Controlled substance	Drug code	Schedule
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Levomethorphan	9210	II
Levorphanol	9220	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to bulk manufacture API quantities of the listed controlled substances for validation purposes and FDA approval.

Dated: March 5, 2020.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–05750 Filed 3–18–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John O. Dimowo, M.D.; Decision and Order

On August 28, 2017, the Drug Enforcement Administration (hereinafter, DEA) Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ), issued a Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD) on the action to revoke the DEA Certification of Registration of John O. Dimowo, M.D. Neither party filed exceptions to the RD. Having reviewed and considered the entire administrative record before me, I adopt the ALJ's RD with minor modifications, where noted herein.*[A]

Overall, with respect to this case, I appreciate Respondent's efforts to limit DEA time and resources by stipulating to many of the Government's fact allegations. However, as explained in the findings and conclusions below, his actions, including prescribing after a court's restriction and prescribing in Texas after his convictions and settlement in California without a DEA registration, contradicted the credibility of his words. The Respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not recur. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,974 (2019). As described herein, Respondent did not convince me or the ALJ that he could be entrusted with a DEA registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration BD3755571 issued to John O. Dimowo, 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 John O. Dimowo to renew or modify this registration, as well as any pending application of John O. Dimowo for registration in California. This Order is effective April 20, 2020.

Dated: March 2, 2020.

Uttam Dhillon,

Acting Administrator.

Paul E. Soeffing, Esq., for the Government

Courtney E. Pilchman, Esq., for the Respondent

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

Charles Wm. Dorman, Administrative Law Judge. On July 21, 2016, the Drug Enforcement Administration (''DEA'' or ''Government'') served John O. Dimowo, M.D., (''Respondent'') with an Order to Show Cause (''OSC''), seeking to revoke his DEA Certificate of Registration (''COR''), Number BD3755571. Administrative Law Judge Exhibit (''ALJ–'') 1, 6. One of the allegations contained in the OSC was that the Respondent lacked state authority to handle controlled substances in California, where he was registered. In response to the OSC, the Respondent timely requested a hearing before an Administrative Law Judge. ALJ–2.

On September 2, 2016, the Government filed a Motion for Summary Disposition. ALJ–7. Therein, the Government argued that the Respondent lacked state authority in California to handle controlled substances, the state where the Respondent was registered with the DEA. ALJ–7, at 2. The Government stated that an Interim Suspension Order was issued against the Respondent by the Medical Board of California (''MBC'') on June 10, 2016. ALJ–7, at 2–3. Attached to the Government's Motion was a copy of the MBC's Interim Order of Suspension. ALJ–7, Ex. 1. The Government also stated that on June 28, 2016, a hearing was held before a California administrative law judge. ALJ–7, at 3. Following that hearing, on July 1, 2016, the state continued the suspension of the Respondent's medical license, and issued an Interim Order of Suspension. ALJ–7, Ex. 2.

On September 16,*[B] 2016, the Respondent filed a Response to the Government Motion for Summary Disposition (''Response''). ALJ–8. Therein, the Respondent acknowledged that his California medical license had been suspended but asserted that he had ''completed negotiation with the [MBC] to resolve the accusations that resulted in the temporary license suspension.'' ALJ–8, at 1. Attached to the Response was a copy of a Stipulated Settlement and Disciplinary Order between the Respondent and the Attorney General of California. ALJ–8, Ex. 1. In the Response, the Respondent requested that ''the hearing on this matter be stayed pending the final approval of the negotiated settlement stipulation by the Executive Director of the [MBC].'' ALJ–8,*[C] at 1.

At that time, both parties agreed that the Respondent currently lacked state authority to handle controlled substances in California. Because there was no genuine question of fact, no adversarial hearing was required. *See, e.g., Jesus R. Juarez, M.D.,* 62 FR 14,945, 14,945 (1997). Therefore, because DEA precedent requires that a practitioner be authorized to handle controlled substances in the jurisdiction in which the practitioner is registered, I granted the Government's Motion for Summary Disposition on October 18, 2016. *See* ALJ–14. On November 15, 2016, I forwarded my October 18, 2016 Order Granting Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (''Recommended Decision'') to the Acting Administrator of the DEA. ALJ–15.

Subsequent to the issuance of the Recommended Decision, the MBC restored a substantial portion of the

*[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. 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 an asterisk and a letter.

*[B] Correction.

*[C] Correction.

Respondent's state authority to practice medicine and handle controlled substances in California, but did limit his ability to prescribe or handle drugs that are listed in Schedules II and III of the California Uniform Controlled Substances Act. In light of the action by the MBC, the Acting Administrator determined that revocation of the Respondent's COR was no longer warranted based on a lack of state authority. ALJ–19, at 2. The OSC, however, contained other allegations, which the Government had alleged as grounds for revocation.

Following input from the parties, ALJ–17, ALJ–18, the Acting Administrator issued an Order in this case on February 23, 2017. ALJ–19.*[D] That Order placed restrictions on the Respondent's COR, prohibiting him from ''prescribing, direct dispensing, purchasing and ordering any controlled substance in schedules II and III of the Controlled Substances Act.'' ALJ–19, at 6. The Order further prohibited the Respondent ''from administering any controlled substance in schedules II and III, except when such administration is for the purpose of providing anesthesia to a patient in a hospital or licensed surgery center.'' *Id.* at 6. Finally, the Acting Administrator remanded this case to the Office of Administrative Law Judges for ''further proceedings consistent with [his] decision.'' *Id.* at 7.

Following that remand, I issued an Order for Prehearing Statements. ALJ–20. The parties filed Prehearing Statements, ALJ–22, ALJ–23, as well as Supplemental Prehearing Statements. ALJ–28, ALJ–29. Afterwards, a hearing in this matter was held in Santa Ana, California on June 27, 2017.

The issue before the Administrator is whether the DEA should revoke the registration of John O. Dimowo, M.D., DEA Certificate of Registration, BD3755571, pursuant to 21 U.S.C. 824(a)(4), and deny any pending application [1]* for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f).

This Recommended Decision is based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

The Remaining Allegations

I. Unlawful Distribution of Controlled Substances to Three Undercover Agents on Five Separate Occasions in Violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), and 2242(a) [2]

1. On March 30, 2012, an undercover law enforcement officer (''UC1'') met with the Respondent. GE–3. During an office visit that day, UC1 rated his pain as a two, on a scale of one to ten; explained that his only pain was caused by exercise and walking a lot; and stated that he was taking a friend's Vicodin and Adderall to self-medicate. *Id.* The Respondent conducted little or no physical examination of UC1 and provided no diagnosis warranting a prescription for controlled substances, yet he prescribed Adderall 10 mg, a schedule II controlled substance, and Norco, a schedule III controlled substance, to UC1. ALJ–1, at 2; GE–4.

2. On May 4, 2012, UC1 again met with the Respondent. GE–5. During an office visit that day, UC1 stated his pain was good; asked for Opana, a schedule II controlled substance, which he said he had been obtaining from someone at a gym; said his pain was caused by exercise; and failed a urine screening for the drugs the Respondent had previously prescribed to him. *Id.* The Respondent conducted little or no physical examination of UC1 and provided no diagnosis warranting a prescription for controlled substances, yet he prescribed Adderall 10 mg, a schedule II controlled substance, and Vicodin, a schedule III controlled substance, to UC1. ALJ–1, at 2; GE–6.

3. On May 4, 2012, UC2 met with the Respondent. GE–7. During an office visit that day, UC2 stated she wanted something to treat her soreness after exercise and she asked for Adderall to stay alert with her children, and Xanax or Vicodin to relax at night. *Id.* The Respondent conducted little or no physical examination of UC2 and provided no diagnosis warranting a prescription for controlled substances, yet he prescribed Adderall 10 mg, Vicodin 5/500 mg, and Xanax 2 mg, all controlled substances in schedules II, III, and IV, respectively. ALJ–1, at 2–3; GE–8.

4. On March 21, 2013, UC3 met with the Respondent. GE–9. During an office visit that day, UC3 complained of generalized pain from an old high school football accident and informed the Respondent that he did not have insurance, but he did what he needed to do to get oxycodone. *Id.* The Respondent conducted little or no physical examination of UC3 and provided no diagnosis warranting a prescription for controlled substances, yet he prescribed Percocet 10/325 mg, a schedule II controlled substance, to UC3. ALJ–1, at 3; GE–10.

5. On April 25, 2013, UC3 met with the Respondent. GE–11. The Respondent conducted little or no physical examination of UC3 and provided no diagnosis warranting a prescription for controlled substances, yet he prescribed Percocet 10/325 mg, to UC3. ALJ–1, at 3; GE–12. *[I am omitting RD Section II and renumbered subsequent sections for brevity due to the Government's dismissal of the charge].[3]

II. State Convictions

6. On May 14, 2015,*[E] a Los Angeles County jury convicted the Respondent of seven felony counts of issuing unlawful controlled substance prescriptions for Adderall, hydrocodone, and alprazolam. On March 28, 2016, the presiding judge reduced the felony convictions to misdemeanors. *Id.* at 4. These convictions may be considered in determining whether the Respondent's registration is inconsistent with the public interest under 21 U.S.C. 823(f)(3) and 824(a)(4).

III. Writing Prescriptions in Texas Without a Valid DEA COR for a Texas Location

7. In March and April 2017, the Respondent issued three prescriptions for Lyrica, a schedule V controlled substance, from his medical practice in El Paso, Texas. In writing these three prescriptions, the Respondent listed his DEA COR for his registered address in California. At the time the Respondent wrote the prescriptions in Texas he did not have a DEA COR for a registered Texas location. Thus, the Respondent violated the separate registration requirements of 21 U.S.C. 822(e) and 21 CFR 1301.12(a) and (b)(3). ALJ–29, at 5–6; GE–23, 24.

*[D] Correction.

[1]* [RD footnote 1 omitted due to lack of relevance of the status of Respondent's registration or application. *See Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019).]

[2] I have taken official notice of Cal. Health & Safety Code § 11153(a) (Westlaw, Current with all laws through Ch. 870 of 2019 Regular Session); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), and 2242(a) (Westlaw, Current with all laws through Ch. 870 of 2019 Regular Session); Tr. 7. *[*See also* GE 1 and GE 2.]

[3] The Government withdrew* [the allegation of issuing prescriptions for office use or for personal use in violation of 21 CFR 1306.04(b)] at the hearing. Tr. 7.

*[E] Correction.

Witnesses

I. The Government's Witnesses

The Government presented no witness during its case-in-chief. Rather, the Government introduced 24 Exhibits, and relied upon the 83 stipulations of fact that the Respondent had entered into with the Government. Following the presentation of the Respondent's case-in-chief, the Government presented two rebuttal witnesses.

