Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. AB2619510 at the registered address of 11525 Brookshire Avenue, Suite 101, Downey, California 90241. RFAAX B, at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on July 31, 2022. *Id.*

The Status of Registrant's State License

On October 4, 2019, the Medical Board of California (hereinafter, the Board) issued an Accusation against Registrant alleging repeated negligent acts and failure to maintain adequate and accurate records throughout his treatment and care of six specific patients. RFAAX B–1, at 9–15. Further, according to the Accusation, ''on or about September 27, 2019, in a prior disciplinary action . . . [Registrant's] license was revoked with revocation stayed for five (5) years of probation for self-prescribing of controlled substances and conviction of crimes substantially related to qualifications, functions, or duties of a physician and surgeon.'' *Id.* at 16. On March 9, 2020, Registrant entered into a Stipulated Surrender of License and Disciplinary Order (hereinafter, Stipulated Surrender) in which he admitted the truth of the allegations in the Accusation and surrendered his California medical license for the Board's formal acceptance without further process. *Id.* at 4–7. The Stipulated Surrender ordered Registrant's medical license surrendered and was signed by Registrant and his attorney. *Id.* at 5–6. On March 30, 2020, the Board adopted the Stipulated Surrender, effective April 29, 2020. *Id.* at 1.

According to California's online records, of which I take official notice, Registrant's medical license is still surrendered.[1] Medical Board of California License Verification, *https://www.mbc.ca.gov/License-Verification* (last visited date of signature of this Order). Accordingly, I find that Registrant is not licensed to engage in the practice of medicine in California, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

According to California statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' Cal. Health & Safety Code § 11010 (West, current with urgency legislation through Ch. 6 of 2022 Reg.Sess.). Further, a ''practitioner'' means a person ''licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.'' *Id.* at § 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will 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. AB2619510 issued to Douglas A. Blose, 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 Douglas A. Blose, M.D. to renew or modify this registration, as well as any other pending application of Douglas A. Blose, M.D. for additional registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07686 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David H. Betat, M.D.; Decision and Order

On August 21, 2019, a former Assistant Administrator of the Diversion Control Division of the Drug Enforcement Administration (hereinafter, Government) issued an

Order to Show Cause (hereinafter, OSC) seeking to revoke the DEA Certificate of Registration, number BB0500365, of David H. Betat, M.D. (hereinafter, Registrant). Government Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 1 (OSC). The OSC sought to revoke Registrant's registration pursuant to 21 U.S.C. 824(a)(4) on the ground that it is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f), and to deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f). *Id.* at 1.

Specifically, the OSC alleged that Registrant, from at least 2012 through at least 2017, prescribed controlled substances to various patients that were not issued for a legitimate medical purpose, that were beneath the standard of care for the practice of medicine in the State of California, and that were not issued in the usual course of professional practice. *Id.* at 2–4. The OSC further alleged that Registrant's controlled substance prescribing practices violated both federal and state law. *Id.* at 4.

In response to the OSC, Registrant submitted a timely request for a hearing. RFAAX 3 (Request for Hearing for the OSC). The case was subsequently assigned to Administrative Law Judge (hereinafter, ALJ) Mark M. Dowd, who ordered that the Government file its prehearing statement by October 16, 2019, and that Registrant file his prehearing statement by November 1, 2019. RFAAX 4 (Order for Prehearing Statements). Registrant failed to file a prehearing statement by November 1, 2019. ALJ Dowd subsequently issued an order to show cause on November 8, 2019, providing Registrant until November 20, 2019, to file both a prehearing statement and a statement demonstrating good cause for failure to meet the original deadline. *See* RFAAX 5 (ALJ Dowd Order to Show Cause). Registrant did not respond to the ALJ's order to show cause. Consequently, ALJ Dowd issued an order finding that Registrant had waived his right to a hearing and terminating the proceedings. RFAAX 6 (Order Terminating Proceedings).

