controlled substance license, stating that ''[a] registration under Section 303 to manufacture, distribute, or dispense a controlled substance . . . may be denied, refused renewal, suspended, or revoked by the Department of Financial and Professional Regulation.'' *Id.* at 570/304(a).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to handle controlled substances in Illinois as his Illinois medical license is suspended and his Illinois controlled substance license is inoperative. As already discussed, a practitioner must hold a valid controlled substance license to dispense a controlled substance in Illinois. Thus, because Registrant lacks authority to handle controlled substances in Illinois, Registrant is not eligible to maintain a DEA registration. Accordingly, I order that Registrant's DEA 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. BH9069205 issued to Kirk A. Hopkins, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Kirk A. Hopkins, M.D. to renew or modify this registration, as well as any other pending application of Kirk A. Hopkins, M.D. for additional registration in Illinois. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kareem Hubbard, M.D.; Decision and Order

On June 4, 2020, the former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Kareem Hubbard, M.D. (hereinafter, Applicant) of San Leandro, California. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter RFAAX) 2 (OSC), at 1 and 12. The OSC proposed to deny Applicant's application for a DEA Certificate of Registration, as well as to deny any applications for any other registrations, pursuant to 21 U.S.C. 824(a)(1) and (4) because Applicant ''materially falsified [his] application'' and because ''[Applicant's] registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* at 1.

The OSC alleged that Applicant's application contained a materially false statement in which Applicant failed to disclose his previous surrender for cause of his DEA registration. *Id.* at 3. According to the OSC, Applicant had surrendered for cause his previous DEA registration ''less than two months before submitting [his] application.'' *Id.* Further, the OSC alleged that Applicant ''violated federal and California law by issuing prescriptions for controlled substances to four patients outside the usual course of professional practice and not for a legitimate medical purpose.'' *Id.* at 4.

The OSC notified Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 11 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to submit a corrective action plan. *Id.* at 11–12 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated July 23, 2020, Applicant requested a hearing through counsel. RFAAX 3 (Request for Hearing), at 1. In his Request for Hearing, Applicant requested that his application for DEA registration be granted, because ''he applied for it in good faith and did not believe his surrender of [his] previous certificate was 'for cause.' '' *Id.* Additionally, Applicant's Request for Hearing included an attachment addressing the Government's allegations in detail. *Id.* at 3–5. On July 23, 2020, Applicant also submitted a Corrective Action Plan in which he offered a ''historical perspective, in addition to [his] interim practice activities and corrective action plan.'' RFAAX 4, at 5. On August 14, 2020, Applicant submitted a Withdrawal of Hearing Request in which he ''with[drew] his request for a hearing in [the] matter'' and ''with[drew] his pending application for a new DEA Certificate of Registration'' [1] without ''waiv[ing] his future right to reapply for [the] same.'' RFAAX 5, at 1; RFAAX 6 (Order Terminating Proceedings). On August 17, 2020, the Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ) terminated the proceedings. RFAAX 6.

On September 23, 2020, the Government forwarded its RFAA, along with the evidentiary record for this matter, to my office. The Government seeks a final order of denial of Applicant's application for DEA registration because Applicant ''materially falsified his application under 21 U.S.C. 824(a)(1), and committed acts which render his continued registration inconsistent with the public interest'' under 21 U.S.C. 824(a)(4) and 823(f). RFAA, at 1. I issue this Decision and Order after considering the entire record before me, 21 CFR 1301.43(e); and I make the following findings of fact.

I. Findings of Fact

A. Application for DEA Registration

On or about April 8, 2019, Applicant applied for a DEA Certificate of Registration as a practitioner in Schedules II through V with a proposed registered address of 15035 E 14th St., San Leandro, CA 94578. RFAAX 1 (Certification of Non Registration), at 1. Applicant's application was assigned Control No. W19032408C and is in a ''new pending'' status. *Id.* On Applicant's application, when presented with the question, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' Applicant answered, ''No.'' *Id.* Applicant previously held DEA Certificate of Registration Control No. FH4372859, which expired on October 31, 2016, and DEA Certificate of Registration Control No. FH4334037, which expired on October 31, 2019. *Id.* at 2. Both of Applicant's previous DEA

[1] After an applicant has received an OSC regarding his or her application for DEA registration, the application may not be withdrawn without the permission of the Administrator. 21 CFR 1309.36(a). Here, Applicant had already received the OSC before attempting to withdraw his application, and he has not demonstrated good cause why his application should be withdrawn, nor do I find that withdrawal would be in the public interest due to the nature and extent of the allegations in front of me and the Applicant's stated intention that he will reapply for a registration. Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Applicant. As additionally noted in *Olsen,* ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community,'' and adjudications inform stakeholders, such as legislators and the public, about the Agency's work and allow them to provide feedback to the Agency, thereby helping shape how the Agency carries out its responsibilities under the CSA. *Id.* Adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrants under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices. I have not permitted Applicant's application to be withdrawn. Accordingly, Applicant's withdrawal is not effective.

registrations are currently in a ''retired'' status. *Id.*

B. Investigation of Applicant

1. Declaration of Group Supervisor

According to a DEA Group Supervisor (hereinafter, the GS 1) in the San Jose Resident Office of the San Francisco Field Division assigned to investigate Applicant, ''DEA began investigating [Applicant] in 2018 after receiving information that he had prescribed large quantities of controlled substances.'' RFAAX 8 (GS's Declaration), at 1. GS stated that in early 2019, ''DEA reviewed [Applicant's] report from CURES, California's Prescription Data Monitoring Program'' and ''identified several red flags of abuse or diversion in [Applicant's] controlled substance prescribing, such as patients traveling long distances and receiving drug cocktails, among other red flags.'' *Id.* On February 21, 2019, DEA served an administrative subpoena on Applicant's practice for Applicant's patient files. *Id.* at 2*; see also id.* at Appendix (hereinafter, App.) A (administrative subpoena). On the same day, DEA also ''interviewed [Applicant] regarding his care of some of the patients whose files were the subject of the administrative subpoena'' and ''informed [Applicant] about several red flags of abuse or diversion (such as long distances traveled by patients, high dosages, and opioid cocktails) that DEA identified in his controlled substance prescribing.'' *Id.* at 2. Accordingly, DEA asked Applicant to voluntarily surrender his DEA Certificate of Registration Control No. FH4334037, and he did. *Id.; see also id.* at App B (Applicant's signed surrender for cause).