The Government's first rebuttal witness was a Diversion Investigator (DI). Tr. 112–130. DI has been a diversion investigator with the DEA for five years and she is assigned to the Los Angeles Field Division, Tactical Diversion Squad. DI attended the basic 12-weeks of training for new diversion investigators at Quantico, VA, and two additional training courses at Quantico concerning financial investigations. As a diversion investigator, DI has conducted regulatory and criminal investigations of individuals and organizations holding DEA registrations to deal with controlled substances. As a member of the Tactical Diversion Squad, DI's investigations primarily concern criminal matters involving doctors and pharmacies. DI became the lead investigator concerning the Respondent when the initial investigator left the Tactical Diversion Squad.

As a rebuttal witness DI provided testimony concerning where the Respondent was registered to handle controlled substances; the prescriptions the Respondent wrote in Texas; and her interaction with the Respondent's MBC probation officer. I find DI's testimony to be thorough, detailed, and internally consistent with Government Exhibits 18, 23, and 24. Therefore, I merit it as credible in this Recommended Decision.

The Government's second rebuttal witness was M.D., who has been an investigator with the California Department of Consumer Affairs for over six years. M.D. is assigned to the Health Quality Investigation Unit of the Department. M.D.'s credentials are further detailed at GE–13, at 8. M.D. was the main investigator concerning the Respondent. Tr. 131. M.D. provided rather limited testimony concerning whether the Respondent had complied with terms of his stipulated settlement with the MBC and his familiarity with reporting requirements contained in such settlements. I find M.D.'s testimony to be thorough, detailed, and internally consistent with Government Exhibit 18. Therefore, I merit it as credible in this Recommended Decision.

II. The Respondent's Witness

The Respondent's case-in-chief included the testimony of the Respondent, reliance upon the 83 stipulations of fact, and introduction of Respondent's Exhibits A–CC. The overall tenor of the Respondent's testimony was his acceptance of responsibility and detailing steps he has taken to ensure that his past violations are not repeated. Tr. 21–112.

The Respondent testified about his medical training and background, as well as describing the various medical positions he has held since being licensed as a medical doctor in the United States and his impressive curriculum vitae. The Respondent testified about actions he took to divest himself of his pain management practice after the MBC visited his clinic in 2013, but before he was charged with any crimes. The Respondent testified concerning his conviction on seven felony counts, later reduced to misdemeanors by the trial judge, and the actions he took following the trial, including performing 353 hours of community service, even though he was only required to perform 130 hours. Tr. 45. During his community service, the Respondent shared his ''story'' with individuals dealing with substance abuse issues in an effort to allow them to learn from his own mistakes. He testified that if he is allowed to keep his COR he would restrict his practice to anesthesiology in a hospital or surgery center, using only the controlled substances those institutions had acquired. The Respondent testified in a very candid and straightforward manner. There were at least six portions of his testimony, however, that strained credulity.

The Respondent testified that, in retrospect, he does not believe he was prepared to enter into a pain management practice in 2010 because he had not reviewed the requirements for substance control; he was not able to identify drug seeking patients; and he was too trusting of patients. Tr. 35–36. The Respondent, however, was board certified in pain management. The Respondent had also completed a two-year pain management fellowship and was a Diplomate of the American Board of Pain Medicine. RE–A, at 1. The Respondent had also been practicing medicine in the United States for 17 years by the time he opened his pain clinic in 2007, and although the primary focus of his practice had been anesthesiology, he worked in a pain clinic before he opened his own pain clinic. I find that the Respondent's assertion of being ill prepared to open a pain clinic rings hollow given his training and experience, which included work in a pain clinic, where 70% of his work was pain management, prior to opening his own pain clinic.

The Respondent testified that he intended to limit his medical practice to anesthesiology. Just this year, however, the Respondent opened a pain clinic in Texas.*[F]

When asked to explain why he had failed to perform examinations of the three undercover patients, the Respondent testified that he had performed a short diagnosis, as he had been trained to do in Nigeria. The Respondent's failure to perform the examinations, however, occurred in 2012, years after he had been trained in Nigeria, and after more than 20 years of medical practice in the United States.

When describing the requirements of his stipulated settlement with the MBC, the Respondent either did not understand the terms of the settlement or he mischaracterized its terms to make it seem more onerous than it is. For example, he testified that he must have a physician to monitor his medical practice. Tr. 59. The settlement provided, however, that he need not have a monitor if he participates in a professional enhancement program. GE–18, at 11. The Respondent testified that the stipulated settlement required that he practice medicine at least 40 hours a month in California. The stipulated settlement contains no such provision. As Respondent's counsel stated, ''the best reflection of the terms and conditions are contained in the stipulated settlement . . . .'' Tr. 136.

With respect to the Respondent's ability to practice medicine following his conviction and sentencing by a California court, the Respondent testified that the sentencing judge did not restrict his ability to practice medicine, stating that the judge left that to the MBC. Tr. 56. That testimony stands in sharp contrast to the Finding of Fact contained in the MBC's Interim Order of Suspension. In the MBC's second finding of fact it states that the court ''ordered Respondent 'not to practice medicine until an order has been made by the Medical Board with respect to your ability to do so in the State of California.' '' GE–17, at 2. Thus, it would appear that the trial judge did prohibit the Respondent from practicing medicine until the MBC had taken action.

The Respondent also testified that when he wrote prescriptions for a

*[F] I am omitting two sentences of the R.D., because they are superfluous and could be misinterpreted as conflicting with my February 23, 2017 Order.

schedule V controlled substance in Texas this year he thought he had authority to do so. He apparently based this belief upon the fact that he had requested a change of mailing address with the DEA and the DEA had acknowledged the new address. He also based it upon the fact that he had called a pharmacy in Texas, and the pharmacy had told him it was okay to issue the prescription. These prescriptions, however, were written after the Respondent had taken a ''PACE'' course on how to write prescriptions, after a motion had been filed to revoke the Respondent's bail prior to his trial for violating a court order not to do so,[4] and after he had been convicted of writing illegal prescriptions. Thus, it would appear that the Respondent's belief that he had the authority to write prescriptions for controlled substances in Texas was an unreasonable belief.

I find that the Respondent presented as a generally credible and sincere witness. The six examples detailed above, however, detract from the Respondent's overall credibility. Thus, to the extent that the Respondent's testimony is in conflict with other evidence of record, or it is based on illogical or unsound reasoning, I defer to that other evidence, logic and/or reasoning.

The Facts

I. Stipulations of Fact

The parties stipulated to the following facts.

1. Respondent is registered with DEA as an individual practitioner in Schedules II–V under DEA registration number BD3755571 at 5857 Pine Avenue, Chino Hills, CA 91709. This registration expires by its terms on June 30, 2017. *[Respondent filed for renewal in May 2017. *See* Tr. 116, 127.]

2. Norco is a hydrocodone combination product. Prior to October 6, 2014, hydrocodone combination products were classified as Schedule III controlled substances. After October 6, 2014, hydrocodone combination products were classified as Schedule II controlled substances.

3. Adderall is a brand name for generic amphetamine. Amphetamine is classified as a Schedule II controlled substance.

4. Vicodin is a hydrocodone combination product. Prior to October 6, 2014, hydrocodone combination products were classified as Schedule III controlled substances. After October 6, 2014, hydrocodone combination products were classified as Schedule II controlled substances.

5. Xanax is a brand name for generic alprazolam. Alprazolam is classified as a Schedule IV controlled substance.

6. Percocet is a brand name for generic oxycodone. Oxycodone is classified as a Schedule II controlled substance.

7. On March 30, 2012, Respondent issued prescriptions to UC1 for 90 dosage units of Norco 10/325 mg and 30 dosage units of Adderall 10 mg.

8. On May 4, 2012, Respondent issued prescriptions to UC1 for 90 dosage units of Vicodin 5/500 mg and 30 dosage units of Adderall 10 mg.

9. On May 4, 2012, Respondent issued prescriptions to UC2 for 30 dosage units of Vicodin 5/500 mg, 60 dosage units of Xanax 2 mg, and 30 dosage units of Adderall 10 mg.

10. On March 21, 2013, Respondent issued a prescription to UC3 for 90 dosage units of Percocet 10/325 mg.

11. On April 25, 2013, Respondent issued a prescription to UC3 for 90 dosage units of Percocet 10/325 mg.

12. On March 22, 2013, investigators with the MBC, assisted by DEA investigators, executed a state search warrant at Respondent's medical offices located at 1120 West La Palma #2, Anaheim, California 92801 and 218 East Anaheim St., Wilmington, California 90744, and seized materials, including all controlled substances from both locations and medical records of patients.

13. On May 14, 2015, a Los Angeles County jury convicted Respondent of seven state felony counts of issuing unlawful controlled substance prescriptions for hydrocodone and Adderall.

14. On March 28, 2016, Respondent was sentenced and the presiding judge, pursuant to the discretion afforded him under state law, reduced the convictions to misdemeanors and sentenced Respondent to probation.

15. On June 10, 2016, the MBC suspended Respondent's medical license with the issuance of an ex parte Interim Order of Suspension.

16. On July 1, 2016,[5] after a hearing, the MBC continued the suspension of Respondent's medical license with the issuance of an Interim Order of Suspension.

17. On December 20, 2016, the MBC issued a Decision adopting a Stipulated Settlement and Disciplinary Order entered into by Respondent and the Attorney General for California on September 9, 2016. The Decision was effective January 19, 2017, and reinstated Respondent's medical license, with restrictions.

18. The parties stipulate to the authenticity and admission of Government Exhibit 1: Cal. Health & Safety Code § 11153(a).

19. The parties stipulate to the authenticity and admission of Government Exhibit 2: Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

20. The parties stipulate to the authenticity and admission of Government Exhibit 3: DVD recording and transcript of undercover visit by UC1 on March 30, 2012. (13 pages)

21. The parties stipulate to the authenticity and admission of Government Exhibit 4: Prescriptions written by John O. Dimowo for UC1 for 90 Norco 10/325 mg and 30 Adderall 10 mg dated March 30, 2012.

22. The parties stipulate to the authenticity and admission of Government Exhibit 5: DVD recording and transcript of undercover visit by UC1 on May 4, 2012.

23. The parties stipulate to the authenticity and admission of Government Exhibit 6: Prescriptions written by John O. Dimowo for UC1 for 90 Vicodin 5/500 mg and 30 Adderall 10 mg dated May 4, 2012.

24. The parties stipulate to the authenticity and admission of Government Exhibit 7: DVD recording and transcript of undercover visit by UC2 on May 4, 2012.

25. The parties stipulate to the authenticity and admission of Government Exhibit 8: Prescriptions written by John O. Dimowo for UC2 for 30 Vicodin 5/500 mg, 60 Xanax 2 mg and 30 Adderall 10 mg dated May 4, 2012.

26. The parties stipulate to the authenticity and admission of Government Exhibit 9: DVD recording and transcript of undercover visit by UC3 on March 21, 2013.

27. The parties stipulate to the authenticity and admission of Government Exhibit 10: Prescription written by John O. Dimowo for UC3 for 90 Percocet 10/325 mg dated March 21, 2013.