On August 17, 2020, the Government forwarded its RFAA, along with the evidentiary record in this matter, to my office. The Government seeks a final order of revocation because Registrant has ''committed acts that render his continued registration inconsistent with the public interest under 21 U.S.C. 824(a) and 823(f).'' RFAA, at 3. 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. Registrant's DEA Registration

Registrant is registered with DEA as a practitioner authorized to handle controlled substances in schedules II through V under DEA Certificate of Registration number BB0500365 at the registered address of 925 Bevins Court, Lakeport, California 95453. RFAAX 7 (Certificate of Registration). Registrant's registration expires by its terms on July 31, 2022. *Id.*

b. Investigation of Registrant

On May 10, 2018, a DEA Diversion Investigator (hereinafter, the DI) served an administrative subpoena on Registrant for patient files reflecting Registrant's treatment of various patients. RFAAX 8 (Declaration of Diversion Investigator), App. A. Registrant provided copies of various patient files in response to DEA's subpoena, including patient files for Patients K.K., G.K., T.L., J.P., and Y.P. RFAAX 8, at 2 and Apps. B–F (Copies of patient files).

In furtherance of the DEA investigation of Registrant, the DI obtained information from the California Controlled Substance Utilization Review Evaluation System (CURES) database regarding Registrant's prescriptions to Patients K.K., G.K., T.L., J.P., and Y.P. for the period of 2012 through 2017. *Id.* at ¶ 13 and App. G (Copy of CURES database report). The DI also issued administrative subpoenas to various pharmacies to obtain copies of Registrant's prescriptions to Patients K.K., G.K., T.L., J.P., and Y.P. *Id.* at ¶ 16. The pharmacies responded with copies of prescriptions for the requested patients. *Id.* at Apps. I–M (Copies of prescriptions from CVS Pharmacy), O–P (Copies of prescriptions from Kmart Pharmacy), R–T, V–X (Copies of prescriptions from North Lake Medical Pharmacies), Z–AA (Copies of prescriptions from Safeway Pharmacy), AC (Copies of prescriptions from Omnicare, Inc.), AE (Copies of prescriptions from Pharmacy Care Concepts), AG–AH (Copies of prescriptions from Lucerne Pharmacy), AJ (Copies of prescriptions from Moran's Pharmacy), AL (Copies of prescriptions from Walmart Pharmacy). In addition to producing copies of Registrant's prescriptions to Patients K.K., G.K, T.L, J.P, and Y.P., two pharmacies informed the DI that there were certain prescriptions they failed to produce because they were unable to locate them or the records had been lost. *Id.* at ¶¶ 48–49, App. AM–AN.

c. The Government Expert's Review of Registrant's Prescriptions

The DEA hired Dr. Timothy A. Munzing to review Registrant's patient files for the patients under review and the CURES report showing Registrant's prescriptions to those patients for the period from 2012–2017. *Id.* at ¶ 15. Dr. Munzing is a physician licensed and practicing in the State of California, who has more than three decades of clinical work and has served as a Medical Expert Reviewer for the Medical Board of California.[1] RFAAX 9, at ¶¶ 1–3 (Declaration of Dr. Munzing); *see also id.* at App. A (Dr. Munzing CV). 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's expert report ''review[ed] the management of the five patients [K.K., G.K., T.L., J.P, and Y.P.] and opine[d] on the controlled substance prescriptions, specifically whether they were medically legitimate and in the usual course of professional practice.'' RFAAX 9, App. B, at 4 (Munzing Report) (emphasis omitted). Dr. Munzing concluded, and I agree, that with regard to patients K.K., G.K., T.L., J.P., and Y.P., Registrant repeatedly issued controlled substance prescriptions without a legitimate medical purpose, outside the usual course of professional practice in the State of California, and ''in violation of the minimum standard of care that governs California physicians with respect to the use of controlled substances in pain management.'' *Id.* at ¶ 15.

