DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–33]

Larry C. Daniels, M.D.; Decision and Order

On June 21, 2019, a former Assistant Administrator of Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Larry C. Daniels M.D., (hereinafter, Respondent or Dr. Daniels) of Shreveport, Louisiana. Administrative Law Judge Exhibit (ALJ–– 1, (OSC) at 1. The OSC proposed to deny his pending application No. W18024499C for a DEA Certificate of Registration (hereinafter, COR or registration) pursuant to 21 U.S.C. 823(f) and 824(a)(1) for the reason that Respondent's ''registration would be inconsistent with the public interest,'' and because he ''materially falsified [his] application for registration.'' *Id.*

In response to the OSC, Respondent requested a hearing before an Administrative Law Judge. ALJ–2. The hearing in this matter was held in Shreveport, Louisiana on November 13–15, 2019. On January 24, 2020, Administrative Law Judge Charles Wm. Dorman (hereinafter, the ALJ) issued Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD), and on February 11, 2020, the Respondent filed exceptions (hereinafter, Resp Exceptions) to the Recommended Decision. The Government filed exceptions (hereinafter, Govt Exceptions) to the Recommended Decision on February 13, 2020. I address the Government's Exceptions, which were limited to the material falsification allegations, in the RD at Section Analysis.III. I address the Respondent's Exceptions, which were focused on the ALJ's finding that Dr. Daniels had not accepted responsibility and his recommended sanction, in the Sanction Section, and I issue the final order in this case following the RD. The ALJ transmitted the record to me on February 19, 2020. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*A

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Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision

*B The issue before the Administrator is whether the record as a whole establishes b a preponderance of the evidence thatg the DEA should den the application for a Certificate of Registration of Larr C. Daniels, M.D., Application Number W18024499C, pursuant to 21 UJ.SC. §§ 823(f) and 824(a)(1) and (a)(4), because he materiall falsified his application and because granting him a registration would be inconsistent with the public interest. ALJ–7.

In issuing this Recommended Decision, I have considered the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

The Allegations

Material Falsification

1. On March 12, 2018, the Louisiana State Board of Medical Examiners (''the Board'') issued a Consent Order that ''imposed a continuing restriction on [Dr. Daniels'] ability to practice medicine and to prescribe controlled substances for pain management or addiction treatment.'' ALJ–1, at 3–4, para. 8(c). Dr. Daniels' application for a DEA certificate of registration, dated March 16, 2018, failed to disclose the restriction imposed by the Board's Consent Order on his Louisiana state controlled substance license. *Id.* at 3–4, paras. 8–9. Dr. Daniels' failure to disclose the restriction imposed by the Board's Consent Order on his state controlled substance license constitutes a material falsification of his application for DEA registration, in violation of 21 U.S.C. 824(a)(1). *Id.*

Addiction Treatment

2. Between May 2016 and September 2017, Dr. Daniels prescribed controlled substances to patients AK, CA, MN, JD, SB, and CM. ALJ–1, at 4, paras. 10–12. Dr. Daniels' prescriptions for controlled substances to these patients exhibited the following deficiencies:

a. Dr. Daniels failed to conduct a physical examination of any of these patients;

b. Dr. Daniels failed to request these patients' medical records concerning prior substance abuse or past treatment of substance abuse;

c. Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for any of these patients;

d. Dr. Daniels failed to address in these patients' medical records the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed;

e. Dr. Daniels failed to document in these patients' medical records his rationale for his medical treatment of these patients, to include his reason for initiating buprenorphine treatment at high dosages. ALJ–1, at 5, para. 12(a)-(e).

3. In addition, Dr. Daniels issued to patients AK, CA, MN, SB, and CM, prescriptions for both buprenorphine (Subutex) and clonazepam. ALJ–1, at 5, para. 13. Prescribing these controlled substances to a patient at the same time can pose potential risks for that patient. *Id.* Dr. Daniels failed to document in the patients' medical records any rationale that justified prescribing buprenorphine and clonazepam at the same time. *Id.* Dr. Daniels also failed to document in the patients' medical records that he discussed with them the risks of taking these controlled substances at the same time. *Id.* Specifically, Dr. Daniels issued the following prescriptions in violation of state and federal law:

a. Between January 2017 and August 2017, Dr. Daniels prescribed AK buprenorphine (Subutex) on nine occasions and clonazepam (Klonopin) on at least eight of those occasions. ALJ–1, at 5, para. 14(a).