28. The parties stipulate to the authenticity and admission of Government Exhibit 11: DVD recording and transcript of undercover visit by UC3 on April 25, 2013.

29. The parties stipulate to the authenticity and admission of Government Exhibit 12: Prescription written by John O. Dimowo for UC3 for 90 Percocet 10/325 mg dated April 25, 2013.

30. The parties stipulate to the authenticity and admission of Government Exhibit 13: Search Warrant dated March 19, 2013.

[4] *See* GE–16, at 4, para 13: GE–19, at 1170.

[5] *See* Tr. 6, lines 24–25 (correcting a typographical error in the Prehearing Ruling).

31. The parties stipulate to the authenticity and admission of Government Exhibit 14: Patient File for UC1.

32. The parties stipulate to the authenticity and admission of Government Exhibit 15: Patient File for UC2.

33. The parties stipulate to the authenticity and admission of Government Exhibit 16: Certified copy of MBC's Interim Order of Suspension (ex parte) dated June 10, 2016.

34. The parties stipulate to the authenticity and admission of Government Exhibit 17: Certified copy of MBC's Interim Order of Suspension dated July 1, 2016.

35. The parties stipulate to the authenticity and admission of Government Exhibit 18: Certified copy of MBC's Decision dated December 20, 2016, and Stipulated Settlement and Disciplinary Order dated September 9, 2016.

36. The parties stipulate to the authenticity and admission of Government Exhibit 19: *California* v. *Dimowo,* Case No. BA417100, Reporter's Transcript of Proceedings (Cal. Sup. Ct. Los Angeles County, Apr. 24–May 14, 2015).

37. The parties stipulate to the authenticity and admission of Government Exhibit 20: *California* v. *Dimowo,* Case No. BA417100, Conviction Minute Order (Cal. Sup. Ct. Los Angeles County, May 14, 2015).

38. The parties stipulate to the authenticity and admission of Government Exhibit 21: *California* v. *Dimowo,* Case No. BA417100, Sentencing Minute Order (Cal. Sup. Ct. Los Angeles County, Mar. 28, 2016).

39. The parties stipulate to the authenticity and admission of Government Exhibit 22: Curriculum Vitae of W.S., M.D.

40. The parties stipulate to the authenticity and admission of Government Exhibit 23: Two prescriptions for Lyrica authorized by Respondent in Texas and filled by ASP Cares Pharmacy.

41. The parties stipulate to the authenticity and admission of Government Exhibit 24: One prescription for Lyrica authorized by Respondent in Texas and filled by Walgreens Pharmacy.

42. The parties stipulate that UC1 is a MBC Investigator who saw Respondent in an undercover capacity posing as UC1 on March 30, 2012, and May 4, 2012.

43. The parties stipulate that the prescription written by John O. Dimowo for UC1 for 90 Norco 10/325 mg, dated March 30, 2012, (Government Exhibit 4) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

44. The parties stipulate that the prescription written by John O. Dimowo for UC1 for 30 Adderall 10 mg, dated March 30, 2012, (Government Exhibit 4) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

45. The parties stipulate that the prescription written by John O. Dimowo for UC1 for 90 Vicodin 5/500 mg, dated May 4, 2012, (Government Exhibit 6) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

46. The parties stipulate that the prescription written by John O. Dimowo for UC1 for 30 Adderall 10 mg, dated May 4, 2012, (Government Exhibit 6) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

47. The parties stipulate that UC2 was a MBC Investigator who saw Respondent posing in an undercover capacity as UC2 on May 4, 2012.

48. The parties stipulate that the prescription written by John O. Dimowo for UC2 for 30 Vicodin 5/500 mg, dated May 4, 2012, (Government Exhibit 8) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

49. The parties stipulate that the prescription written by John O. Dimowo for UC2 for 60 Xanax 2 mg, dated May 4, 2012, (Government Exhibit 8) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

50. The parties stipulate that the prescription written by John O. Dimowo for UC2 for 30 Adderall 10 mg, dated May 4, 2012, (Government Exhibit 8) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).

51. The parties stipulate that UC3 is a California Department of Health Care Services Investigator who saw Respondent in an undercover capacity posing as UC3 on March 21, 2013, and April 25, 2013.

52. The parties stipulate that the prescription written by John O. Dimowo for UC3 for 90 Percocet 10/325 mg, dated March 21, 2013, (Government Exhibit 10) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).[6]

53. The parties stipulate that the prescription written by John O. Dimowo for UC3 for 90 Percocet 10/325 mg, dated April 25, 2013, (Government Exhibit 12) was issued for no legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), 2242(a).[7]

54. The parties stipulate that during March and April 2017, Respondent maintained a principal place of business or professional practice in Texas from which he issued three prescriptions for Lyrica (Government Exhibits 23 and 24), which is a brand name for generic pregabalin a Schedule V controlled substance. The parties further stipulate that during March and April 2017, Respondent was not registered in Texas with DEA.

55. The parties stipulate to the authenticity and admission of Respondent's Exhibit A: CV of Dr. Dimowo.

56. The parties stipulate to the authenticity and admission of Respondent's Exhibit B: Character letter from P.B., D.O., dated December 3, 2013.

57. The parties stipulate to the authenticity and admission of Respondent's Exhibit C: Character letter from R.B., M.D.

58. The parties stipulate to the authenticity and admission of Respondent's Exhibit D: Character letter from S.B., D.P.M., dated November 26, 2013.

[6] *See* Tr. 107–08 (deleting reference to 21 U.S.C. 841(a)(1), and Cal. Health & Safety Code § 11153(a)).

[7] *See* Tr. 107–08 (deleting reference to 21 U.S.C. 841(a)(1), and Cal. Health & Safety Code § 11153(a)).

59. The parties stipulate to the authenticity and admission of Respondent's Exhibit E: Character letter from E.G., M.D., dated December 5, 2013.

60. The parties stipulate to the authenticity and admission of Respondent's Exhibit F: Character letter from S.V., M.D., dated December 3, 2013.

61. The parties stipulate to the authenticity and admission of Respondent's Exhibit G: Character letter from R.R., M.D., dated December 13, 2013.

62. The parties stipulate to the authenticity and admission of Respondent's Exhibit H: Character letter from J.L., M.D., dated December 3, 2013.

63. The parties stipulate to the authenticity and admission of Respondent's Exhibit I: Character letter from K.K., M.D., dated December 19, 2013.

64. The parties stipulate to the authenticity and admission of Respondent's Exhibit J: Certificate of completion of Medical Record Keeping Course, UC San Diego PACE program, dated July 18–19, 2013.

65. The parties stipulate to the authenticity and admission of Respondent's Exhibit K: Certificate of completion of Physician Prescribing Course, UC San Diego PACE program, dated July 15–17, 2013.

66. The parties stipulate to the authenticity and admission of Respondent's Exhibit L: Certificate of attendance Medical Ethics and Professional Boundaries Program, April 8, 2017.

67. The parties stipulate to the authenticity and admission of Respondent's Exhibit M: Certificate of completion Drug and Alcohol Awareness Class, dated November 3, 2015.

68. The parties stipulate to the authenticity and admission of Respondent's Exhibit N: Chronic Pain Management, dated April 15, 2015.

69. The parties stipulate to the authenticity and admission of Respondent's Exhibit O: Acute Pain Management, dated April 15, 2015.

70. The parties stipulate to the authenticity and admission of Respondent's Exhibit P: Pain Review Course, dated August 20, 2015.

71. The parties stipulate to the authenticity and admission of Respondent's Exhibit Q: Medical Ethics for Physicians, dated August 12, 2015.

72. The parties stipulate to the authenticity and admission of Respondent's Exhibit R: Opioid Use Disorder, dated August 22, 2015.

73. The parties stipulate to the authenticity and admission of Respondent's Exhibit S: Prescription Opioid: Risk Management and Strategies for Safe Use, dated August 22, 2015.

74. The parties stipulate to the authenticity and admission of Respondent's Exhibit T: Family Healing Center community service, dated September 16, 2016, for 42 hours.

75. The parties stipulate to the authenticity and admission of Respondent's Exhibit U: Chosen Few/Thin Line Sober Living community service, dated September 8, 2016, for 70 hours.

76. The parties stipulate to the authenticity and admission of Respondent's Exhibit V: Chosen Few/Thin Line Sober Living community service, dated December 14, 2015, for 54 hours.

77. The parties stipulate to the authenticity and admission of Respondent's Exhibit W: Chosen Few/Thin Line Sober Living community service, dated March 22, 201,6 for 16 hours.

78. The parties stipulate to the authenticity and admission of Respondent's Exhibit X: Recovery Can Conquer Home community service, dated September 18, 2015, for 24 hours.

79. The parties stipulate to the authenticity and admission of Respondent's Exhibit Y: Recovery Can Conquer Home community service, dated December 12, 2015, for 36 hours.

80. The parties stipulate to the authenticity and admission of Respondent's Exhibit Z: The House of Courage community service, dated August 25, 2015, for 2 hours.

81. The parties stipulate to the authenticity and admission of Respondent's Exhibit AA: Jubilee House community service, dated September 25, 2015, for 13 hours.

82. The parties stipulate to the authenticity and admission of Respondent's Exhibit BB: Jubilee House community service, dated December 16, 2015, for 12 hours.

83. The parties stipulate to the authenticity and admission of Respondent's Exhibit CC: Jubilee House community service, dated March 23, 2016, for 48 hours.

II. Findings of Fact

Respondent's Education, Training and Work Experience

1. The Respondent graduated from medical school in Nigeria in 1983. Tr. 21–22; RE–A, at 1.

2. Following medical school, the Respondent completed a one year rotating internship in one of the busiest hospitals in Nigeria. Tr. 22.

3. After completing his internship, the Respondent worked as a general practitioner for five years before he immigrated to the United States. Tr. 22; RE–A, at 2.

4. The Respondent took over a psychiatric medical practice for two years in Nigeria. Tr. 89–90.

5. The Respondent immigrated to the United States in 1989, and after he passed the exam for foreign medical graduates, he began an internship in pediatrics at the Medical College of Ohio. Tr. 22–23; RE–A, at 1.

6. Upon completion of his internship in Ohio, the Respondent began a three-year residency in anesthesiology at Vanderbilt University Medical Center, completing the program in 1994. Tr. 23; RE–A, at 1–2.

7. The Respondent then obtained a fellowship at the University of Southern California Medical Center (''USCMC'') and completed a one-year obstetrical anesthesia fellowship. Tr. 23; RE–A, at 1.

8. Following his residency at USCMC, the Respondent was appointed as an instructor in anesthesiology and a consultant anesthesiologist at the Vanderbilt University Medical Center in 1995–96. Tr. 23–24; RE–A, at 1.

9. Between 1997 and 1999, the Respondent completed a pain management fellowship at Emory University Hospital. RE–A, at 1.