i. Standard of Care in California

Dr. Munzing attested that several statutes inform the standard of care in California for the use of controlled substances in pain management. RFAAX 9, at ¶ 10. Among them, 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.'' California Business and Professional Code 2241.5 permits California physicians to treat patients under their care for pain, including intractable pain, by prescribing controlled substances, but requires them to ''exercise reasonable

[1] Currently named California Department of Consumer Affairs, Division of Investigation, and Health Quality Investigation Unit (''HQIU''). RFAAX 9, at ¶ 3.

care in determining whether a particular patient or condition, or the complexity of a patient's treatment, . . . requires consultation with, or referral to, a more qualified specialist.'' Finally, California Business and Professional Code 2242 provides that ''[p]rescribing, dispensing, or furnishing'' controlled substances to a patient ''without an appropriate prior examination and a medical indication'' is ''unprofessional conduct'' by the prescribing physician. RFAAX 9, at ¶ 10. Dr. Munzing further noted that California's applicable standard for the use of controlled substances in pain management is also informed by the ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,'' Medical Board of California, 7th ed. 2013 (hereinafter, the Guide). *Id.* at ¶ 11.

Dr. Munzing opined that, as informed by the above statutes and the Guide, the California standard of care for the use of controlled substances in pain management requires, among other things, that a physician prescribing controlled substances:

''(1) perform a sufficient physical examination and take a medical history;

(2) make an assessment of the patient's pain, their physical and psychological function, and their history of prior pain treatment;

(3) make an assessment of any underlying or coexisting diseases or conditions and order and perform diagnostic testing if necessary;

(4) discuss with the patient the risks and benefits of the use of controlled substances or any other treatment modules;

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

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

Id. at ¶ 12. Dr. Munzing also opined that the California standard of care imposes additional requirements for certain specific controlled substance prescriptions that Registrant prescribed to the subject patients. First, a physician must closely monitor patients prescribed opioid doses equivalent to or greater than 100 mg of morphine per day due to the substantially increased risks of overdose and death.[2] *Id.* at ¶ 13; *see also id.* at App. B, at 62 and 66 (referencing Centers for Disease Control guideline [3] that encourages keeping opioid dosing less than 50 mg per day MED if possible). In particular, Dr. Munzing attested that a California physician must specifically counsel the patient on the risks posed by such prescriptions and document that counseling; conduct urine drug screens of the patient and review the patient's profile in the CURES database at least every 3–4 months; refer the patient for co-management by a specialist in pain management where appropriate; and attempt to lower the medication dosage prescribed as much as possible. *Id.* at ¶ 13.

Second, a physician prescribing both opioids and benzodiazepines to a patient must exercise extra caution because both groups of drugs are respiratory depressants and simultaneous prescriptions can increase the patient's risk of overdose and death. *Id.; see also id.* at App. B, at 63 (referencing Food and Drug Administration 2016 ''Black Box Warning'' on the serious risks associated with the combined use of certain opioid medications and benzodiazepines and the Centers for Disease Control 2016 *Guideline for Prescribing Opioids for Chronic Pain*). Dr. Munzing attested that a physician who simultaneously prescribes both an opioid and a benzodiazepine should document the medical necessity for prescribing both, discuss the risks of prescribing with the patient, and document that conversation. *Id.*

Third, a physician prescribing opioids for pain management must avoid issuing overlapping prescriptions with the same therapeutic effect, commonly referred to as therapeutic duplication. *Id.* at ¶ 13. Fourth, a physician prescribing methadone to a patient for an extended term must exercise special care because methadone increases the risk of cardiac arrhythmia in certain patients. *Id.; see also id.* at App. B, at 64–66 (citing Food and Drug Administration November 2006 ''Black Box Warning'' regarding methadone hydrochloride). In particular, Dr. Munzing attested that a physician should conduct a baseline EKG test and conduct follow-up EKGs at least annually. *Id.*