2. Declaration of Diversion Investigator T.B.

A DEA Diversion Investigator (hereinafter, the DI) assigned to investigate Applicant's application found that Applicant voluntarily surrendered for cause his previous DEA Certificate of Registration Control No. FH4334037 on February 21, 2019. RFAAX 7 (DI's Declaration), at 2. The DI also found that Applicant ''did not previously possess a DATA (Drug Addiction Treatment Act)[ ] Waiver number, which authorizes registrants to prescribe controlled substances for maintenance or detoxification treatment.'' *Id.*

Additionally, the DI obtained Applicant's 2017–2019 report from the CURES database to review Applicant's controlled substance prescribing from 2017–2019. *Id.* at 3; *see also id.* at App. B (CURES Report for Applicant dated from May 1, 2017 to June 30, 2019). In response to administrative subpoenas served to various pharmacies, the DI obtained copies of the controlled substance prescriptions issued by Applicant to Patients L.C., P.B., S.N., and J.H. *Id.* at 3; *see also id.* at Apps. C–F (copies of patient prescription records). Further, the DI determined the respective distances between Applicant's previous registered address and the home addresses for Patients L.C., P.B., and S.N. by entering the addresses online into Bing Maps. *Id.* at 3; *see also id.* at App. G (printouts from Bing Maps). The DI found that the distance between Patient L.C.'s home address and Applicant's previous registered location was at least 30 miles; the distance between Patient P.B.'s home address and Applicant's previous registered location was nearly 80 miles; and the distance between Patient S.N.'s home and Applicant's previous registered location was at least 35 miles. *Id.* at 4; *see also id.* at App. G (printouts from Bing Maps). Finally, in response to administrative subpoenas served to Applicant's practice, the DI obtained copies of the patient files for Patients L.C., P.B., S.N., and J.H. *Id.; see also id.* at Apps. H(i)–K (copies of patient files).

C. The Government Expert's Review of Applicant's Prescriptions

The DEA hired Dr. Timothy Munzing, M.D. to opine on Applicant's controlled substance prescribing based on the CURES report and the patient files described above. *Id.* at 4. Dr. Munzing is a physician licensed in California who has been the Family Medicine Residency Program Director at Kaiser Permanente Orange County for three decades. RFAAX 9 (Dr. Munzing's Declaration), at 1; *see also id.* at App. A (Dr. Munzing's CV). Dr. Munzing has also held an appointment as a full Clinical Professor at the University of California, Irvine School of Medicine since 2005 and has served on the Board of Directors of the Orange Academy of Family Physicians for over twenty years as well as on the Board of Directors for the California Academy of Family Physicians for five years. *Id.* Dr. Munzing currently serves on several other national and state boards and committees overseeing quality of care and residency and medical student training and in his three decades of practice has formally taught and/or lectured to thousands of physicians and students the core principles and guidelines of appropriate opioid and controlled substance medication prescribing. *Id.* at 1–2; *see also id.* at App. A. I find that Dr. Munzing is an expert in the standard of care for prescribing controlled substances in California, and I give his report full credit.

Dr. Munzing was retained as an expert to determine whether or not Applicant's prescribing was ''consistent with the usual course of professional practice, as required under 21 CFR 1306.04(a), and with California law.'' *Id.* at 2. Accordingly, Dr. Munzing's Declaration ''explain[ed] [his] expert opinion on the standard of care in California for medical practice, particularly with respect to the prescribing of controlled substances, and [his] conclusions as to [Applicant's] prescribing outside of that standard of care with regard to specific prescriptions that [Applicant] issued to [the] four different patients'' described above. *Id.*

1. The Standard of Care in California

Dr. Munzing attested that various state laws and regulations, as well as two guidelines published by the Medical Board of California, informed his opinion as to California's standard of care for the practice of medicine, particularly with respect to the prescribing of controlled substances for pain. *Id.* at 3–7. Dr. Munzing noted that California Health and Safety Code § 11153(a) requires that '' '[a] prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.' '' *Id.* at 3. Further, California Health and Safety Code § 11154(a) states that '' 'no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition.' '' *Id.* Dr. Munzing also cited California Business and Professions Code §§§ 2242(a), 2234, and 725(a), noting that unprofessional conduct subject to sanction includes '' '[p]rescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication' . . . '[g]ross negligence'; '[r]epeated negligent acts'; '[i]ncompetence'; or '[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon' . . . and '[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs . . .' '' *Id.* at 3–4. Finally, the two Medical Board of California guidelines referenced by Dr. Munzing included the Guide to the Laws Governing the Practice of

Medicine by Physicians and Surgeons [2] and the Guidelines for Prescribing Controlled Substances for Pain.[3] *Id.* at 3.

Dr. Munzing opined that, as informed by the above statutes and guidelines, the California standard of care requires that before prescribing controlled substances, at minimum, a practitioner must:

(1) ''obtain a medical history and perform an appropriate physical examination'';

(2) ''assess the patients' pain, physical and psychological functions, substance abuse history, and history of prior pain treatment (such as reviewing past medical records, laboratory studies, and imaging studies to establish a diagnosis and medical necessity)'';

(3) ''assess any underlying or coexisting diseases or conditions and order and perform diagnostic testing if necessary'';

(4) ''discuss the risks and benefits of using controlled substances and any other treatment modalities (such as non-opioid therapeutic options)'';

(5) ''periodically review the course of pain treatment or gather any new information, if any, about the etiology of a patient's state of health'';

(6) ''give special attention to patients who, by their own words and actions, pose a risk for medication misuse and/or diversion'';

(7) ''maintain accurate and complete records''; and

(8) ''document the presence of a recognized medical indication for the use of a controlled substance.''

Id. at 4. Additionally, Dr. Munzing opined that, as informed by guidelines from the Centers for Disease Control and Prevention (hereinafter, CDC) [4] and from the Food and Drug Administration (hereinafter, FDA),[5] the California standard of care imposes additional requirements and considerations for prescribing opioids as well as for prescribing benzodiazepines in combination with opioids. RFAAX 9, at 5–6. These additional requirements and considerations include that:

(1) ''[o]pioids prescribed at Morphine Milligram Equivalent ('MME') dosages above 90 mg per day significantly increase a patient's risk of overdose and death'';

(2) practitioners must ''carefully adjust, as well as closely monitor, patients who are prescribed MME dosages above 90 MME a day—a dangerously high dosage of opioids'';

(3) ''required monitoring when high-dosage opioids are prescribed include[s]: Periodic and close evaluations or examinations to determine the appropriateness of high-dosage opioids or [the consideration of] non-opioid alternatives; frequent and periodic review of a patient's report from [CURES]; and periodic urine drug screens'';

(4) MME dosages above 90 mg per day should be avoided or carefully justified;

(5) ''[t]he FDA requires 'Black Box' warnings about combining benzodiazepines with opioids'' because ''taking benzodiazepines with opioids can cause profound sedation, respiratory depression, coma, and death'';

(6) ''the combination of opioids and benzodiazepines should be avoided except in limited circumstances given the heightened risk of overdose and death when opioids and benzodiazepines are taken in combination'';

(7) ''[t]he combination of oxycodone, a benzodiazepine, and the muscle relaxant carisoprodol, is a dangerous drug cocktail known as the 'Holy Trinity' '';

(8) ''[t]he 'Holy Trinity' cocktail, as well as the combination of an opioid and a benzodiazepine, are both red flags of abuse or diversion''; and

(9) ''[t]he 'Holy Trinity' cocktail, in particular, is a combination of drugs that is popular among the drug-abusing community.''