10. From the time that the Respondent was admitted to medical practice in the United States until 2007 his primary area of practice was anesthesiology. Tr. 26–30.

11. While practicing anesthesiology, the Respondent has never had any malpractice complaints filed against him nor had his employment as an anesthesiologist been terminated. Tr. 30–31.

12. The Respondent was a Diplomate of the American Board of Pain Medicine. RE–A, at 1.

13. The Respondent was board certified in pain management. GE–19, at 660, 894.

14. Beginning in April 2007 the Respondent was employed as a pain management specialist and staff anesthesiologist with the Las Vegas Pain Institute, where 70% of his practice was pain management. Tr. 31; RE–A, at 2.

15. In 2007, the Respondent started the California Advanced Pain Clinic Institute, which was located across the street from the Anaheim Memorial Medical Center. Tr. 72–73; RE–A, at 1.

16. From February 2008 to September 2010, the Respondent worked part-time as a staff anesthesiologist at the St. Bernadine Medical Center in San Bernardino, CA. The Respondent

worked part-time at the St. Bernadine Medical Center because he was starting a solo practice in pain management at the same time. Tr. 32–33; RE–A, at 2.

17. The Respondent stopped working as an anesthesiologist in September 2010, because the patients he treated in his pain clinic occupied most of his time. Tr. 33.

18. The Respondent began to make changes in his medical practice in 2013 after the medical board sent some observers to his clinic to pick up patient charts. Tr. 36. At that time, the Respondent started looking for someone to take over his pain management practice, and by July 2013 he had found someone to do that. Tr. 37.

19. By July 2013, the Respondent was only doing interventional pain management in association with Dr. K., who had taken over the Respondent's practice. Tr. 38, 98. By then, the Respondent had stopped writing new pain prescriptions, though he did fill prescriptions for about 10 patients who were already on morphine pumps. Tr. 38.

20. Also in July 2013, the Respondent completed a 48-hour continuing medical education course called Physician Assessment and Clinical Education Program (''PACE''), which has been adopted by the MBC. Tr. 39; RE–J–K; GE–18, at 9.

21. In the PACE course, the Respondent studied record keeping; how to write proper prescriptions; the essence of controlled substances; and prescription-writing ethics. Tr. 39; RE–J–K.

22. The PACE course also provided instruction in how to identify drug seeking patients. Tr. 41.

Undercover Office Visits

23. The Respondent required each of his pain patients to sign a form swearing under penalty of perjury that, ''I am not an undercover agent of any law-enforcement. I do no work for the DEA, the FBI, the police or any other law enforcement agency.'' GE–14, at 12; GE–15, at 12; GE–19, at 941.

24. With respect to the treatment the Respondent provided to the undercover patients, he believes he took adequate patient histories, but he did not perform appropriate physical exams. Tr. 35–36. The Respondent issued prescriptions to those patients based on what he thought was appropriate from the information the patients provided him in their patient history. Tr. 36.

25. Regarding UC1, the Respondent gave him a ''short diagnosis,'' as he was trained to do in medical school in Nigeria. Tr. 75. UC1 complained of pain in his arms and legs after exercise, but to the Respondent's observation there was nothing significantly wrong with his arms and legs. Tr. 76. Therefore, the Respondent did not think UC1 required a full body exam. Tr. 76.

26. During his first appointment with the Respondent, UC1 informed the Respondent that he was obtaining Vicodin and Adderall from a friend. GE–3, at 9. During his second appointment, UC1 informed the Respondent that he was obtaining Opana from someone at the gym. GE–5, at 5.

27. The Respondent acknowledged that he did not do a comprehensive exam on UC2. Tr. 78.

28. With respect to UC3, the Respondent testified that he did conduct some physical exam of that patient and ''maybe that was why they acquitted me of that one.'' Tr. 78. UC3 informed the Respondent that he did what he had to do to obtain oxycodone. GE–9, at 4.

29. At the Respondent's criminal trial, UC3 testified that during his first office visit with the Respondent, when the Respondent asked him to walk on his toes, he did so in ''the normal way you'd walk on your toes.'' GE–19, at 626. UC3 did not walk in a manner to illustrate an injury. *Id.* UC3 testified that the Respondent did not do anything else to detect UC3's range of movement or his difficulty with pain. *Id.*

30. The Respondent acknowledged that his treatment of UC3 fell below acceptable medical standards. Tr. 85.

31. The Respondent acknowledged that the prescriptions that he wrote to UC3 on March 21, 2013, and April 25, 2013, were issued for no legitimate medical purposes and were outside the usual course of professional practice. Tr. 111.

The Respondent's Convictions

32. On October 9, 2013, a Felony Complaint and Arrest Warrant was filed against the Respondent. GE–16, at 3. The Respondent was charged with eight felony counts regarding prescribing scheduled drugs. Tr. 44.

33. On October 15, 2013, the Respondent was arrested and his arrest was covered by the Los Angeles Times. Tr. 52; GE–16, at 3.

34. On May 14, 2015, the Respondent was convicted of seven of those original eight felony counts. Tr. 44; GE–19, at 1161–1167.

35. When the Respondent was sentenced on March 28, 2016, the trial judge reduced the felony charges to misdemeanors, and the Respondent was placed on 36 months of probation. Tr. 55; GE–21, at 1–2.

36. The Respondent testified that the sentencing judge did not restrict the Respondent's ability to practice medicine, stating that the judge left that to the MBC. Tr. 56. The Finding of Fact contained in the MBC's Interim Order of Suspension, however, indicates that the court ''ordered Respondent 'not to practice medicine until an order has been made by the Medical Board with respect to your ability to do so in the State of California.''' GE–17, at 2.

37. The Respondent has taken several continuing medical education courses, to include: Pain management review courses; a course presented by the American Academy of Addiction Psychiatry; a 16-hour course concerning the problems of substance abuse; a medical ethics course; and a course prescribed by courts to alcohol and drug crime clients. Tr. 43. Most of these courses were completed in 2015 after the Respondent was convicted. RE–M, P, R–S. The Respondent completed two of these courses in 2015 prior to his conviction. RE–N–O, Q.

38. The Respondent was also sentenced to perform 130 hours of community work. Tr. 45. The Respondent chose to perform those hours working with patients who suffered from addiction problems. Tr. 45.

39. The Respondent performed 353 community service hours to show his remorse. Tr. 45–46.

40. Some of the Respondent's community service hours were performed with a psychiatrist in an addiction medicine practice where the Respondent observed, educated, and talked to patients who came to the psychiatry addiction clinic. Tr. 46. The Respondent shared his story with those patients concerning his arrest. Tr. 46.

41. The Respondent also performed community service hours at sober living facilities where he counseled those with addictions and instructed on the dangers of addiction by using a PowerPoint presentation. Tr. 47–51. The Respondent also helped to maintain the cleanliness of the facilities. Tr. 47–51.

42. The physicians the Respondent worked with, to include those who wrote letters of recommendation on his behalf, are all aware that he was arrested. Tr. 52–54; RE–B–I. Most of these letters are dated in 2013. *Id.*

43. Representatives from the various organizations at which the Respondent performed his community service hours also wrote letters in support of the Respondent. RE–T–CC.

44. The Respondent's probation *[with Superior Court was scheduled to expire] in March 2019. Tr. 56.

The Stipulated Settlement

45. The Respondent entered into a Stipulated Settlement (''Settlement'') with the MBC on December 20, 2016, with an effective date of January 19, 2017. Tr. 57–58; GE–18, at 1. The Settlement allows the Respondent to practice medicine, but prohibits him from writing prescriptions for Schedule II and Schedule III controlled substances. Tr. 57; GE–18, at 4. The Settlement, however, allows the Respondent to use controlled substances in any Schedule, including II and III, while practicing anesthesia in an operating room or surgical center. Tr. 57; GE–18, at 4. The Settlement placed the Respondent on probation for seven years. Tr. 58; GE–18, at 4.

46. The Respondent understands that if he were to write a prescription for a Schedule II or a Schedule III controlled substance his California medical license could be revoked. Tr. 62.

47. The State of California can run a ''CURES'' report anytime to monitor prescriptions the Respondent may write. Tr. 61.

48. The Respondent has not written any prescription for Schedule II or III drugs since he was placed on probation by the MBC. Tr. 61–62.

49. The Settlement does not state that the Respondent can only practice medicine in California. Tr. 119.

50. The Respondent testified that he is in compliance with his probation with the MBC, as well as with his probation with the Superior Court of California. Tr. 62.

51. The Settlement, however, requires the Respondent to report any practice of medicine outside of California to the MBC. Tr. 134; GE–18, at 13.* [It is noted that at hearing the Respondent's attorney argued that the Settlement only required such notification to the MBC after a certain period of days. Tr. 136. The Settlement does include a thirty-day minimum time period for intent to move or travel to another state to trigger the notification requirement, and it is not entirely clear from the language in the Settlement whether or not that time period applies to practicing medicine in another state in the subsequent paragraph; however, the Respondent testified that he moved in February, when he changed his address with the DEA, and he prescribed in Texas on April 28, 2017, so it appears that the timeframe of both his stay and his practice of medicine in Texas exceeded thirty days, triggering the notification requirement to the MBC in the Settlement. Tr. 93, GE–23 and GE–24.] The Respondent did not report that he had been practicing medicine outside of California. Tr. 119, 134.

52. The Respondent submitted a quarterly report to the MBC, but it arrived late. Tr. 119; GE–18, at 12.

53. The MBC required that the Respondent take a course concerning medical ethics, which he completed in April 2017. Tr. 92; GE–18, at 8; RE–L.

54. The Settlement requires that the Respondent either have a practice monitor, who would provide quarterly evaluations to the MBC of the Respondent's medical practice or, in lieu of a monitor, the Respondent could participate in a sanctioned professional enhancement program. GE–18, at 11.

55. The Respondent is not currently practicing medicine because he had a stroke in January 2016, and he is waiting for a letter that says that he is medically qualified to resume his practice in anesthesiology. Tr. 60. The Respondent was informed by his neurologist that he could not find any residual deficits as a result of the stroke. Tr. 60. The Respondent does not currently have a practice manager assigned because he is not currently practicing medicine. Tr. 59–60.

Texas Allegations

56. The Respondent has been licensed to practice medicine in Texas since 1998 and he went there in 2017 to find an anesthesiology job. Tr. 65–66. The Respondent found an anesthesia job in Texas, but once his employer learned of the Respondent's background, the employer stopped inviting him to participate in the care of its patients. Tr. 65–66.

57. The Respondent requested that DEA change his mailing address in February 2017 from California to Texas. Tr. 95, 115.

58. The Respondent's request to change his mailing address from California to Texas was approved by DEA. Tr. 115.

59. The Respondent opened a medical practice in Texas in March 2017. Tr. 95. The heading on the prescription pad for the Respondent's office in Texas reads, ''El Paso Advanced Pain Institute.'' GE–23, at 2.