Finally, Dr. Munzing opined that the California standard of care for the use of controlled substances in pain management requires physicians to be vigilant for the ''red flags'' of drug abuse or diversion of controlled substances. *Id.* at ¶ 14. A physician who encounters a red flag of abuse or diversion must address it, including through documented discussions with the patient, closer monitoring, adjusting the prescribed medication, or discontinuing treatment. *Id.* Dr. Munzing attested that the following are examples of well-known red flags of abuse and diversion of controlled substances: Extended gaps between patient visits or prescription refills; early requests for refills of controlled substances; filling prescriptions at multiple pharmacies, which could indicate the patient is attempting to avoid oversight by the pharmacist; and prescribing a ''Trinity cocktail'' of a narcotic painkiller, a benzodiazepine, and a muscle relaxer, which is combination widely known to be abused and/or diverted and which is dangerous because each component causes respiratory depression. *Id.*

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—in particular that it is consistent with the explicit text of California law, the Guide, and the Medical Board of California's 2014 *Guidelines for Prescribing Controlled Substances for Pain*.[4] As such, I apply the standard of care of the state of California as described by Dr. Munzing and California law.

ii. The Subject Patients

Patient K.K.

Registrant issued at least 244 controlled substance prescriptions to Patient K.K. between January 2012 and November 2016, including prescriptions for methadone, morphine sulfate, oxycodone, oxycodone-acetaminophen, hydromorphone, and zolpidem tartrate. RFAAX 9, at ¶ 17; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. I, O, R, V, Z, AG, and AJ (copies of prescriptions from the filling pharmacies). Registrant's prescriptions to K.K. also included various strengths and quantities across different prescriptions for the same controlled substances. For example, at different times, Registrant prescribed morphine sulfate to K.K. in 30mg, 60mg, and 100mg strengths. *See* RFAAX 8, App. G.

[2] Dr. Munzing explained that a patient's daily dosage of opioids is evaluated using morphine milligram equivalency (''MME''), also known as the daily morphine equivalent dosage (''MED''), under which each different opioid is assigned a value to represent its potency relative to morphine sulfate. RFAAX 9, at n. 1.

[3] Although the Government's evidence did not include the Centers for Disease Control and Prevention (CDC), *Guideline for Prescribing Opioids for Chronic Pain,* 2016, it is publically available at: *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[4] Dr. Munzing referenced the 2007 and 2014 Medical Board of California *Guidelines for Prescribing Controlled Substances for Pain* in his expert report. RFAAX 9, App. B, at 66. Although the Government's evidence did not include the Guidelines, the 2014 update is publically available at: *http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf.*

After reviewing the prescriptions and Registrant's patient file for Patient K.K., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for K.K. RFAAX 9, at ¶ 17. First, Registrant repeatedly issued ''dangerous levels of opioids'' to Patient K.K., including daily morphine equivalent doses ranging from over 1,600 mg per day to as high as 3,780 mg per day, without monitoring the patient through checks of the CURES database or co-management by a specialist in pain management.[5] *Id.* Registrant also issued prescriptions to K.K. for opioids with duplicated therapeutic effects, including overlapping prescriptions for oxycodone and oxycodone-acetaminophen and overlapping prescriptions for hydromorphone and oxycodone. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient K.K., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to K.K. *Id.*

Finally, Patient K.K. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances, the use of multiple pharmacies to fill controlled substance prescriptions, and an extended gap in care during 2013, without an adequate explanation. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient K.K represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 18.

Patient G.K.

Registrant issued at least 269 controlled substance prescriptions to Patient G.K. between January 2012 and July 2017, including prescriptions for hydrocodone-acetaminophen, hydromorphone, methadone, oxycodone, oxycodone-acetaminophen, temazepam, and tramadol. RFAAX 9, at ¶ 19; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. J and P (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient G.K., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for G.K. RFAAX 9, at ¶ 19. Registrant repeatedly issued ''dangerous levels of opioids'' to Patient G.K., including daily morphine equivalent doses ranging from 600 mg per day to as high as 1,820 mg per day, without monitoring the patient through checks of the CURES database, co-management by a specialist in pain management, or discussing and documenting the discussion of the risks posed by the high levels of opioids prescribed. *Id.* There is also no record that Registrant ever conducted EKG testing to detect abnormalities caused by long-term methadone use despite prescribing methadone to Patient G.K. from 2012 through at least 2017. *Id.* Registrant additionally issued prescriptions to G.K. for opioids with duplicated therapeutic effects, including overlapping prescriptions for hydromorphone and oxycodone, and concurrently prescribed G.K. with opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or document any discussion with G.K. regarding the risks of doing so. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient G.K., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to G.K. *Id.*