Id. Finally, Dr. Munzing opined that the California standard of care requires ''practitioners prescribing controlled substances to monitor and address red flags of abuse or diversion, such as long distances traveled, inconsistent urine drug screen results, early refills, and drug cocktails'' and to ''document how they addressed or resolved red flags of abuse or diversion.'' *Id.* at 6. Specifically, Dr. Munzing noted that, per the California standard of care:

(1) ''[p]atients willing to travel long distances to see a physician to obtain controlled substances is a red flag of abuse or diversion'' and physicians must address or resolve this red flag;

(2) ''[p]eriodic urine drug screening is part of a physician's duty to perform ongoing monitoring of patients prescribed controlled substances'' and physicians prescribing controlled substances must ''address or resolve inconsistent urine drug screen results, which are red flags of abuse or diversion'';

(3) ''[i]nconsistent urine drug screen results that must be addressed or resolved are: (1) Positive results for non-prescribed controlled substances; and (2) negative results for prescribed controlled substances'';

(4) ''[e]ven should a physician address or resolve an inconsistent urine drug screen result,'' the physician must ''proceed to closely monitor the patient, which may include additional and more frequent urine drug screens''; and

(5) ''[p]atients with a history or pattern of obtaining or requesting early refills is a red flag of abuse or diversion'' and physicians must address or resolve this red flag.

Id. at 6–7.

Having read and analyzed all of the record evidence and law, I find that Dr. Munzing's declaration concerning a California physician's standard of care when prescribing controlled substances is supported by substantial evidence and is consistent with the explicit text of California law as well as state and federal guidelines. As such, I apply the standard of care of the state of California as described by Dr. Munzing.

2. The Subject Patients

i. Patient L.C.

From May 1, 2017, to February 21, 2019, and on an approximately monthly basis, Applicant prescribed Patient L.C. various opioids including oxycodone, hydrocodone-acetaminophen, Nucynta, Belbuca (buprenorphine), and hydromorphone, which Dr. Munzing calculated to amount to at least 420 mg MME per day. RFAAX 9, at 8; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. C (prescription records for Patient L.C.), and Apps. H(i)–(ii) (patient file for Patient L.C.). Based upon his review of Patient L.C.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient L.C. off such high dosages.'' RFAAX 9, at 8. In particular, ''[Applicant's] frequent concurrent prescribing for Patient L.C. of oxycodone and hydrocodone-acetaminophen (both short-acting opioids) was therapeutically duplicative and therefore medically unnecessary.'' *Id.* Dr. Munzing also stated that, ''[t]here was no medical justification for [Applicant's] Belbuca (buprenorphine) prescriptions for Patient L.C.'' and noted that ''[Applicant] could not have prescribed Belbuca (a Schedule III opioid) for maintenance or detoxification treatment (for which Belbuca is usually prescribed) because [Applicant] did not possess a DATA-waiver at the time he issued these prescriptions.'' *Id.* Moreover, according to Dr. Munzing, ''given all the other high-dosage opioids Patient L.C. was prescribed, there was no legitimate medical purpose for additionally prescribing buprenorphine for pain management.'' *Id.*

Additionally, Dr. Munzing concluded, based upon his review of Patient L.C.'s file, that ''[Applicant] frequently prescribed to Patient L.C. either (1) a combination of opioids and the

[2] Available at: *http://web.archive.org/web/20210921192242/http://www.mbc.ca.gov/Download/Documents/laws-guide.pdf.*

[3] Available at: *https://www.mbc.ca.gov/Download/Publications/pain-guidelines.pdf.*

[4] The CDC guidelines referenced by Dr. Munzing included the CDC publication, ''Calculating Total Daily Dose of Opioids for Safer Dosage'' and the CDC's ''Guideline for Prescribing Opioids for Chronic Pain'' published in 2016. *Id.* at 5; *see https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf* and *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[5] Dr. Munzing referenced the FDA publication, ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' published in 2016. RFAAX 9, at 5–6; *see https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm518110.htm.*

benzodiazepine, clonazepam . . . or (2) the 'Holy Trinity' cocktail, which consists of an opioid; a benzodiazepine, such as clonazepam; and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify these combinations.'' *Id.* at 8–9. Specifically, Dr. Munzing noted that by February 6, 2018, Patient L.C. reported experiencing ''side effects attributable to [Applicant's] controlled substance prescriptions and which [Applicant] did not adequately examine or evaluate.'' *Id.* at 9. Further, ''[Applicant] improperly continued to prescribe these dangerous drug cocktails after February 6, 2018[,] without further examining or evaluating Patient L.C.'s reported side effects.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient L.C.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* First, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient L.C.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient L.C. and that Patient L.C. had not filled the prescriptions anywhere in California according to CURES reports, some of which were dangerous in combination with the high-dosage opioids that Applicant had prescribed to Patient L.C. *Id.* at 9–10. Patient L.C.'s urine drug screen results also included negative results for controlled substances for which Applicant had issued prescriptions to Patient L.C. and which Patient L.C. had filled. *Id.* at 10. Second, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved evidence of Patient L.C.'s early refills of controlled substances on at least 34 occasions between 2017 and 2019.[6] *Id.* at 10–11. Finally, Dr. Munzing noted that there was no documentation that Applicant addressed or resolved evidence that Patient L.C. traveled a long distance (at least 60 miles roundtrip from Martinez, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.; see also* RFAAX 7, App. G (printouts from Bing Maps), at 3.

[6] Dr. Munzing noted that ''[e]ven though [Applicant] documented on several occasions about providing early refills due to Patient L.C. claiming to have lost her tablets from vomiting, there was no legitimate medical purpose for consistently continuing to provide early refills for this reason without first treating Patient L.C.'s issues with vomiting.'' *Id.* at 11.

ii. Patient P.B.