60. The Respondent testified that he assumed that the DEA had approved his request to change the address of his COR to Texas, but that he has no plans to move to Texas. Tr. 68, 93.

61. Before the Respondent started issuing prescriptions in Texas, he called the pharmacy that would be filling the prescription and the pharmacy told the Respondent it was okay. Tr. 96. The Respondent testified that he believed that he successfully changed the address of his COR in February 2017, before he issued the prescriptions in Texas. Tr. 97–98, 103–07.

62. The Respondent wrote prescriptions for Lyrica, a Schedule V controlled substance, for three patients who had been on Schedule II controlled substances in an effort to get them off of Schedule II controlled substances. Tr. 66, 121, 125. These prescriptions were written in April and March* [correction] 2017. GE–23 and GE–24.

63. The pharmacist-in-charge of ASP Cares Pharmacy indicated that the prescription was written from a pain clinic across the street from the pharmacy. Tr. 117–18.

64. Lyrica is not the type of controlled substance that, by itself, would raise a red flag for a pharmacist. Tr. 128–129.

65. The Respondent requested a change in the registered location for his COR in May 2017 upon his application for renewal. Tr. 116, 127.

66. The Respondent's request to change the location of his COR is still pending, and the Respondent does not have any DEA authority in Texas. Tr. 116.

Additional facts required to resolve the issues in this case are included in the Analysis section of this Recommended Decision.

Analysis

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR 1301.44(e).*[G] Under 21 U.S.C. 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration ''inconsistent with the public interest.'' The DEA considers the following five factors to determine whether continued registration is in the public interest:

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

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

(3) The [registrant'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.

*[G] *See also Director, Office of Workers' Compensation Programs, Dep't of Labor* v. *Greenwich Collieries,* 512 U.S. 267, 277 (1994) (affirming *Steadman's* interpretation of the Administrative Procedure Act standard of proof as the preponderance of evidence standard and clarifying that the ''burden of proof'' in 5 U.S.C. 556(d) refers to the burden of persuasion).

(5) Such other conduct which may threaten the public health and safety.[8]

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

These public interest factors are considered separately. *See 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). Further, 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). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009).

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the evidence. *See Steadman,* 450 U.S. at 100–03. If the Government makes a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate.*H *Medicine Shoppe—Jonesborough,* 73 FR 364387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (citations omitted). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38385 (2013).

I. The Government's Position

The Government submitted its Proposed Findings of Fact and Conclusions of Law (''Government's Brief'') on August 11, 2017.[9] Of note, the Government's proposed findings of fact are primarily based upon the stipulations the Respondent entered into prior to the hearing, which, the Government argues, established a *prima facie* case for revocation of the Respondent's COR. ALJ–37, at 1–8. Based upon the evidence presented, the Government seeks to revoke the Respondent's COR based upon Factors Two, Three, and Four. ALJ–37, at 8. Under Factors Two and Four, the Government argues that the unlawful prescriptions that the Respondent wrote to three undercover investigators and those he wrote in Texas, where he does not have a DEA registration warrant the revocation of the Respondent's COR. ALJ–37, at 8–9. Under Factor Three, the Government argues that the Respondent's California conviction of seven counts of unlawfully issuing prescriptions for controlled substances also serves as a basis for revocation and ''adds to the gravity of the Respondent's conduct.'' [10] ALJ–37, at 9–10.

The Government also argues that the Respondent has not unequivocally accepted responsibility for his conduct. ALJ–37, at 10–12. While acknowledging that the Respondent had generally accepted responsibility, the Government argued that the Respondent vacillated on whether the prescriptions he had written to UC3 were improper. ALJ–37, at 10. In addition, the Respondent testified that he believed he had authority to write the prescriptions he wrote in Texas. ALJ–37, at 11. In support of its position that a registrant's acceptance of responsibility must be unequivocal the Government cited to numerous cases, to include: *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801 (2015); *Hatem M, Ataya, M.D.,* 81 FR 8221, 8242 (2016); and *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 820 (10th Cir. 2011). ALJ–37, at 11–12.

Finally, the Government argues that, even if the Respondent were found to have accepted full responsibility, revocation would still be appropriate in this case to deter others. ALJ–37, at 12. In support of this position, the Government cites to *Peter F. Kelly, D.P.M.,* 82 FR 28676, 28691 (2017). ALJ–37, at 12. The Government also argues that ''[i]n the midst of the current opioid crisis, violations of the prescribing requirements such as occurred here should result in revocation of the underlying registration.'' [11]

II. The Respondent's Position

The Respondent submitted his closing statement (''Respondent's brief'') on August 25, 2017.[12] The overall theme of the Respondent's brief is that he has accepted responsibility for his actions and has taken numerous remedial steps to ensure he does not again violate the Controlled Substances Act (''CSA''). Noting that the Respondent's medical practice since 1993 had centered around anesthesiology in a hospital setting, he argues that when it came to treating pain patients he ''may have been a naïve physician who was not fully prepared to deal with patients who may be drug seeking. He relied on what his patients told him, rather than conduct examinations to corroborate those statements.'' ALJ–38, at 2.

The Respondent correctly argues that revocation of a DEA certificate of registration is not mandatory for violations of 21 U.S.C. 824(a)(4). The Respondent then, incorrectly, argues that 21 U.S.C. 824(a)(4) is the only section that the Government is relying upon in its request for revocation. ALJ–38, at 3–4. In fact, the Respondent goes on to analyze this case under the five factors of 21 U.S.C. 823(f). ALJ–38, at 4–8.

The Respondent suggests that Factor One weighs in his favor. He notes that after the MBC reviewed all the facts of his case it determined that ''public safety would be met by allowing [the Respondent] to continue to practice medicine, specifically, anesthesiology . . . .'' ALJ–38, at 4–5. With respect to Factor Two, the Respondent notes that he has not had ''any discipline or issues with his practicing anesthesiology.'' ALJ–38, at 5. The Respondent argues that the only legal issues he has dealt with related to his practice of outpatient pain management, asserting that he will no longer be practicing in that area. ALJ–38, at 5.

[8] The Government has not made any Factor Five allegations against the Respondent.

*H I am clarifying this statement slightly. DEA caselaw has stated that the burden shifts to the Respondent to ''show why its continued registration would nonetheless be consistent with the public interest.'' *Medicine Shoppe—Jonesborough,* 73 FR 364387 (2008) (collecting cases). DEA caselaw has further explained that where the Government has established grounds for revocation by a preponderance of the evidence, the Respondent must ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)).

[9] The Government's Brief has been marked as ALJ–37.

[10] The Respondent's convictions are based upon the same conduct as is alleged in paragraphs 3a–3e of the OSC. ALJ–1, at 2–3. Accordingly, I do not find that the Respondent's convictions add ''gravity'' to his conduct. The allegations are essentially multiplicitous.

[11] The Government's position suggests that had the Respondent engaged in the same conduct, but there was no opioid crisis, that that same conduct might not merit revocation. For that reason, I reject the suggestion that a registrant should lose his or her registration based on whether the nation is in an opioid crisis or not. *[Although I agree with ALJ Dorman on this point, I do not wish to imply that the opioid crisis is never properly considered by DEA in enforcing the Controlled Substances Act.]

[12] The Respondent's Brief has been marked as ALJ–38. I note that the Respondent's brief was filed nine days late and it is not in conformance with 21 CFR 1316.64, which requires ''specific and complete citations of the pages of the transcript and exhibits.'' Nevertheless, I have considered the Respondent's Brief.

Under Factor Three, the Respondent argues that the reduction of his felony convictions to misdemeanors suggests that his ''conduct and/or intention was not as aggravated as those of other physicians who are prosecuted.'' [13] ALJ–38, at 6. Again the Respondent notes that the convictions were the result of his practicing pain management and not anesthesiology. He argues that his ''conduct was not one of greed or intentional wrongdoing rather inexperience and naïveté . . . .'' ALJ–38, at 6.

With respect to Factor Four, the Respondent argues that he has been fully compliant with all state, federal, and local laws concerning the handling of controlled substances since he was arrested. The Respondent further argues that the allegation that he wrote prescriptions in Texas without authority from the DEA is ''unclear at best . . . and not supported by any evidence.'' ALJ–38, at 7. Finally, with respect to Factor Five, the Respondent asserts that there is no other evidence that he is a danger to the public. ALJ–38, at 8.

The Respondent's brief concludes with a discussion of acceptance of responsibility and mitigation. ALJ–38, at 8–10. He argues that he has taken full responsibility for his actions, noting the stipulations he entered into with the MBC and during these proceedings. ALJ–38, at 9. The Respondent argues that since his ''arrest he has made strong and concerted efforts to show his remorse and take full responsibility for his actions.'' [14] ALJ–38, at 8. With respect to mitigation, the Respondent ''has performed over 300 hours of community service in sober living homes, he has completed continuing education in the area of substance abuse and prescribing and he has abided by all that has been asked of him.'' ALJ–38, at 9.

The Respondent argues that the evidence of record is sufficient to allow for the exercise of discretion to conclude that public safety would not be endangered by allowing him to retain his COR. ALJ–38, at 9–10. Significantly, the Respondent cites to the action of the MBC, which has allowed him to continue practicing medicine as an anesthesiologist. ALJ–38, at 10. He notes that the function of the MBC is similar to that of the DEA, to ensure public safety. ALJ–38, at 10.

III. Factor One: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

The Respondent suggests that Factor One weighs in his favor because the MBC entered into a stipulated settlement wherein the Respondent has been allowed to continue his medical practice, but he may not prescribe schedule II or III controlled substances, and may only administer them while practicing anesthesiology in a hospital or licensed surgical center. ALJ–38, at 4; GE–18, at 5. In addition, the stipulated settlement placed the Respondent on probation for seven years. *Id.* *[I am omitting some language from the RD and adding the below until the end of this section, to clarify the analysis of Factor One.

In determining the public interest, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.*[1] *See, e.g., Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.''). However, some more recent Agency decisions could be read to imply that Factor One should be more narrowly focused on recommendations from the appropriate state entity that specifically address the registrant's DEA COR; therefore, I am providing some clarification to the Agency's consideration of Factor One below. *See Garrett Howard Smith, M.D.,* 83 FR 18882 n.30 (2018).