Finally, Patient G.K. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances and the use of multiple pharmacies to fill controlled substance prescriptions. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient G.K represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 20.

Patient T.L.

Registrant issued at least 120 controlled substance prescriptions to Patient T.L. between January 2012 and July 2017, including prescriptions for hydromorphone, methadone, and oxycodone. RFAAX 9 at ¶ 21; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. K, W (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient T.L, Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for T.L. RFAAX 9, at ¶ 21. First, Registrant repeatedly issued ''dangerous levels of opioids'' to Patient T.L., including daily morphine equivalent doses ranging from over 1,100 mg per day to as high as 2,380 mg per day. *Id.* Registrant also issued prescriptions to T.L. for opioids with duplicated therapeutic effects, including overlapping prescriptions for hydromorphone and oxycodone. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient T.L., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to T.L. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient T.L represent a departure from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 22.

Patient J.P.

Registrant issued at least 409 controlled substance prescriptions to Patient J.P. between January 2012 and July 2017, including prescriptions for clonazepam, diazepam, fentanyl, hydrocodone-acetaminophen,

[5] Dr. Munzing's declaration also states that Registrant's prescriptions to K.K., G.K., T.L., and J.P. fell below the standard of care in part because he prescribed high levels of opioids without monitoring the patients through urine drug screens. RFAAX 9, at ¶¶ 17, 19, 21, and 23. All of the patients' files, however, contain results for at least one urine drug screen during the relevant five year time period. *See, e.g.,* RFAAX 8, at App. B at 122, App. C at 93, App. D at 113, and App. E at 384. Dr. Munzing's declaration and report focused on the absence of urine drug screens, and did not provide an opinion regarding the frequency with which a physician prescribing the levels of opioids that Registrant was prescribing should conduct drug testing to meet the applicable standard of care. Accordingly, I cannot find substantial evidence that Registrant's urine drug screening fell below the standard of care in California based on the record evidence, and therefore, I am not sustaining the Government's allegations related to urine drug testing for any of these patients.

hydromorphone, methadone, morphine sulfate, oxycodone, temazepam, and tapentadol. RFAAX 9, at ¶ 23; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. L, T, AA, AC, AE, and AH (copies of prescriptions from the filling pharmacies). Registrant's prescriptions to J.P. also included various strengths and quantities across different prescriptions for the same controlled substances. For example, at different times, Registrant prescribed clonazepam to J.P. in .5 mg, 1 mg, and 2 mg strengths. *See* RFAAX 8, App. G.

After reviewing the prescriptions and Registrant's patient file for Patient J.P., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for J.P. RFAAX 9, at ¶ 23. Registrant repeatedly issued ''dangerous levels of opioids'' to Patient J.P., including daily morphine equivalent doses ranging from 150 mg per day to as high as 2,460 mg per day, without monitoring the patient through checks of the CURES database or co-management by a specialist in pain management. *Id.* The prescribed opioids included prescriptions for methadone ''beginning in 2012 and continuing through at least 2016 even though EKG testing in October 2014 revealed that patient J.P. had developed a prolonged QT interval,'' meaning that, in Dr. Munzing's opinion, ''continued use of methadone put J.P. at increased risk of death.'' *Id.* Registrant also concurrently prescribed J.P. opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or documenting any discussion with J.P. regarding the risks of doing so. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient J.P., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to J.P. *Id.*

Finally, Patient J.P. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances and the use of multiple pharmacies to fill controlled substance prescriptions. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient J.P represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 24.