On an approximately monthly basis, Applicant prescribed Patient P.B. various opioids including OxyContin, oxycodone, Nucynta, and levorphanol tartrate, which Dr. Munzing calculated to amount to at least 840 mg MME per day. RFAAX 9, at 11; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. D (prescription records for Patient P.B.), and App. I (patient file for Patient P.B.). Based upon his review of Patient P.B.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient P.B. off such high dosages.'' RFAAX 9, at 11–12. In particular, Dr. Munzing stated that, ''[Applicant's] concurrent prescribing for Patient P.B. of oxycodone and Nucynta (both short-acting opioids) on at least one occasion was therapeutically duplicative and therefore medically unnecessary.'' *Id.* at 12. Additionally, Dr. Munzing concluded, based upon his review of Patient P.B.'s file, that ''[Applicant] frequently prescribed to Patient P.B. either (1) a combination of opioids and the benzodiazepine, clonazepam . . . or (2) the ''Holy Trinity'' cocktail, which consists of an opioid; a benzodiazepine, such as clonazepam; and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify these combinations.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient P.B.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* Specifically, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient P.B.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient P.B. and for which Patient P.B. had not filled the prescriptions anywhere in California according to CURES reports. *Id.* at 12–13. Patient P.B.'s inconsistent urine drug screen results also included a negative result for a controlled substance for which Applicant had issued prescriptions to Patient P.B. and which Patient P.B. had filled. *Id.* at 13. Dr. Munzing also noted that there was no documentation that Applicant addressed or resolved evidence that Patient P.B. traveled a long distance (at least 160 miles roundtrip from Newman, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.* at 14; *see also* RFAAX 7, App. G (printouts from Bing Maps), at 4.

iii. Patient S.N.

On an approximately monthly basis, Applicant prescribed Patient S.N. various opioids including OxyContin, oxycodone, and Xtampza, which Dr. Munzing calculated to amount to at least 405 mg and 885 mg MME per day. RFAAX 9, at 14; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. E (prescription records for Patient S.N.), and App. J (patient file for Patient S.N.). Based upon his review of Patient S.N.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient S.N. off such high dosages.'' RFAAX 9, at 14.

Additionally, Dr. Munzing concluded, based upon his review of Patient S.N.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* First, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient S.N.'s inconsistent urine drug screen results, which included a positive result for controlled substances that Applicant had not prescribed to Patient S.N. and for which Patient S.N. had not filled the prescriptions anywhere in California according to CURES reports. *Id.* Dr. Munzing also noted that ''[Applicant] failed to document any test results for Patient S.N.'s three subsequent urine drug screens performed in 2018.'' *Id.* at 14–15. Second, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved evidence of Patient S.N.'s early refills of controlled substances on at least three occasions between 2017 and 2019. *Id.* at 15. Finally, Dr. Munzing noted that there was no documentation that Applicant addressed or resolved evidence that Patient S.N. traveled a long distance (at least 70 miles roundtrip from Pittsburg, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.; see also* RFAAX 7, App. G (printouts from Bing Maps), at 1–2.

iv. Patient J.H.

On an approximately monthly basis, Applicant prescribed Patient J.H. various opioids including oxycodone, oxycodone-acetaminophen, OxyContin, and fentanyl, which Dr. Munzing calculated to amount to at least 1,350 mg MME per day. RFAAX 9, at 15; *see also* RFAAX 7, App. B (Applicant's

CURES Report), App. F (prescription records for Patient J.H.), and App. K (patient file for Patient J.H.). Based upon his review of Patient J.H.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient J.H. off such high dosages.'' RFAAX 9, at 15. In particular, ''[Applicant's] frequent concurrent prescribing for Patient J.H. of oxycodone and oxycodone-acetaminophen (both short-acting opioids) was therapeutically duplicative and therefore medically unnecessary.'' *Id.*

Dr. Munzing also concluded, based upon his review of Patient J.H.'s file, that ''[Applicant] frequently prescribed Patient J.H. the 'Holy Trinity' cocktail, which consists of an opioid; a benzodiazepine, such as alprazolam . . . and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify this combination.'' *Id.* at 15–16. Specifically, Dr. Munzing noted that by January 29, 2018, Patient J.H. reported having experienced ''side effects attributable to [Applicant's] controlled substance prescriptions and which [Applicant] did not adequately examine or evaluate.'' *Id.* at 16. Further, ''[Applicant] improperly continued to prescribe the 'Holy Trinity' after January 29, 2018[,] without further examining or evaluating Patient J.H.'s reported side effects.'' *Id.* Dr. Munzing also concluded, based upon his review of Patient J.H.'s file, that, ''[Applicant] frequently prescribed stimulants, either amphetamine salts . . . or modafinil . . . without any legitimate medical purpose.'' *Id.* Dr. Munzing noted that he did not find any apparent medical diagnosis or evaluation in Patient J.H.'s file for Attention-Deficit Hyperactivity Disorder (ADHD), ''for which amphetamine salts are normally used to treat.'' *Id.* Additionally, Dr. Munzing noted that ''while amphetamine salts and modafinil can be used to treat drowsiness or extreme sleepiness, the use of such stimulants for Patient J.H. was not medically appropriate as the patient's drowsiness or sleepiness were likely side effects of his prescribed high-dosage opioids.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient J.H.'s file, that Applicant failed to address or resolve several red flags of abuse or diversion. *Id.* Specifically, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient J.H.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient J.H. and for which Patient J.H. had not filled the prescriptions anywhere in California according to CURES reports, some of which were dangerous in combination with the high-dosage opioids that Applicant had prescribed to Patient J.H. *Id.* at 16–17. Applicant's inconsistent urine drug screen results also included positive results for alcohol, which Dr. Munzing noted can ''amplify the risk of overdose and death associated with the 'Holy Trinity' cocktail [Applicant] prescribed Patient J.H.'' *Id.* at 17. Moreover, Applicant's inconsistent urine drug screen results included negative results for controlled substances for which Applicant had issued prescriptions to Patient J.H. and which Patient J.H. had filled. *Id.* at 17–18.

Based on his expert medical opinion, Dr. Munzing concluded, and I agree, that ''the controlled substance[ ] prescriptions issued by [Applicant] for Patients L.C., P.B., S.N., and J.H. between May 1, 2017, and February 21, 2019[,] were issued without a legitimate medical purpose and were issued beneath the standard of care for the practice of medicine in the State of California, and therefore outside of the usual course of professional practice.'' *Id.* at 7.