b. Between June 2016 and September 2017, Dr. Daniels prescribed CA buprenorphine (Subutex) and clonazepam (Klonopin) on at least 19 occasions, an amphetamine-dextroamphetamine mixture (Adderall) on 18 of those occasions. *Id.* at 6, para. 14(b). Dr. Daniels failed to document in CA's medical record any rationale for prescribing Adderall to CA. *Id.* at 6, para. 14(b)(i).

c. Between May 2017 and August 2017, Dr. Daniels prescribed MN buprenorphine (Subutex) and clonazepam (Klonopin) on at least five occasions. *Id.* at 6, para. 14(c).

d. Between August 2016 and August 2017, Dr. Daniels prescribed JD buprenorphine (Subutex) on at least 15 occasions. *Id.* at 6, para. 14(d).

e. Between January 2017 and July 2017, Dr. Daniels prescribed SB

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

*B I have submitted the RD's discussion of the procedural histor to avoid repetition with m introduction.

buprenorphine (Subutex) and clonazepam (Klonopin) on at least seven occasions. *Id.* at 6, para. 14(e).

f. Between May 2016 and September 2017, Dr. Daniels prescribed CM buprenorphine (Subutex) on at least 18 occasions and clonazepam (Klonopin) on 10 of those occasions. *Id.* at 6, para. 14(f).

4. For the reasons listed in Allegations 2 and 3, the prescriptions that Dr. Daniels issued to AK, CA, MN, JD, SB, and CM, were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose, in violation of 21 U.S.C. 841(a), 842(a); 21 CFR 1306.04(a); La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); La. Admin. Code tit. 46, Pt. XLV, §§ 6919, 6921; and La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731. ALJ–1, at 4–6, paras. 10–15.

Pain Management

5. Dr. Daniels issued controlled substance prescriptions for pain management to JW that exhibited the following deficiencies:

a. Dr. Daniels' records for follow-up visits with JW lack any indicia of a meaningful doctor-patient relationship, because the physical examination records for JW are incomplete, cursory, non-diagnostic, non-contributory, and/or lack notations of vital signs. ALJ–1, at 6, para. 16(a).

b. Dr. Daniels duplicated the therapeutic effect of the opioids he prescribed to JW by prescribing JW oxycodone-acetaminophen (Percocet), oxycodone extended release (OxyContin), and hydrocodone-acetaminophen (Lortab), after initially prescribing him methadone. *Id.* at 6, para. 16(b). Therapeutic duplication increases the risk of unintentional overdose. *Id.*

c. Between March 2014 and January 2017, Dr. Daniels prescribed JW OxyContin and methadone at the same time. *Id.* at 7, para. 16(c). In July 2014, Dr. Daniels prescribed JW Percocet and Lortab at the same time. *Id.* Dr. Daniels failed to document in JW's medical records any justification for these prescriptions. *Id.* at 7, para. 16(d).

d. In addition, Dr. Daniels failed to document in JW's medical records any justification for increasing JW's monthly methadone prescription in January 2016 from 150 units of methadone 10 mg to 180 units. *Id.* at 7, para. 16(d).

e. Between August 2013 and April 2017, Dr. Daniels issued to JW at least 56 prescriptions for Percocet; 7 prescriptions for OxyContin (5 at the same time as Percocet); and 1 prescription for Lortab. ALJ–1, at 7, para. 17.

f. Between January 2016 and March 2017, Dr. Daniels issued to JW at least 15 prescriptions for methadone at the increased dosage of 180 units, 5 at the same time as prescriptions for Percocet. *Id.* at 7, para. 17.

6. For the reasons listed in Allegation 5, the prescriptions that Dr. Daniels issued to JW were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose, in violation of 21 U.S.C. 841(a), 842(a); 21 CFR 1306.04(a); La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); and La. Admin. Code tit. 46, Pt. XLV, §§ 6919, 6921. ALJ–1, at 6–7, paras. 16–17.

Undercover Officer (''TC'')

7. On September 13, 2017, Dr. Daniels prescribed 60 units of Suboxone (buprenorphine/naloxone) 8/2 mg to TC. ALJ–1, at 7, para. 18. Among other issues, this prescription exhibited the following deficiencies:

a. Dr. Daniels failed to conduct a physical examination of TC;

b. Dr. Daniels failed to request any medical records of TC's prior substance abuse or past treatment for substance abuse;

c. Dr. Daniels failed to obtain a *[Prescription Monitoring Program (hereinafter,] PMP) report for TC. *Id.* at 7, para. 19.

