant issued prescriptions for various quantities of alprazolam 0.5 mg and acetaminophen-hydrocodone 325/10 mg (a Schedule II opioid) to R.R. *Id.* Again, Registrant issued these controlled substance prescriptions without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits, and treatment options with the patient. *Id.* On several of these occasions, Registrant prescribed opioids with a benzodiazepine, which Registrant is deemed to have admitted is a drug cocktail that is associated with diversion, without adequately documenting his reasoning for issuing

[1] According to Agency records, Registrant's registration expired on April 30, 2024. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474, 68,476–68,479 (2019).

[2] Based on the Government's submissions in its RFAA dated December 5, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the RFAA indicates that on October 16, 2023, Registrant was personally served with the OSC by a DEA Diversion Investigator. RFAA, at 1; RFAAX 2.

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

prescriptions for an opioid and benzodiazepine.[4] *Id.* at 4.

D. Prescribing to T.F.

Registrant is deemed to have admitted that between April 2018 and November 2018, on an approximately monthly basis, Registrant issued prescriptions for various quantities of oxycodone 10 mg, oxycodone 15 mg, and alprazolam 1 mg to T.F. *Id.* Registrant also issued a prescription for testosterone 200 mg (a Schedule III steroid) to T.F. *Id.* Registrant issued these controlled substance prescriptions without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits, and treatment options with the patient. *Id.* Registrant admits that he increased the oxycodone dosage from 10 mg to 15 mg without medical justification. *Id.* As with R.R., on several of these occasions, Registrant prescribed opioids with a benzodiazepine to T.F. without adequately documenting his reasoning. *Id.* at 4–5.

E. Prescribing to B.P.

Between March 2018 and December 2018, on an approximately monthly basis, Registrant issued prescriptions for various quantities of acetaminophen-oxycodone 325/10 mg (a Schedule II opioid), lisdexamfetamine 30 mg (a Schedule II stimulant), and lisdexamfetamine 40 mg to Patient B.P. *Id.* at 5. Registrant issued these controlled substance prescriptions without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits, and treatment options with the patient. *Id.* Furthermore, Registrant admits that he increased the lisdexamfetamine dosage from 30 mg to 40 mg without medical justification. *Id.*

F. Inadequate and Fraudulent Patient Records

In addition to his improper prescribing detailed above, Registrant is deemed to have admitted that on December 11, 2018, in response to a subpoena, his office represented to the South Carolina Department of Labor, Licensing and Regulation Office of Investigations and Enforcement that his office had no documentation for patients C.R, K.D., R.R., T.F., and B.P. *Id.* Registrant is also deemed to have admitted that on August 15, 2019, pursuant to a search and seizure warrant from the South Carolina Department of Health and Environmental Control, his office provided fraudulent and doctored patient records. *Id.*

G. The Government's Expert

According to the OSC, DEA retained an independent medical expert to review information regarding all of the controlled substance prescriptions detailed above, as well as Registrant's patient files for Patients C.R., K.D., R.R., T.F., and B.P. *Id.* Based on Registrant's numerous deviations from the standard of care, the medical expert concluded, and Registrant is deemed to have admitted, that the prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *Id.* Accordingly, Registrant is deemed to have admitted and the Agency finds that the above-listed controlled substance prescriptions were issued beneath the standard of care. *Id.*

II. Discussion

A. The Five Public Interest Factors

Under the 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 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),[5] the Government's evidence in support of its *prima facie* case for revocation of Registrant's registration is confined to Factors B and D. *See* RFAAX 1, at 3. 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 Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

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 Registrant violated both federal and state law regulating controlled substances. RFAAX 1, at 1–3. Specifically, under federal regulations, a prescription for a controlled substance is valid only if ''issued for a legitimate medical purpose