''Interpretation of a statute must begin with the statute's language.'' *Mallard* v. *U.S. Dist. Court,* 490 U.S. 296, 300–301 (1989) (citing *e.g., United States* v. *Ron Pair Enterprises, Inc.,* 489 U.S. 235, 241 (1989); *Landreth Timber Co.* v. *Landreth,* 471 U.S. 681, 685 (1985)). The dictionary indicates a breadth of possible interpretations of ''recommend,'' the root word of ''recommendation'' in 21 U.S.C. 823(f)(1), including: ''(1)(a) to present as worthy of acceptance or trial; (1)(b) to endorse as fit, worthy, or competent; (2) entrust, commit (3) to make acceptable; (4) to suggest an act or course of action.'' ''Recommend.'' *Merriam-Webster's Online Dictionary.* 2020. *https://www.merriam-webster.com/dictionary/recommend* (last visited Feb. 4, 2020). Most of the entries would appear to encompass the action of the appropriate state entity were it to present the practitioner as worthy of acceptance for a DEA COR, make the practitioner acceptable for a DEA COR in retaining the state authority or even to continue to entrust the practitioner with state controlled substance authority after considering the facts that provide the basis for DEA action. These definitions could easily encompass the actions of the appropriate state entity on the state licensure. Only the fourth entry would support a reading that would require the appropriate state entity to explicitly recommend a course of action regarding the DEA COR, and even that definition implies some latitude in specificity in using the term ''suggest.'' Additionally, if the agency were to limit consideration under Factor One to specific recommendations about DEA registrations, the practical implementation of such a narrow interpretation would likely read out the applicability of the Factor in its entirety, as very few cases contain such specific recommendations.*[J] *See e.g., Tyson D.*

[13] This statement is not supported by any evidence in the record. Furthermore, even if true, it is irrelevant.

[14] This is not an accurate statement. At his criminal trial, the Respondent pled not guilty and testified that the exams he conducted on the three undercover investigators were sufficient and that he had been betrayed by the undercover investigators. GE–19, at 905–07. That hardly seems like taking full responsibility for his actions after his arrest. Even at the hearing before me, the Respondent was reluctant to take responsibility for the unlawful prescriptions he issued to UC3 because he had been found not guilty of prescribing oxycodone to him.

*[1] Regarding Factor One, I am distinguishing the fact findings of an appropriate state entity from the ultimate recommendation of such entity, the latter of which is relevant under Factor One. *But see Ralph J. Chambers, M.D.,* 79 FR 4962, 4970 (2014) (stating that the possession of state ''authority is not dispositive of the public interest'' but then discussing under Factor One the rationale for not relying on the fact findings of the board). The fact findings themselves are more appropriately considered under other public interest factors.

*[J] It is unclear whether many appropriate state entities would have the requisite authority to provide a specific recommendation regarding a DEA registration, and practically, how they would obtain a full view of the facts and legal bases underlying the OSC in order to provide such a specific recommendation. Additionally, a narrow interpretation of Factor One could present challenges across the wide variety of state statutory authorities. *See Scott D. Fedosky, M.D.,* 76 FR 71375 (2011) (finding that the ''vote[ ] to allow [the respondent] to apply for a new DEA registration'' of the Arkansas State Medical Board did not constitute a specific ''recommendation,'' because it did not include any advice about whether DEA should grant the application).

Quy, M.D., 78 FR 47,412, 47,417; *Vincent J. Scolaro, D.O.,* 67 FR at 42,065; *but see, John Porter Richards, D.O.,* 61 FR 13,878, 13,879 (1996) (wherein the West Virginia Board sent a letter supporting the respondent's application for a DEA COR, which the Administrator considered under Factor One along with the actions of the disciplinary boards in two states).

The available legislative history supports the Agency's broader reading of ''recommendation.'' *[K] The public interest factors for practitioners' applications for registration were added to Section 823 in 1984. Controlled Substances Penalties Amendments Act of 1984, Public Law 98–473, 511, 98 Stat. 1837, 2073 (1984) (codified at 21 U.S.C. 823(f)(1)–(5)). Prior to the addition of these public interest factors, practitioner applicants would be granted a registration if they were ''authorized to dispense . . . [controlled substances] under the law of the State in which they practice[d].'' Controlled Substances Act, Public Law 91–513, 303, 84 Stat. 1236, 1255 (1970) (codified at 21 U.S.C. 823(f)). The Senate Report explained that ''because of a variety of legal, organizational, and resource problems, many states are unable to take effective or prompt action against violating registrants.'' *[L] Senate Report, at 266, 1984 U.S.C.C.A.N., at 3448. After pointing out that the practitioner public interest factors are ''similar to those applicable under current law to registration applications on the part of the manufacturers and distributors of controlled substances,'' the Senate Report noted that ''the amendment would continue to give deference to the opinions of the state licensing authorities,'' because of the inclusion of Factor One. Senate Report, at 267, 1984 U.S.C.C.A.N., at 3449; *see also Oregon* v. *Ashcroft,* 368 F.3d 1118, 1122 (9th Cir. 2004) (quoting the Senate Report). The breadth of the intended meaning of ''recommendation'' is further explained in a Senate Report footnote describing Factor One: ''it would no longer be necessary that the state authority have in fact revoked the practitioner's license or registration before federal registration could be denied.'' Senate Report, at 266 n.36, 1984 U.S.C.C.A.N., at 3448 n.36. In other words, the Senate Report acknowledges both that an appropriate state entity's ''recommendation'' precedes the effective date of any revocation, and makes clear that the addition of Factor One directs the Agency's focus to an existing ''recommendation,'' separate from any finalized revocation.

Further, I agree with prior Agency decisions' functional reading of ''recommendation.'' In *Vincent J. Scolaro, D.O.,* for example, the Agency carefully analyzed the respondent's interactions with the state licensing board, law enforcement, and other offices. 67 FR at 42060–65. Based on this analysis, my predecessor determined that the state licensing board ''implicitly'' agreed that respondent was ready for a DEA registration. 67 FR at 42065. In other words, it would be contrary to the amended language to not at least consider the actions of an appropriate state entity on the same matters, particularly where it rendered an opinion regarding the practitioner's medical practice in the state due to the same facts alleged in the DEA OSC. *Id.*[M] Although statutory analysis may not definitively settle this matter, the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state. *See Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) (the Administrator can '' 'give each factor the weight [he] determines is appropriate.' '' (quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In this case, the MBC has not made a direct recommendation to the Agency regarding whether the Respondent's COR should be suspended or revoked.[N] As already discussed, after suspending the Respondent's medical license and continuing the suspension after a hearing before a state Administrative Law Judge, the MBC entered into a stipulated settlement allowing Respondent to continue his medical practice and, regarding controlled substances, allowing Respondent to administer only schedule II or III controlled substances while practicing anesthesiology in a hospital or licensed surgical center. GE–18; ALJ–38. Older Agency decisions can be read to give more than nominal weight in the public interest determination to a state's decision to restore or maintain a practitioner's authority to dispense controlled substances. *Brian Thomas Nichol, M.D.,* 83 FR 47352, 47362 (collecting cases) (2018). However, these cases do not change longstanding federal law that it is the Administrator who makes a determination of whether granting a COR is in the public interest as defined by the CSA. *Ajay S. Ahuja, M.D.,* 84 FR at 5490.

It is noted that the Board's reinstatement of Respondent's medical license in California was severely limited in the stipulated settlement, including compliance with seven years of probation, which does not indicate a substantial amount of trust in the Respondent. *See* ALJ–38, at 5. Finally, the Board's settlement on January 19, 2017, predated the March and April 2017 instances where the Respondent wrote prescriptions without a valid DEA COR for a Texas location, and therefore, the Board's decision did not encompass all of the allegations and facts that are before this Agency. *See* GE–23 and GE–24; GE 18. Accordingly, the terms of the MBC's stipulated settlement with the Respondent are not dispositive of the public interest inquiry in this case, and although I have considered it in favor of the Respondent, it is also minimized by the circumstances described above. *See*

*[K] There is no conference report specifically for the Comprehensive Crime Control Act of 1984. It was passed as part of Public Law 98–473, the 1985 Continuing Appropriations Act. The controlled substances-related provisions of that law were taken from S. 1762 as reported by the Senate Judiciary Committee and addressed in Senate Report No. 98–225 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182 (hereinafter, Senate Report).

Part B of Title V of the Comprehensive Crime Control Act of 1984 is called the ''Diversion Control Amendments.'' According to the Senate Report's discussion of Title V, between 60% and 70% of all drug-related deaths and injuries ''involve drugs that were originally part of the legitimate drug production and distribution chain.'' Senate Report, at 260, 1984 U.S.C.C.A.N., at 3442. In addition, according to the Senate Report, ''diversion of legally produced drugs often evidences the same sort of large-scale trafficking more commonly associated with the trade in wholly illicit drugs.'' *Id.* To illustrate this finding, the Senate Report cites ''Operation Script'' in which twenty-one practitioners registered to dispense controlled substances were ''responsible for the diversion of approximately 21.6 million dosage units of controlled substances.'' Senate Report, at 261, 1984 U.S.C.C.A.N., at 3443.

*[L] The Senate Report also stated that the ''limited grounds for revoking or denying a practitioner's registration have been cited as contributing to the problem of diversion of dangerous drugs.'' Senate Report, at 266, 1984 U.S.C.C.A.N., at 3448.

*[M] It is noted that Agency decisions have long held that in considering Factor One, the appropriate state entity's actions are distinct from its inactions—an interpretation which is supported by both a reading of the active word ''recommend,'' and the rationale given by the Senate Report for adding the public interest factors. *See Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.''); *see also MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 817–819 (10th Cir. 2011) (noting that the Agency decision found that the lack of action from an appropriate state entity was not a recommendation under Factor One and holding that the Deputy Administrator did not misweigh the public interest factors).

*[N] The Government called an investigator for the California Department of Consumer Affairs to provide official testimony during the hearing. Tr. 129–35. That testimony, however, was not a recommendation from the Board.

Brian Thomas Nichol, M.D., 83 FR at 47,362–63.]

IV. Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances *[O]

The Government alleges that revocation of the Respondent's COR is appropriate under Factors Two and Four because the Respondent: (1) Issued unlawful prescriptions to three undercover investigators on five separate occasions; and (2) wrote three prescriptions for a controlled substance out of an office he maintained in Texas, even though he did not have a DEA COR for that office. The Government further alleges that by writing the prescriptions to the undercover investigators the Respondent violated 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a); Cal. Health & Safety Code § 11153(a); and Cal. Bus. & Prof. Code §§ 725(a), 2241(b), 2241.5(c), and 2242(a). In addition, the Government alleges that by writing the three prescriptions in Texas the Respondent violated 21 U.S.C. 822(e) and 21 CFR 1301.12(a) and (b)(3).

Under the CSA, it is unlawful for a person to distribute controlled substances, except as authorized under the CSA. 21 U.S.C. 841(a)(1). To combat drug abuse and trafficking of controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). To maintain this closed regulatory system, controlled substances may only be prescribed if a DEA registrant writes a valid prescription. *Carlos Gonzalez, M.D.,* 76 FR 63118, 63141 (2011). As the Supreme Court explained, ''the prescription requirement . . . ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. at 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

A controlled substance prescription is not valid unless it 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). Federal regulations further provide that ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of [controlled substance laws].'' *Id.; see* 21 U.S.C. 842(a)(1) (establishing that, under the CSA, it is illegal for a person to distribute or dispense controlled substances without a prescription, as is required under 21 U.S.C. 829).