Patient Y.P.

Registrant issued at least 122 controlled substance prescriptions to Patient Y.P. between January 2012 and July 2017, including prescriptions for carisoprodol, diazepam, hydrocodone-acetaminophen, and oxycodone-acetaminophen. RFAAX 9, at ¶ 25; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. M, X, and AL (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient Y.P., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for Y.P. RFAAX 9, at ¶ 25. Registrant concurrently prescribed Y.P. opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or documenting any discussion with Y.P. regarding the risks of doing so. *Id.* Registrant also repeatedly prescribed the ''Trinity cocktail'' to Patient Y.P., which as noted above, Dr. Munzing opined to be a dangerous combination of controlled substances widely known to be abused and/or diverted. Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient Y.P., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to Y.P. *Id.*

Finally, Patient Y.P. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances, the use of multiple pharmacies to fill controlled substance prescriptions, and multiple extended gaps in care including from October 2012 to December 2013, from December 2013 to March 2014, from June 2014 to October 2014, and from December 2015 to March 2016. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions and the prescriptions for the ''Trinity cocktail,'' Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient Y.P represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 26.

II. Discussion

Under Section 304 of the Controlled Substances Act (hereinafter, 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 by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . 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). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . 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; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth

Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

DEA regulations state, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[6] I find that the evidence satisfies the Government's *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Registrant has not produced any evidence to rebut the Government's *prima facie* case. Registrant filed a request for a hearing upon receipt of the OSC but did not make any subsequent filings and failed to respond to an order issued by the ALJ. The ALJ, therefore, properly determined that Registrant had waived his right to a hearing and terminated the proceedings.

a. Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

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

i. Allegations of Violations of Federal Law

The Government has alleged that from at least January 2012 through at least December 2017, Registrant unlawfully issued prescriptions for controlled substances in violation of the CSA. OSC, at 4. Specifically, the Government alleges that Registrant repeatedly violated 21 CFR 1306.04 by issuing prescriptions for controlled substances to Patients K.K., G.K., T.L., J.P., and Y.P. beneath the standard of care in California, the state in which Registrant holds DEA registration, outside the usual course of professional practice, and without a legitimate medical purpose. *Id.*

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 the California Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons, 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 and document the discussions, and give special attention to patients who pose a risk for medication misuse and diversion. Based on the credible and unrebutted opinion of the Government's expert, I also found above that Registrant issued at least 1,164 controlled substance prescriptions, often for extremely high doses of opioids and in dangerous combinations of opioids and benzodiazepines, without performing or documenting physical examinations or conducting medical histories adequate to justify the prescribed medications, and often without counseling the patients on the risks posed by their medications; proper ongoing monitoring; or resolving or documenting resolution of red flags of abuse and/or diversion as required by the standard of care. *See supra* I.c.ii.

My findings demonstrate that Registrant 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). For example, I found, based on Dr. Munzing's credible and unrebutted expert opinion, that Registrant did not perform adequate physical exams or take appropriate medical histories before issuing controlled substances to the five subject patients.

I also found that Registrant repeatedly ignored signs of abuse and/or diversion. Dr. Munzing credibly opined that a California physician who prescribes controlled substances for pain management within the standard of care and in the usual course of professional practice must be vigilant for red flags of abuse or diversion of controlled substances and must address any such red flags he encounters, including through ''documented discussions with the patient, closer monitoring, adjusting the medication or quantity of medication prescribed, or discontinuing treatment.'' RFAAX 9, at ¶ 14. As discussed *supra,* I found four of the subject patients presented red flags of abuse and diversion of controlled substances, including early requests for refills of controlled substances. Registrant, however, did not document discussions with the patients regarding the majority of the red flags, and there is no evidence in the patient files that Registrant otherwise addressed the red flags of abuse and diversion presented by Patients K.K., G.K., J.P., and Y.P. Registrant's failure to document and address the red flags was a violation of the standard of care in accordance with the credible and unrebutted opinion of the Government's expert.