[4] The OSC also alleges that Registrant's combined prescribing of an opioid and a benzodiazepine ''disregarded the Centers for Disease Control and Prevention (CDC) guidance to 'use particular caution when prescribing opioid pain medication and benzodiazepines concurrently.' '' *Id.* (*citing CDC Guidelines for Prescribing Opioids for Chronic Pain,* 71 Morbidity and Mortality Weekly Report, 3, 16 (2022)). The Summary for the CDC Guidance carefully states that its ''[r]ecommendations should not be applied as inflexible standards of care across patient populations.'' *CDC Guidelines for Prescribing Opioids for Chronic Pain,* at 1. Accordingly, the Agency's decision relies not on the CDC Guidelines, but on the Government's Expert, who opined that Registrant had ''numerous deviations from the standard of care.'' RFAAX 1, at 5.

[5] As to Factor A, the record contains no evidence of a recommendation from any state licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence ''does not weigh for or against a determination as to whether continuation of the [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). Agency cases have found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Finally, 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.

by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

As for South Carolina state law, grounds for disciplinary action against a physician include when the physician has: ''engaged in dishonorable, unethical, or unprofessional conduct that is likely either to deceive, defraud, or harm the public''; ''violated the code of medical ethics adopted by the [State Board of Medical Examiners] or has been found by the [State Board of Medical Examiners] to lack the ethical or professional competence to practice''; ''failed to prepare or maintain an adequate patient record of care provided''; ''engaged in behavior that exploits the physician-patient relationship in a sexual way''; and ''improperly managed medical records, including failure to maintain timely, legible, accurate, and complete medical records.'' S.C. Code Ann. § 40–47–110.

Further, South Carolina regulations require that prior to prescribing to a patient, a physician must establish a proper physician-patient relationship, which entails that the physician ''make an informed medical judgment based on the circumstances of the situation and on the [physician's] training and experience''; ''personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan''; ''discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options''; and ''ensure the availability of the [physician] or coverage for the patient for appropriate follow-up care.'' *Id.* § 40–47–113(A).[6]

Here, consistent with Registrant's admissions, the Agency finds that Registrant repeatedly issued prescriptions for controlled substances without conducting an appropriate evaluation, without making a proper diagnosis, without providing a therapeutic plan, and without discussing the risks, benefits and treatment options with his patients. RFAAX 1, at 3–5. Registrant has also admitted and the Agency finds that Registrant: engaged in sexual conduct with a patient prior to issuing the patient prescriptions for controlled substances; issued a cocktail prescription of opioids and a benzodiazepine to multiple patients on multiple occasions while failing to document his reasoning for so doing; and increased the dosages of controlled substance prescriptions for multiple patients without medical justification for so doing. *Id.* Based on Registrant's numerous deviations from the standard of care, DEA's medical expert concluded, and the Agency finds, that these prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *Id.* at 5. Registrant has further admitted that he failed to provide adequate patient records to one group of state officials, then provided fraudulent patient records to another group of state officials. *Id.* As such, the Agency finds that Registrant violated 21 CFR 1306.04(a) and South Carolina Code §§ 40–47–110 and 40–47–113.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Registrant's registration and thus finds Registrant's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Registrant failed to provide any evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds for revocation, 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). To establish that he can be entrusted with registration, a registrant 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); *see also Michele L. Martinho, M.D.,* 86 FR 24012, 24019 (2021); *George D. Gowder, III, M.D.,* 89 FR 76152, 76154 (2024). 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, Registrant failed to answer the allegations contained in the OSC and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted.

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. BR6910803 issued to David Carlos Rodriguez, 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 David Carlos Rodriguez, M.D., to renew or modify this registration, as well as any other pending application of David Carlos Rodriguez, M.D., for additional registration in South Carolina. This Order is effective November 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 15, 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. 2024–24575 Filed 10–22–24; 8:45 am]

BILLING CODE 4410–09–P

[6] South Carolina Code of Regulations § 81–60, entitled Principles of Medical Ethics, states in subsection A that ''a physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.''

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1438]

Bulk Manufacturer of Controlled Substances Application: Irvine Labs, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Irvine Labs, Inc. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.