8. Furthermore, Dr. Daniels initiated Suboxone treatment for TC at 16/4 mg per day despite TC's negative urine drug screen; TC's report to Dr. Daniels that he had not taken any opioids for two-to-three weeks; and Dr. Daniels' recognition that TC's presentment of addiction was not severe. ALJ–1, at 8, para. 19.

9. Dr. Daniels' medical records for TC fail to provide adequate information about Dr. Daniels' evaluation and treatment plan for TC, and are so cursory that they lack credibility. ALJ–1, at 8, para. 19.

10. For the reasons listed in Allegations 7–9, the prescription that Dr. Daniels issued to TC was beneath the standard of care for the practice of medicine in Louisiana and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1306.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). ALJ–1, at 8, para. 19.

Witnesses

I. The Government's Witnesses

The Government presented its case through the testimony of three witnesses. The Government first presented the testimony of a Diversion Investigator (''the DI''). Tr. 25–72. The DI also testified as a rebuttal witness. Tr. 588–99.

This witness has been a Diversion Investigator for 11 years. Tr. 26. She briefly testified concerning her work history with the DEA and her training. Tr. 26–28. The DI became familiar with Dr. Daniels after the Shreveport Resident Office of the DEA received information that Dr. Daniels was prescribing excessive amounts of controlled substances. Tr. 28.

The DI reviewed the Consent Order (''the Order'') issued to Dr. Daniels by the Louisiana State Board of Medical Examiners (''the Board''), highlighting restrictions placed on Dr. Daniels' ability to practice medicine by that Order. Tr. 33–34. The DI then reviewed Dr. Daniels' application for a DEA Certificate of Registration, noting that he had provided affirmative answers to two of the liability questions on the application. Tr. 38–39. The DI testified that had Dr. Daniels provided information that was more consistent with the content of the Order, that that information would have been relevant in assisting the DEA when making a decision about what action to take on Dr. Daniels' application. Tr. 39–41. *[The DI stated that the Order was ''ambiguous'' and that ''it's a requirement for the registrant to notify DEA that he has specific restrictions as in reference to controlled substances.'' Tr. 65; *see also* Tr. 72.] *[The DI testified that] the application itself, however, does not inform an applicant to provide the *[incident result] information that the DI asserted was missing from Dr. Daniels' application, which *[DEA alleged] constituted a material misrepresentation. [Tr. 70]. The information Dr. Daniels provided on his application, however, placed the DEA on notice that it should not summarily approve Dr. Daniels' application, but rather DEA should investigate it. Tr. 71.

Testifying as a rebuttal witness, the DI identified Government Exhibit 29 as a subpoena issued to the Louisiana Board of Pharmacy's Prescription Monitoring Program. Tr. 590. She also identified Government Exhibit 30 as the response to Government Exhibit 29. Tr. 593. In response to the subpoena, the Board of Pharmacy produced a 20-page history of Dr. Daniels' logins to the Louisiana PMP from June 2, 2016, through September 9, 2019. Tr. 593, 599. The history showed that Dr. Daniels had queried the PMP with respect to only two of the named patients in the OSC, patients TC and CA. Tr. 597. Both inquiries were made on September 13, 2017. Tr. 598.

During the Government's case-in-chief, and as a rebuttal witness, the DI presented her testimony in a professional, clear, and concise manner, and her demeanor was appropriate. Accordingly, I fully credit her testimony.

The Government's second witness was Task Force Officer (''TC''), a detective with the DeSoto Parish Sheriff's Office. Tr. 73–104. TC provided a brief overview of his law enforcement training. Tr. 74–76. He became aware of Dr. Daniels during undercover operations, in which he went to the doctor's office. Tr. 76. TC went to Dr. Daniels' office twice in September 2017, and made audio and video recordings during each visit. Tr. 76–77, 80; GE–24, 27. TC testified that Government Exhibit 24 is a complete and accurate recording of his visit with Dr. Daniels on September 13, 2017. Tr. 85.

TC detailed what happened during his visit to the clinic on September 12, 2017. Tr. 77–80. During that visit, TC provided a urine sample, his vitals were taken, and he talked with a counselor. *Id.* The details of what he told the counselor are documented in the counselor's notes. Tr. 87; GE–23, at 2–6. TC's urine screen was negative. Tr. 89; GE–23, at 9.