For these reasons, in addition to the reasons I detailed *supra* I.c.ii, I find that the Government has presented substantial evidence that between 2012 and 2017 Registrant issued controlled substance prescriptions to the five subject patients that were issued outside the usual course of professional practice and beneath the applicable standard of care in California. Accordingly, I am

[6] As to Factor One, there is no record evidence of disciplinary action against Registrant'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 Registrant's 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 Registrant has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f). However, as prior Agency decisions 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. *Dewey C. MacKay, M.D.,* 75 FR at 49973. Those Agency decisions have therefore concluded that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

The Government's case includes no allegation under Factor Five.

sustaining the Government's allegation that Registrant violated 21 CFR 1306.04.

ii. Allegations of Violations of California Law

The Government has also alleged that Registrant's prescribing practices in regards to the subject patients violated state law. OSC, at 4–7. 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). Therefore, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Registrant violated this provision with respect to the controlled substance prescriptions for Patients K.K., G.K., T.L., J.P., and Y.P. I also find based on the uncontroverted evidence that Registrant issued these same controlled substance prescriptions without ''an appropriate prior examination and a medical indication,'' which is a violation of Cal. Bus. & Prof. Code 2242(a).[7]

In sum, I find that the record contains substantial evidence that Registrant 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 the professional practice, and in violation of federal and state law. I, therefore, find that Factors Two and Four weigh in favor of revocation. *See Mark A. Wimbley, M.D.,* 86 FR 20713, 20726 (2021).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's registration should be revoked because his continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''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 at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 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 registrant; 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).

In this matter, Registrant did not 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 or made any demonstration that he can be trusted with a registration. The evidence presented by the Government of Registrant's conduct clearly indicates that he cannot be so entrusted.

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

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and § 823(f), I hereby revoke DEA Certificate of Registration No. BB0500365. 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 David H. Betat, M.D. to renew or modify this registration, as well as any other pending application of David H. Betat, M.D. for registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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[7] The Government has also alleged that Registrant violated Cal. Bus. & Prof. Code § 2241.5. Section 2241.5 permits California physicians to treat pain, including intractable pain, but requires them, among other requirements, to ''exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, . . . requires consultation with, or referral to, a more qualified specialist.'' Dr. Munzing's expert report did not address whether Registrant failed to exercise reasonable care in determining whether the subject patients' treatment required consultation with, or referral to, a more qualified specialist. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Registrant violated Cal. Bus. & Prof. Code § 2241.5.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–38]

Craig S. Rosenblum, M.D.; Decision and Order

I. Introduction

On August 8, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration to Craig S. Rosenblum, M.D. (hereinafter, Respondent), of Palm Desert, California. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC)), at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificates of Registration BR0869719, BA7661564, and DATA-Waiver No. XR0869719 ''because . . . [his] continued registration constitute[d] 'an imminent danger to the public health and safety.' '' [1] *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Respondent ''committed such acts as would render . . . [his] registration under 21 U.S.C. 823(f) inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4).'' *Id.* at 2. Specifically, the OSC alleges that Respondent issued unlawful controlled substance prescriptions, that this ''conduct reflects negative experience in prescribing with respect to controlled substances in violation of 21 U.S.C. 823(f)(2),'' and that Respondent ''failed to comply with applicable federal and state laws relating to controlled substances in violation of 21 U.S.C. 823(f)(4).'' *Id.* The OSC also alleges that a California medical expert reviewed Respondent's medical files and Controlled Substance Utilization Review and Evaluation System (hereinafter, CURES) reports and concluded that Respondent's ''issuance of each prescription fell below minimal

[1] Registration No. BR0869719 is assigned to Respondent. Registration No. BA7661564 is assigned to Aurora Surgery Center. OSC, at 2. Nothing in the record transmitted to me challenges Respondent's responsibility for both of these registrations. *See also infra* section III.A.