II. Discussion

A. Government's Position

In its RFAA, the Government sought denial of Applicant's application for DEA registration because Applicant ''materially falsified his application under 21 U.S.C. 824(a)(1), and committed acts which render [granting his] registration inconsistent with the public interest.'' RFAA, at 1 (citing 21 U.S.C. 824(a)(1), (a)(4) and 823(f). Specifically, the Government argued that Applicant had materially falsified his application when he falsely provided a ''No'' response to the liability question asking him whether he had ever surrendered for cause a federal controlled substance registration and when he knew or should have known that his ''No'' response was false. *Id.* at 19. The Government also argued that Applicant had repeatedly violated state and federal law by issuing prescriptions for controlled substances to four patients outside of the standard of care in the State of California and outside of the usual course of professional practice. *Id.* at 21. The Government concluded its RFAA by requesting that Applicant's application for DEA registration be denied and that any applications by Applicant for any other registrations be denied. *Id.* at 25.

B. Applicant's Position

Within his Request for Hearing and his Corrective Action Plan, both submitted in response to the OSC, Applicant offered explanation as to his misconduct, however, Applicant did not offer supporting evidence nor any ability for me to assess the credibility of his unsworn statements.[7] *See* RFAAX 3 (Request for Hearing) and RFAAX 4 (Corrective Action Plan). In his Request for Hearing, Applicant addressed the allegations of material falsification and stated that when, on February 21, 2019, DEA investigators visited Applicant's registered location to serve an administrative subpoena for patient files from his practice, the investigators ''explained that the DEA was concerned about certain red flags associated with [his] controlled substance prescribing, including but not limited to, long distances traveled by patients, high dosages, and drug cocktails.'' RFAAX 3, at 3. Applicant stated that he ''believed that if [he] surrendered [his] DEA certificate that [he] would be demonstrating good faith that [he] had done nothing wrong.'' *Id.* Applicant also stated that he ''was unaware and did not understand that [he] was being asked to surrender [his] DEA certificate 'for cause.' '' *Id.*

In both his Request for Hearing and his Corrective Action Plan, Applicant offered a ''historical perspective'' regarding the improper prescribing allegations. RFAAX 3, at 3–5; RFAAX 4, at 5. According to Applicant, in 2018, he ''acquired a medical practice from anesthesiologist/pain medicine specialist [M. J.], a frequent prescriber of schedule II and III medications.'' RFAAX 4, at 5. Applicant stated that prior to considering the purchase of M. J.'s practice, and before working with him, Applicant ''discussed with him his patient population'' and '' [a] contract was drawn up ensuring that all [M. J.] was doing was within state and deferral [sic] laws.'' RFAAX 3, at 3. Applicant stated that he and M. J. agreed that M. J. would continue to work with Applicant for the first year and then turn the practice over to Applicant. *Id.* The contract was signed by both

[7] Applicant specifically did not opt to submit a written statement in lieu of a hearing under 21 CFR 1316.49. In this case, I have considered these unsworn submissions minimally to represent Applicant's position because they address the underlying allegations. Even if I afforded these unsupported and unsworn statements the weight of a written statement, they would be insufficient to rebut the Government's case for denial of Applicant's application for the reasons stated herein.

Applicant and M. J. and witnessed by a third party. *Id.* According to Applicant, CDC guidelines were also discussed, and M.J. ''informed [Applicant] that [they] were recommendations, not mandates.'' *Id.* M.J. said that patients had been established with him for 20–30 years. *Id.* Further, M.J. discussed the ''tolerance displayed by long term chronic pain patients,'' their ''functionality'' (that patients could ''go to work, address activities of daily life, [and] enjoy the benefits of being sociable'') and ''an overall high level of productivity of patients.'' *Id.* M.J. further stated that ''if there had been any problems, he would not [have been] allowed to operate for all this time, incident free.'' *Id.*

According to Applicant, upon his evaluation of the patients, he realized that ''many patients were not getting the proper workups, diagnostic studies[,] and referrals needed to improve their pain.'' *Id.* Further, ''[m]any of them were exhibiting chronic pain due to lack of early appropriate treatment'' and ''patients had been pushed toward interventional procedures that either were not indicated or ended up hurting them.'' *Id.* Applicant stated that ''[t]his was all done under the guise of performing a 'trial' '' and that ''[m]edications had been escalated due to failed 'trials' and recommended due to inability to control pain with interventions.'' *Id.* Applicant stated that ''[a]s medications were elevated and encouraged by [M.J.], patients had become dependent on their current regimens, and had been educated that their pain was so severe that high medication dosages were indicated.'' *Id.*

According to Applicant, in April 2019, he was the victim of a cyber crime when ransomware was placed onto his servers and corrupted all of his electronic medical records. *Id.* at 4. Applicant stated that ''[although] no HIPPA violation occurred and the charts were retrieved on an external hard drive, upon attempting to upload the data, the external hard drive became corrupted leading to loss of all charting information.'' *Id.* As a result of the data loss, Applicant was only able to provide management details for the four patients referenced in the OSC by memory and not by specific references to their patient records. *Id.* Applicant stated that ''[a]ll four patients cited in the [OSC] were patients managed or at one time managed by [M.J.].'' *Id.* Further, ''[n]one of them were naïve to opioids and were elevated to the regimens in question by [M.J.].'' *Id.* Applicant concluded that ''[a]ll of these patients, from the moment [he] inherited them, were already and for years [had been] above the current state, federal[,] and CDC guidelines.'' *Id.*

Regarding Patient L.C., Applicant stated that her medications had been escalated prior to her becoming Applicant's patient. *Id.* According to Applicant, Patient L.C. had indicated that ''she had tried many procedures for her condition including [ ] a trial of a Spinal Cord Stimulator (SCS).'' *Id.* However, Patient L.C. said that during the SCS trial she had been hurt and she ''frequently had her mother [with her] at appointments to advocate that she would never have [an] SCS [again] due to the adverse experience during the trial.'' *Id.* Applicant stated that he and other physicians believed that Patient L.C. was getting too much medication and Applicant ''used [other] opinions to further bolster [his own],'' but Patient L.C. disagreed and ''cit[ed] [M.J.].'' *Id.* Applicant then started Patient L.C. on a ''slow wean'' of her medications. *Id.* According to Applicant, Patient L.C. was also undergoing a trial of Belbuca for her pain, and as he was weaning down her medications, Belbuca was used ''to continue to cover her chronic pain.'' *Id.* Applicant stated that Belbuca ''is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.'' *Id.* For Patient L.C., Belbuca was ''not being used for maintenance or detoxification treatment.'' *Id.*