Much like the federal regulations, the California Health and Safety Code, Section 11153(a), provides, in part, 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.'' Further, Section 2242(a) of the California Business and Professions Code states that, ''[p]rescribing, dispensing, or furnishing dangerous drugs . . . without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.'' *Id.* Section 725(a) provides that it is considered to be unprofessional conduct for a physician to engage in ''repeated acts of clearly excessive prescribing.'' *Id.* * [I am omitting the ALJ's finding of a violation of state law under Cal. Bus. & Prof. Code § 2241(b). *See* Original RD, at 40. Section 2241 is generally permissive and sets forth the circumstances under which a practitioner may prescribe, dispense or administer to an addict for treatment of substance abuse. 2241(b) provides that ''[n]othing in this subdivision shall authorize a physician and surgeon to prescribe, dispense, or administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for non medical purposes.'' Cal. Bus. & Prof. Code § 2241(b) (Westlaw, current with all laws through Ch. 870 of 2019 Regular Session). I cannot find any evidence that this subdivision is intended to provide a separate violation of law. The underlying violation for prescribing ''not in the course of professional treatment or as part of an authorized narcotic treatment program,'' was already alleged in the OSC in Cal. Health & Safety Code § 11153(a). Therefore, I find that although Cal. Bus. & Prof. Code § 2241(b) is useful in determining whether a violation of Cal. Health & Safety Code § 11153(a) *[P] has occurred, it does not provide for a separate violation in and of itself.] Additionally, Section 2241.5(c) of the Cal. Bus. & Prof. Code is merely an administrative provision concerning the authority of the MBC. Cal. Bus. & Prof. Code § 2242(a) (Westlaw, current with urgency legislation through Ch 706 of the 2019 Regular Session). *[Although I am not sustaining state law violations for Sections 2241.5(c) or 2241(b) of the Cal. Bus. & Prof. Code, the Respondent's multiple blatant violations of Cal. Health & Safety Code § 11153(a), eight of which were the basis for his conviction in state court, are more than enough to demonstrate violations of state law and weigh heavily in favor of revocation. *See* GE–20 (Respondent's Conviction).] * [Omitted sentences for brevity].

DEA recognizes several methods to show that a registrant wrote prescriptions without a legitimate medical purpose and outside of the usual course of professional practice. *See Jack A. Danton, D.O.,* 76 FR 60900, 60901 (2011). In this case, however, the Respondent has admitted he did so. Stip. 42–53. In addition, a review of several of the Government exhibits reveals that at the time the Respondent wrote prescriptions to the undercover investigators he knew or had reason to believe they would be using the prescriptions for nonmedical reasons. For example, on March 30, 2012, UC1 informed the Respondent that he had been using Vicodin and Adderall, which he obtained from a friend. GE–3, at 9. Then when UC1 returned to see the Respondent on May 4, 2012, UC1 had none of the prescribed drugs in his urine. GE–5, at 5; GE–14, at 14. In addition, UC1 once again informed the Respondent that he was obtaining Opana from someone at his gym, and that his pain level was good. GE–5, at 5. Nevertheless, on each occasion, the Respondent issued UC1 prescriptions for controlled substances. GE–4, at 1; GE–6, at 1.

With respect to UC2, the Respondent prescribed controlled substances to her on her first office visit with him after she told the Respondent that her pain was not bad,[15] that she got sore from working out, and that she needed something to relax. GE–37, at 3–4; GE–15, at 13. At that visit, the Respondent provided UC2 with prescriptions for

*[O] I have omitted the first paragraph of the ALJ's analysis of Factors 2 and 4, because I found it unnecessary to my analysis of the factors under the caselaw.

*[P] It also appears that the Government could have alleged violations of Cal. Health & Safety Code § 11156, which states that ''[e]xcept as provided in Section 2241 of the Business and Professions Code, no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such.'' *See Daniel Brubaker, D.O.,* 77 FR 19322, 19328.

[15] UC2 listed her pain level as a 1 out of 10 on her in-take form on May 4, 2012. GE–15, at 2. On her pain assessment form UC2 indicated that her pain was a 1 out of 10 at its worst. GE–15, at 3.

Vicodin, Xanax, and Adderall. GE–8, at 1.

The third undercover investigator presented to the Respondent on March 21, 2013, almost a year after the visits by UC1 and UC2. GE–9, at 1. UC3 informed the Respondent that he was taking oxycodone for an old injury he sustained playing high school football. *Id.;* GE–19, at 910. When the Respondent asked where UC3 was getting the oxycodone, UC3 replied, ''I don't know if you really want me to say where I've been getting it or not. I don't have insurance you know, so I do what I gotta do.'' GE–9, at 1. While the Respondent did have UC3 walk around on his heels and toes, he did not do so to assess UC3's pain level. Rather, the Respondent was trying to determine if UC3 had a more severe problem that would require referral to a specialist. GE–19, at 911–12. At that first visit with the Respondent, the Respondent prescribed Percocet 10 mg to UC3 even though he knew that UC3 was obtaining oxycodone on the street. GE–10, at 1; GE–19, at 910. UC3 returned to see the Respondent on April 25, 2013. A review of the video recording of that visit reveals that the Respondent spent about ten minutes talking with UC3, but he did not conduct an examination. GE–11. On that date, the Respondent again prescribed Percocet for UC3. GE–12, at 1.

[I am omitting the portion of the R.D. where the ALJ sustained the allegations related to the prescriptions to the undercover investigators. I agree with the ALJ's findings and conclusions on these allegations *Q and incorporate them herein; however, it is unnecessary to repeat them considering that the Respondent stipulated to them and I am removing them to condense this opinion. All of the allegations related to prescribing beneath the standard of care and outside of the usual course of professional practice are sustained and weigh in favor of revocation of the Respondent's Registration.]

The Texas Prescriptions

In the Government Supplemental Prehearing Statement, the Government alleged that the Respondent wrote three prescriptions for a controlled substance in Texas in April and May 2017 without having a valid DEA COR for Texas. ALJ–29, at 5–6. The Government alleges that by writing these prescriptions the Respondent violated 21 U.S.C. 822(e), and 21 CFR 1301.12(a) and 1301.12(b)(3). ALJ–29, at 6. Title 21 of the U.S. Code, Section 822(e) requires a separate COR at each principal place of business where a registrant is prescribing controlled substances.[16] 21 CFR 1301.12(a) essentially reinforces the cited provision of the U.S. Code, 21 CFR 1301.12(b)(3) is not specifically applicable. Rather, it defines places that are deemed not to be places where controlled substances can be prescribed.

In this case the Government has alleged that the Respondent issued three prescriptions for Lyrica, a schedule V controlled substance. ALJ–29, at 5–6; FF 62. Specifically, the Respondent wrote the first prescription for 30 tablets of Lyrica 50 mg for patient L.C. on March 15, 2017, and it was filled at a Walgreens Pharmacy in El Paso, Texas, on March 27. 2017. ALJ–29, at 5, GE–24, at 2–3. The Respondent then called in a prescription to an ASP Cares Pharmacy in El Paso, Texas, for patient F.D. for 60 tablets of Lyrica 25 mg, on April 17, 2017, and it was filled the same day. ALJ–29, at 5; GE–23, at 4–5. The Respondent wrote his third Texas prescription on April 28, 2017. ALJ–29, at 5; GE–23, at 2. This third prescription was written for patient R.A. for 60 tablets of Lyrica 75 mg on a prescription pad containing the heading, ''El Paso Advanced Pain Institute.'' ALJ–29, at 5; GE–23, at 2. The prescription was filled at an ASP Cares Pharmacy in El Paso, Texas on May 1, 2017. ALJ–29, at 5; GE–23, at 3. All three prescriptions contain the Respondent's California COR number. GE–23, at 2–5, GE–24, at 2. That COR, however, lists the Respondent's principal place of business as 5857 Pine Avenue, Chino Hills, California 91709. Stip. 1.

Under 21 CFR 1306.05(a),*R a doctor is required to include his or her name, address, and registration number on any prescription the doctor writes. Here, the Respondent issued at least one prescription on a prescription pad bearing an El Paso address and phone number. GE–23, at 2, and the other two prescriptions contained the Respondent's El Paso phone number. GE–23, at 4–5; GE–24, at 2. Further, the Respondent acknowledged that he opened a medical practice in Texas in March 2017. FF 59; Stip. 54. During March and April 2017, the Respondent did not have a COR for his El Paso medical practice. FF 66; Stip. 54.

Both the CSA and its implementing regulations require a ''separate registration . . . at each principal place of business or professional practice where the applicant . . . dispenses controlled substances . . . .'' 21 U.S.C. 822(e)(1); 21 CFR 1301.12(a); *Clarification of Registration Requirements for Individual Practitioners,* 71 FR 69,478 (2006); *Joe W. Morgan,* 78 FR 61,961 (2013); *David Moon, D.O.,* 82 FR 19,385, 19,389 (2017). This requirement also applies where a doctor is merely prescribing controlled substances. 21 U.S.C. 802(10); *Moon,* 82 FR at 19,389. Accordingly, the Government's allegation, contained in its Supplemental Prehearing Statement, that the Respondent violated 21 U.S.C. 822(e), and 21 CFR 1301.12(a) by issuing prescriptions in Texas without having a COR for his Texas office is *sustained* by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government.[17] The allegation concerning the Respondent violating 21 CFR 1301.12(b)(3), however, is *not sustained.*

V. Factor Three: Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In paragraph 6 of the OSC, the Government alleged that a Los Angeles County jury convicted the Respondent of seven felony counts of issuing unlawful controlled substance prescriptions for Adderall, hydrocodone, and alprazolam on March 28, 2016. ALJ–1, at 4. These felony convictions were reduced to misdemeanors upon sentencing. ALJ–1, at 4. The Government asserts that these convictions may be considered in determining whether the Respondent's registration is inconsistent with the public interest under 21 U.S.C. 823(f)(3) and 824(a)(4). *Id.*

As to Factor Three, the Respondent has been convicted of seven offenses violating California law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3); FF 34–35. A review of GE–19 and GE–20 reveals that the Respondent's convictions were directly

*Q It appears that the ALJ inadvertently left out one of the prescriptions in the stipulated facts for Xanax, a schedule IV controlled substance to UC2 on May 4, 2012. *See* Original RD, at 35–36; *see also* Stip. 48, 49, 50; RD, at 14, 15; GX 8. In addition to the ALJ's findings, I find that this prescription was for no legitimate medical purpose and issued outside the usual course of professional practice, in violation of 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a), Cal. Health & Safety Code § 11153(a), and the Cal. Bus. & Prof. Code §§ 725(a), and 2242(a).

[16] 21 U.S.C. 822(e) uses the terms ''dispenses controlled substances.'' 21 U.S.C § 802 (10) includes ''prescribing'' in the definition of the term ''dispense.''

*R The Government did not allege a violation of 21 CFR 1306.05(a), and therefore, I am only considering this requirement and the lack of the DEA registration number on the prescription pad as evidence that Respondent knew or should have known that he was not registered in Texas.

[17] I reject the Respondent's argument that this allegation is unclear and not supported by any evidence. ALJ–38, at 7.

related to the Respondent's unlawful prescriptions the Respondent wrote to UC1, UC2, and UC3. Specifically, the Respondent was convicted of seven misdemeanor counts of issuing unlawful prescriptions for the controlled substances of Adderall, hydrocodone, and alprazolam. Stip. 13, 14; GE–20, at 6–9.

The Government has proven the allegations contained in paragraph 6 of the OSC through the Stipulations and Government Exhibits 19 and 20. In addition, the Respondent testified that he had been convicted of seven counts involving the prescriptions he wrote for controlled substances. Tr. 44. Accordingly, the allegations, contained in paragraph 6 of the OSC, concerning the Respondent's conviction of unlawfully writing prescriptions for controlled substances are *sustained,* and weigh in favor of the revocation sought by the Government.

Discussion and Conclusions of Law

*[Although I have considered Factor One in favor of Respondent, it is minimized by the circumstances described above, and it is ultimately outweighed by the Factors weighing against him.] *S In its Brief, the Government asserted that it was only proceeding under Factors Two, Three, and Four. Accordingly, Factor Five does not weigh for or against revocation in this case. The Government has presented documents, testimony, and has relied on stipulations that establish by a preponderance of the evidence that the Respondent: Unlawfully prescribed controlled substances to three undercover agents on five separate occasions; was convicted in state court of seven misdemeanors for issuing unlawful prescriptions for controlled substances; and that he wrote three prescriptions in Texas without a valid DEA COR for a Texas location.

After the Government presents a *prima facie* case for revocation, the Respondent has the burden of production to present ''sufficient mitigating evidence'' to show why he can be entrusted with a DEA registration. *See Medicine Shoppe—Jonesborough,* 73 FR at 387 (quoting *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Stodola,* 74 FR at 20734–35.

The Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. *See Leslie,* 68 FR at 15228. To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 FR 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *See Wesley G. Harline, M.D.,* 65 FR 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct, *Jeffrey Patrick Gunderson, M.D.,* 61 FR 26208, 26211 (1996), and acknowledge the scope of his misconduct, *Arvinder Singh, M.D.,* 81 FR 8247, 8250–51 (2016) *T [(calling for Respondent to acknowledge the ''full scope of his criminal behavior and the risk of diversion it created''). Additionally, ''the Agency has previously weighed against a finding of acceptance of full responsibility'' attempts to minimize the egregiousness of Respondent's misconduct. *Jeffrey Stein, M.D.,* 84 FR at 46,973 (collecting cases).]

It is clear in this case that the Respondent attempted to accept full responsibility for his actions. It is clear because, prior to the hearing, the Respondent entered into extensive stipulations of fact, essentially relieving the Government of the need to present any evidence of the Respondent's conduct that violated the CSA and its implementing regulations. The Record clearly demonstrates that the Respondent understood the importance of those stipulations. The Respondent acknowledged that by entering into the stipulations that essentially admitted to all the facts the Government would need to prove its allegations against him. Tr. 14. He also acknowledged that if no other evidence had been admitted in the case, that I could issue a well-founded recommendation that his COR be revoked. Tr. 14–15. The Respondent also acknowledged that the stipulations shifted the burden of proof to him to ''demonstrate contrition and remedial actions that would convince me that in spite of the conduct [he] admitted to, that I should make a recommendation to . . . not revoke [his] certificate of registration.'' Tr. 15. The Respondent has not met that burden.

Here, the Government accurately argued in its Brief that while the Respondent ''generally accepted responsibility for his improper prescribing to the three undercover investigators, his admission of wrongdoing was not without some vacillation.'' ALJ–37, at 10. To be accurate, the only vacillation concerned the Respondent's testimony relative to the prescriptions the Respondent wrote for UC3, on March 21, 2013 and April 25, 2013. Indeed, the Respondent waivered on his acceptance of responsibility in writing those prescriptions. While he testified that he did do ''some exam'' of UC3, it seems that the only exam he conducted was to have UC3 perform a heel and toe walk on March 21, 2013. Tr. 78; GE–19, at 625–26. Further, the Respondent's purpose in having UC3 perform a heel and toe walk was not to assess UC3's pain level, but rather to determine if he needed to send UC3 to a specialist. GE–19, at 911–12. No examination was conducted on April 25, 2013. *See* GE–11. Clearly, at the hearing before me, the Respondent was reluctant to admit culpability for the prescriptions he wrote to UC3 because he had been acquitted of writing prescriptions for oxycodone.[18] *See* Tr. 78, 110–11. In addition, during the hearing, the Respondent withdrew from the two stipulations he had originally entered into concerning the two prescriptions he wrote to UC3, and later entered into a modified stipulation, which did not address violations of 21 U.S.C. 841(a)(1), and Cal. Health & Safety Code § 11153(a). Tr. 80–81, 108.

The Respondent also had problems in accepting responsibility for the three prescriptions he wrote in Texas. Initially, the Respondent stipulated that he had maintained a principal place of business in Texas, but he was not registered with the DEA in Texas. Stip. 54. During his testimony, however, he again ''vacillated.'' When asked if he had a certificate of registration for Texas, the Respondent testified that he had submitted a change of address and that he believed the DEA had approved the change. Tr. 92–93. The Respondent further testified that when he wrote the prescriptions in Texas, he believed he had the authority to do so. Tr. 105–107. The Respondent could have presented testimony that when he wrote the prescriptions in Texas he believed he had authority to do so, but now he realizes that he was wrong in that belief. But, the Respondent did not do so.

*S I changed the first two sentences and third sentences based on my revised Factor One analysis.

*T I am tweaking the caselaw descriptions slightly and adding some additional caselaw that bolsters the ALJ's position, with which I agree.

[18] There are many reasons, however, why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 822 (10th Cir. 2011). The Agency has, therefore, held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.* *[Omitted sentence].

Through his testimony, the Respondent made clear that he has not accepted responsibility for the prescriptions he wrote in Texas without having a DEA COR for a place of business in Texas.

In this case, the Government has established that the Respondent unlawfully wrote prescriptions for controlled substances to three undercover investigators on five separate occasions beginning in March 2012 and ending in April 2013. After the Respondent was arrested, the Government filed a motion to revoke his bail because he continued writing prescriptions. GE–16, at 4; GE–19, at 1170, 1173. Then, as a result of these unlawful prescriptions, in May 2015 the Respondent was convicted in the Superior Court of the State of California, County of Los Angeles, of seven counts concerning issuing unlawful prescriptions for Adderall, hydrocodone, and alprazolam. That court imposed a sentence in March 2016. Then in June 2016, the MBC suspended the Respondent's medical license, a suspension which remained in effect until January 2017. In February 2017, the Acting Administrator of the DEA issued an Order restricting the Respondent's COR, and remanded the Respondent's case to the Office of Administrative Law Judges for further proceedings. Then in March and April of 2017, the Respondent wrote three prescriptions for Lyrica, a Schedule V controlled substance, in Texas, without having the authority to write such prescriptions from the DEA.

At his hearing the Respondent accepted some responsibility for his actions. I find, however, that the Respondent's limited acceptance of responsibility is outweighed by his prescribing transgressions detailed above, particularly considering the timeline and the fact that the Respondent's acceptance of responsibility is equivocal. *[*See Alra Labs, Inc.* v. *Drug Enf't Admin.,* 54 F. 3d 450, 452 (7th Cir. 1995) (''The DEA had to decide whether to believe [registrant's] protestation that its problems are behind it. It did not have to accept that assertion.'' (citations omitted).] *U

When considering whether the Respondent's continued registration is consistent with the public interest, an ALJ must consider both the egregiousness of the registrant's violations and the DEA's interest in deterring future misconduct by both the registrant as well as other registrants. *Ruben,* 78 FR at 38364. *[Omitted additional citations].

*U Replaced citation.

In this case, the Respondent's numerous transgressions are sufficiently egregious to warrant revocation.[19] *See Dewey C. MacKay, M.D.,* 75 FR 49956, 49974 n.35 (2010) (''[U]nder the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.''). I find the Respondent's transgressions egregious for several reasons. First, the Respondent issued prescriptions for controlled substances to UC1 even though he knew that UC1 was obtaining controlled substances on the street, and he reissued that prescription to UC1 even knowing that none of the controlled substances the Respondent prescribed to UC1 were detected in his urine test. Second, almost a year later, the Respondent again prescribed oxycodone, this time to UC3, knowing that UC3 had been obtaining oxycodone on the street. Finally, after being caught, convicted and sentenced for writing illegal prescriptions; after having had his medical license suspended by the MBC for writing illegal prescriptions; after taking courses on writing prescriptions through PACE; and then less than three months after he had his medical license reinstated; he wrote illegal prescriptions in Texas. This misconduct, particularly on this timeline, engenders absolutely no confidence that the Respondent can be entrusted with a DEA certificate of registration.

Recommendation

The Government established that the Respondent's continued registration is inconsistent with the public interest because of his improper prescribing, and his state conviction relating to his unlawful prescribing of controlled substances. While the Respondent admitted to many of the Government's factual allegations, he failed to fully accept responsibility for his actions. Furthermore, even had the Respondent accepted full responsibility, the egregiousness of his violations may *T have outweighed his acceptance of responsibility and the remedial measures he has taken. Accordingly, I *recommend* that the Respondent's DEA COR be *revoked* and that any application for renewal or modification of his registration be *denied.*

Dated: August 28, 2017.

Charles Wm. Dorman,

U.S. Administrative Law Judge.

[FR Doc. 2020–05751 Filed 3–18–20; 8:45 am]

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[19] I acknowledge that the Respondent has taken some remedial steps to reduce the likelihood that his actions would result in future violations of the CSA and/or its implementing regulations. *See, e.g.,* ALJ–38, at 8–9. Nevertheless, a registrant does not accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR 62,316, 62,346 (2012). Further, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016). *[In this case, Respondent has taken responsibility for most of the allegations related to his conduct related to his criminal conviction; however, through his vacillations, and as a result of his conduct in Texas, I have reason to doubt the sincerity of his words. Therefore, I agree with the ALJ that the egregiousness of his conduct even in the stipulated facts must be considered in determining whether sanction is appropriate.]

*T I changed the word ''would'' to ''may,'' because I decline to foreclose definitively the ability of the Respondent to have convinced me that he could have been entrusted with a registration. Most importantly, in this case he did not

DEPARTMENT OF JUSTICE

Drug Enforcement Ainistration

[Docket No. DEA–591]

Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before May 18, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 6, 2019, Siegfried USA, LLC, 33 Industrial Park Road, Pennsville, New Jersey 08070–3244 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Dihydromorphine	9145	I
Hydromorphinol	9301	I
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Codeine	9050	II
Oxycodone	9143	II