Regarding Patient P.B., Applicant stated that her medications had been escalated prior to her becoming Applicant's patient. *Id.* According to Applicant, there had been no diagnostic studies on file for Patient P.B. and weaning down of her medications occurred once diagnostic studies were performed. *Id.*

Regarding Patient S.N., Applicant stated that his medications had also been escalated prior to him becoming Applicant's patient. *Id.* at 5. According to Applicant, Patient S.N. ''cited tailbone pain that made sitting for long periods difficult'' and ''had a job where he often traveled by plane and was not able to stop and take breaks from sitting.'' *Id.* ''Refills made early usually represented a documented trip he had on behalf of his profession.'' *Id.* According to Applicant, Patient S.N. ''had never been worked up for his pain'' and ''[m]ultiple diagnostic studies were conducted in attempts to find a solution.'' *Id.* Applicant stated that he started Patient S.N. on a weaning down of his medication and ''[a]fter S.N. transferred care to obtain medication from another provider, he continued to work with [Applicant] in an attempt to solve his pain.'' *Id.* Applicant also stated that Patient S.N. ''attempted a nerve block to further investigate a solution to his pain, though no opioids were being prescribed by [Applicant] at the time.'' *Id.*

Finally, regarding Patient J.H., Applicant stated that his medications too had been escalated prior to him becoming Applicant's patient. *Id.* According to Applicant, Patient J.H. had sustained an occupational injury and was being managed under a workers' compensation insurer. *Id.* Patient J.H. previously had a failed surgical procedure and was a candidate for a revision procedure. *Id.* Applicant stated that he had agreed with the revision procedure as an option, but that the procedure was denied by the insurer. *Id.* According to Applicant, ''[o]ther non-opioid options were recommended to help decrease [Patient J.H.'s use of] opioids and [to] manage his pain.'' *Id.*

Applicant concluded his Request for Hearing by asserting that his patients ''had been taught that issues that could have normally been mitigated by appropriate treatment were instead only able to be addressed with high levels of medication'' and that ''[t]he belief had been ingrained that medications were the only option.'' *Id.* Applicant asserted that his patients in turn became dependent on their medications and that ''[a]s a competent, caring doctor, [he] could not abandon them.'' *Id.* Applicant stated that he ''was working diligently to reduce their medication use, but found a number of patients who had been on long term opiate use'' and thus ''[had] to very slowly wean them.'' *Id.*

In his Corrective Action Plan, Applicant stated, ''Given my training in physical medicine and rehabilitation, my focus was to taper his patients from high dose opioids and offer them an array of alternative treatment options.'' RFAAX 4, at 5. According to Applicant, ''[o]n February 23, 2019, in the midst of this process, DEA officers presented to the clinic and requested that [he] surrender [his] DEA license'' to which Applicant ''voluntarily complied.'' *Id.* Applicant further stated that ''[a]t that time, patients who were on scheduled medications were provided the option of tapering off their medications or provided a list of alternative physicians for transfer of care, including an addiction medicine specialist.'' *Id.* Applicant asserted that ''[f]or those patients who decided to taper/discontinue their medications, [he] continued to provide them care in the framework of holistic treatment options such as physical and behavioral therapies, procedures, durable medical

equipment, self-directed exercise, and other non-medical pain management strategies.'' *Id.*

Applicant stated that he ''proceeded to close the practice, and after full disclosure, [he has] been evaluating and treating patients at RehabOne Medical Group, Inc.'' *Id.* Applicant chose to work at RehabOne ''because of their positive reputation in the community [and] their focus on functional restoration.'' *Id.* Applicant also chose RehabOne for ''their attentiveness to documentation, record keeping, and compliance [as well as] medical provider supervision[,] oversight, and collaboration.'' Finally, Applicant chose RehabOne for their ''adherence with evidence-based guideline recommendations for prescribing controlled substances.'' *Id.* Applicant stated that ''[a]lthough [he has] not personally prescribed any scheduled medications, RehabOne has a strong risk management policy that utilizes opioid and addiction risk screening tools, long-term controlled substance agreements, routine CURES analysis, initial and random urine toxicology, and '5 As' monitoring.'' *Id.* Further, ''[w]hen opioid or non-opioid medications are considered appropriate as part of a treatment plan, all efforts are made to utilize the lowest dose and frequency possible to achieve optimal outcomes.'' *Id.* According to Applicant, ''[a]t RehabOne, medications are very carefully considered as part of an overall, comprehensive treatment strategy with the primary goal of functional restoration and quality of living.'' *Id.*

Applicant concluded his Corrective Action Plan by stating that ''[m]oving forward, [he plans] to strictly adhere to these practices and principles as [he strives] to help [his] patients lead full and meaningful lives.'' *Id.* Applicant stated that he ''will continue to review and implement the most current evidence-based guidelines for the treatment of chronic pain'' and requested that ''[DEA] reinstate [his] DEA license so that [he] can utilize appropriate medications as one tool in the toolbox to achieve these outcomes.'' *Id.*

C. Analysis

1. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

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

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

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

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). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *Drug Enf't Admin.,* 861 F.2d 72, 76–77 (4th Cir. 1988). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009) (basing sanction on all evidence on record).

The Government does not dispute that Applicant holds a valid state medical license and is authorized to dispense controlled substances in the State of California where he practices. *See* RFAAX 2 (OSC), at 2. While I have considered all of the public interest factors[8] in 21 U.S.C. 823(f), the Government's evidence in support of its *prima facie* case for denial of Applicant's application is confined to Factors Two and Four. *See* RFAA, at 19–25. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44. I find that the Government's evidence satisfies its *prima facie* burden of showing that Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(f). I further find that Applicant failed to provide sufficient evidence to rebut the Government's *prima facie* case.

i. Factors Two and Four

Evidence is considered under Public Interest Factors Two and Four when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. Established violations of the CSA, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable when considering whether granting a registration is consistent with the public interest.

Here, the Government has alleged that from at least May 1, 2017, through at least February 21, 2019, Applicant unlawfully issued prescriptions for controlled substances in violation of the CSA. RFAAX 2 (OSC), at 2 and 4–10. Specifically, the Government alleges that Applicant repeatedly violated 21 CFR 1306.4(a) by issuing prescriptions for controlled substances to Patients L.C., P.B., S.N., and J.H. beneath the standard of care and outside the usual course of professional practice in California—the state in which Applicant is applying for DEA registration. *Id.*

[8] As to Factor One, there is no record evidence of disciplinary action against Applicant's state medical license. 21 U.S.C. 823(f)(1). 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 [or granting of a] DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Applicant 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(f)(3). 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 FR 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 Five, the Government's evidence fits squarely within the parameters of Factors Two and Four and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). Accordingly, Factor Five does not weigh for or against Applicant.

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). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

I found above that the Government's expert credibly declared, as supported by California law and federal and state guidelines, that the standard of care in California requires physicians to, among other things, perform a sufficient physical exam and take a medical history, counsel patients on the risks and benefits of the use of particular controlled substances, periodically review the course of treatment and adjust as needed, give special attention to patients who pose a risk for medication misuse and diversion, and monitor and address any red flags of abuse or diversion. Further, the standard of care in California requires additional care and consideration for the prescribing of opioids, as well as for the prescribing of benzodiazepines in combination with opioids.

Based on the credible and unrebutted opinion of the Government's expert, I found above that Applicant issued a high number of controlled substance prescriptions to at least four different patients, often for extremely high doses of opioids and in dangerous combinations of opioids and benzodiazepines, without performing detailed examinations or evaluations, dependably considering non-opioid alternatives, reliably weaning patients off such high dosages, or resolving or documenting resolution of red flags of abuse and/or diversion as required by the standard of care. *See supra* I.C.2.i–iv. My findings demonstrate that Applicant repeatedly violated the applicable standard of care when prescribing controlled substances and that his conduct was not an isolated occurrence, but occurred with multiple patients. *See Kaniz Khan Jaffery,* 85 FR 45667, 45685 (2020); *Wesley Pope, M.D.,* 82 FR 42961, 42986 (2017). As such, I find that the Government has presented substantial evidence that from May 1, 2017, to February 21, 2019, Applicant issued controlled substance prescriptions to the four subject patients beneath the applicable standard of care in California and outside the usual course of professional practice. Accordingly, I am sustaining the Government's allegation that Applicant violated 21 CFR 1306.04(a).

The Government has also alleged that Applicant's prescribing practices in regard to the subject patients violated California State law. RFAAX 2, at 2–3 and 4–10. Echoing the federal regulations, California law requires that a ''prescription for a controlled substance shall only be issued for a medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a).[9] Further, California Business and Professions Code § 2242(a) states, ''Prescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication[ ] constitutes unprofessional conduct.'' [10] Accordingly, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Applicant violated these provisions with respect to the controlled substance prescriptions for Patients L.C., P.B., S.N., and J.H.

In sum, I find that the record contains substantial evidence that Applicant issued a multitude of prescriptions for controlled substances, including high dosages of opioids, to multiple patients beneath the applicable standard of care, outside the usual course of professional practice, and in violation of federal and state law. I, therefore, find that Factors Two and Four weigh in favor of denial of Applicant's application and thus find Applicant's registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(f).

2. 21 U.S.C. 824(a)(1): Material Falsification

In addition to the public interest allegations, as previously mentioned, the OSC in this matter also alleges that Applicant's application for registration should be denied, because Applicant's application contains a materially false response to a liability question. RFAAX 2, at 1 and 3–4; *see supra* I.A–B.1. The CSA, however, places the provision addressing the ramification of a material falsification with the bases for revocation or suspension of a registration. 21 U.S.C. 824(a). Prior Agency decisions have addressed whether it is appropriate to consider a material falsification and other provisions of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *See, e.g., Lisa M. Jones, N.P.,* 86 FR 52196 (2021), *Robert Wayne Locklear,* 86 FR 33738 (2021) (collecting Agency decisions). These decisions offer multiple bases and analyses for that conclusion. 86 FR at 33744–45.

Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant surrendered (for cause) his previous DEA registration on February 21, 2019. *See supra* I.A–B.1. Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that when presented with the liability question, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?''—Applicant answered, ''No.'' *Id.* Applicant's false answer to this liability question in his application implicates two of the public interest factors that the CSA requires me to consider (*see supra* II.C.1): Applicant's experience in dispensing controlled substances and Applicant's compliance with applicable federal laws relating to controlled substances. 21 U.S.C. 823(f)(2) and (4); *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45234 (2020). As such, Applicant's false response to this liability question in his application was ''predictably capable of affecting, *i.e.,* had a natural tendency to affect'' my official decision on Applicant's application. *Frank Joseph Stirlacci,*

[9] The Government also alleged that Applicant violated California Health and Safety Code § 11154(a), which states that ''no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition.'' Dr. Munzing's expert report did not address whether Applicant knowingly prescribed controlled substances to or for any person not under his treatment for a pathology or condition. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Applicant violated California Health and Safety Code § 11154(a).

[10] The Government also alleged that Applicant violated California Business and Professions Code §§ 2234 and 725(a), which state that unprofessional conduct includes ''[g]ross negligence''; ''[r]epeated negligent acts''; ''[i]ncompetence''; or ''[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon'' as well as ''[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs.'' Dr. Munzing's expert report did not address whether Applicant engaged in these particular forms of unprofessional conduct. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Applicant violated California Business and Professions Code §§ 2234 and 725(a).

M.D., 85 FR at 45238. Accordingly, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant's application for DEA registration contains a material falsification, which is an independent basis for the denial of Applicant's application.

III. Sanction

The Government has established grounds to deny a registration; therefore, I will review any evidence and argument that Applicant submitted to determine whether or not Applicant has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR at 23853; *John H. Kennnedy,* M.D., 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

A. Acceptance of Responsibility

As previously discussed, although Applicant initially requested a hearing and submitted a Corrective Action Plan on July 23, 2020, Applicant later withdrew his hearing request on August 14, 2020, and the proceedings were terminated. *See* RFAAX 3 (Request for Hearing); RFAAX 4 (Corrective Action Plan); RFAAX 5 (Withdrawal of Hearing Request); RFAAX 6 (Order Terminating Proceedings). As such, there is no credible, sworn evidence on the record regarding acceptance of responsibility for me to consider. Further, even if I could consider the explanations that Applicant offered in his initial Request for Hearing and Corrective Action Plan, they do not demonstrate sufficient acceptance of responsibility or evidence of remedial measures that would aid me in entrusting Applicant with registration. *See* RFAAX 3 and RFAAX 4.

As to the allegations of material falsification, Applicant claimed that, at the time he surrendered his DEA certificate for cause, he misunderstood that he was doing so and believed instead that he was ''demonstrating good faith that [he] had done nothing wrong.'' [11] RFAAX 3, at 3. Whether or not Applicant's claims are truthful, they do not demonstrate acceptance of responsibility for his (intentional or not) materially false response to a liability question. Rather, Applicant's claims demonstrate an attempt to either shift the blame to DEA investigators for failing to properly explain the situation to him or to simply use his ignorance as an excuse, neither of which inspire confidence that Applicant fully appreciates an applicant's obligation to provide truthful and accurate responses on an application for DEA registration.

As to the allegations of improper prescribing, Applicant claimed that he had inherited the subject patients from his purchase of another physician's practice and that the physician he had purchased the practice from had assured him that all was proper regarding the practice and his patients. RFAAX 3, at 3; RFAAX 4, at 5. However, Applicant claimed that he only later realized that all was *not* proper regarding the practice and the patients that he had inherited and that he had done the best that he could to wean the four subject patients off of their high dosages of controlled substances. RFAAX 3, at 3–5; RFAAX 4, at 5. Again, Applicant's statements do not demonstrate acceptance of responsibility for his improper prescribing, but instead demonstrate an attempt to shift the blame to the physician whom he had inherited the subject patients from or, at the very least, a failure to acknowledge that, regardless of his intentions, his prescribing was beneath the applicable standard of care and outside the usual course of professional practice.

As for remedial measures, I do not consider them when an Applicant has not unequivocally accepted responsibility, however, even if I were to consider Applicant's remedial measures here, I do not find them to be sufficient. Applicant discussed how since surrendering his DEA registration, he has closed his practice and has begun treating patients at another practice, one which he lauds for its adherence to best practices for prescribing controlled substances. RFAAX 4, at 5. Applicant also stated his own commitment to adhering to these best practices moving forward, however, Applicant did not specify in what ways he would ensure this adherence. *Id.* As such, Applicant has not sufficiently demonstrated that he is ready to be entrusted with the responsibility of registration.

B. Specific and General Deterrence

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 74,800, 74,810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the registrant for the protection of the public at large. *Id.* In this case, I believe that denial of Applicant's application for DEA registration would deter Applicant and the general registrant community from the improper prescribing of controlled substances as well as from ignoring their obligation to provide accurate and truthful responses on an application for DEA registration.

C. Egregiousness

The Agency also looks to the egregiousness and the extent of the misconduct as significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). Here, the record contains substantial evidence that Applicant issued a high number of prescriptions for controlled substances, including high dosages of opioids and dangerous combinations of opioids and benzodiazepines, to at least four different patients beneath the applicable standard of care and outside the usual course of professional practice. Further, Applicant gave a materially false response to a liability question on his application for DEA registration that directly concerned his improper prescribing practices and his negative history with DEA registration.

As discussed above, to be granted a registration when grounds for denial

[11] It is noted that in spite of Applicant's claims that he did not know that he was surrendering his previous registration ''for cause,'' RFAAX 3, at 3, the DEA Form 104 that Applicant signed was clearly entitled, ''Surrender *for Cause* of DEA Certificate of Registration,'' RFAAX 8, App. B (emphasis added).

exist, an Applicant must convince the Administrator that his acceptance of responsibility is sufficiently credible to ensure that his misconduct will not reoccur and that he can be entrusted with registration. I find that Applicant has not met this burden. In sum, Applicant has not offered any credible evidence on the record to rebut the Government's case for denial of his application and Applicant has not demonstrated that he can be entrusted with the responsibility of registration. Accordingly, I will order the denial of Applicant's application below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control Number W19032408C, submitted by Kareem Hubbard, M.D., as well as any other pending application of Kareem Hubbard, M.D. for additional registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–17]

Noah David, P.A.; Decision and Order

On March 9, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Noah David, P.A. (hereinafter, Respondent) of Richmond, Virginia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. MD3130717 (hereinafter, COR or registration) and the denial of ''any pending application for renewal or modification of such registration and any applications for any other DEA registrations, pursuant to 21 U.S.C. 824(a)(4), because [Respondent's] registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

On April 7, 2020, the Respondent timely requested a hearing, which commenced (and ended) on September 22, 2020, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On December 8, 2020, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). By letter dated January 5, 2021, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*[A]

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II

Chief Administrative Law Judge

December 8, 2020

*[B] After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

I. Findings of Fact

A. Allegations

The Government alleges that the Respondent's COR should be revoked because he has committed acts which render his continued registration against the public interest. ALJX 1, at 1. Specifically, the Government contends that on numerous occasions between April 2014 and November 2018, the Respondent unlawfully prescribed controlled substances to his wife without establishing a *bona fide* practitioner-patient relationship and without properly documenting treatment. *Id.* at 3–4. The Government additionally alleges that the Respondent conspired with colleagues to unlawfully receive controlled substances. *Id.* at 4.

B. Stipulations

The parties entered into a robust set of factual stipulations which were accepted by the tribunal. Accordingly, the following factual matters are deemed conclusively established in this case:

1. The Respondent is registered with the DEA as a practitioner to handle controlled substances in Schedules II–V under DEA COR No. MD3130717 at 5211 West Broad Street, Suite 101, Richmond, Virginia 23230–3000.

2. DEA COR No. MD3130717 was issued on May 15, 2019 and expires by its own terms on June 30, 2022.

3. The Respondent is presently licensed as a physician assistant in Virginia under License No. 0110004505, which expires April 30, 2021.

4. Respondent Exhibit 1 is a true and correct copy of the Respondent's COR.

5. The Respondent prescribed the following controlled substances on the following dates to his wife, B.D.:

(1) 11/28/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(2) 11/20/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(3) 11/08/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(4) [10/30/2018: Oxycodone-Acetaminophen 5–325, 36 tablets]
(5) 10/01/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(6) 9/21/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(7) 9/13/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(8) 9/06/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(9) 8/22/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(10) 8/17/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(11) 7/23/2018: Oxycodone-Acetaminophen 5–325, 42 tablets
(12) 7/10/2018: Oxycodone-Acetaminophen 5–325, 84 tablets
(13) 7/03/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(14) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets
(15) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets (refill)
(16) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets (refill)
(17) 5/21/2018: Oxycodone-Acetaminophen 5–325, 12 tablets
(18) 5/08/2018: Diazepam 5mg, 30 tablets
(19) 4/24/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(20) 3/16/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(21) 2/15/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(22) 2/09/2018: Oxycodone-Acetaminophen 10–325, 12 tablets
(23) 1/23/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(24) 1/19/2018: Oxycodone-Acetaminophen 10–325, 12 tablets
(25) 1/05/2018: Oxycodone-Acetaminophen

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.