TC also detailed what happened when he returned to the clinic on September 13, 2017. Tr. 80–85. During that visit, he informed Dr. Daniels of his prior use of Lortab, Percocet, Adderall, and Suboxone, which he obtained ''off the street.'' Tr. 82–84. He also told Dr. Daniels that he drank alcohol. Tr. 82. Dr. Daniels did not caution TC about combining medications with each other or with alcohol and he did not physically examine TC. Tr. 82–84; GE–25. TC left the appointment with a prescription for Suboxone that Dr. Daniels issued to him. Tr. 85; GE–23, at 1.

TC presented his testimony in a professional, clear, and concise manner. In addition, his testimony was consistent with other evidence of record. Accordingly, I credit his testimony.

The third witness called by the Government was its expert, Dr. Gene Kennedy, M.D. He testified during the Government's case-in-chief, Tr. 106–416, and as a rebuttal witness. Tr. 600–04.

Dr. Kennedy currently maintains his own pain practice, Island Pain Care, on St. Simon's Island, Georgia. Tr. 107. He detailed his education, training, and professional experience. Tr. 107–111. Dr. Kennedy graduated from LSU with a degree in biology. Tr. 107. He obtained his medical degree from New York Medical College, and he then did a residency in family medicine in Wheeling, West Virginia, and then practiced family medicine in Ohio for many years. *Id.* In 2000, Dr. Kennedy relocated to Georgia. Tr. 109. Dr. Kennedy has been involved in pain management since his residency because a lot of family practice deals with pain management. *Id.* Dr. Kennedy opened his pain management clinic in 2004–05. Dr. Kennedy also treats patients who have substance abuse disorders, and he prescribes Suboxone to them. Tr. 109–10. Dr. Kennedy has a DEA Certificate of Registration, which includes an ''X'' number. Tr. 111. Dr. Kennedy identified Government Exhibit 26 as his resume. Tr. 111–12. Dr. Kennedy lectures on the differences between legitimate and illegitimate prescribing of controlled substances. Tr. 114–15. He has also testified as an expert witness at administrative hearings, and in both civil and criminal cases. Tr. 115. Dr. Kennedy testified that the standard of care that a doctor needs to meet is, for the most part, standard across the country, recognizing that individual states may have individual requirements. Tr. 119–34. *[He further testified that ''there are individual variations with states, and understanding that nobody's medical records are perfect then you analyze the chart and apply the regulations as best you reasonably can when doing a review.'' Tr. 120.]

There being no objection [*C] raised by Dr. Daniels, I accepted Dr. Kennedy as an expert in the areas of addiction treatment, pain management, and the standard of care for prescribing controlled substances for addiction treatment, and for pain management in the State of Louisiana. Tr. 134, 140.

Dr. Kennedy testified that the standard of care for prescribing controlled substances for the treatment of chemical dependency requires: An adequate physical examination; obtaining a medical history and past medical records; obtaining PMP reports; conducting drug screening; and maintaining complete and accurate medical records. Tr. 141–51. Dr. Kennedy recognized that no doctor can document everything that occurs during a patient encounter, but the doctor should document the important, pertinent information such that it will give a picture of what happened during the encounter to an objective reviewer of those records. Tr. 151–52. Dr. Kennedy also acknowledged that a reviewer of medical records must keep an open mind, and, at times, afford the treating doctor the benefit of the doubt. Tr. 153, 294, 296–98, 336.

In preparation for his testimony, Dr. Kennedy reviewed the medical records and the PMP reports of the patients identified in the Order to Show Cause. Tr. 159. In rendering his opinions concerning the prescriptions he reviewed, Dr. Kennedy noted that ''rarely is [his opinion] based on a single thing,'' rather it is developed after reviewing medical records and ''[i]t reaches a point where . . . it's simply not possible to say that what I'm looking at is credible medical care.'' Tr. 195. Dr. Kennedy further noted that accidents do happen in medical records, ''but when you have a repetitive pattern of medical records missing critical information, it's not excusable.'' Tr. 295. With respect to treatment plans, Dr. Kennedy testified that he does not criticize a treatment plan ''as long as I can determine that there is a rationale behind it.'' Tr. 298.

Dr. Kennedy proceeded to review the patient files contained in this case, and rendered his opinion that most of the prescriptions identified in the Order to Show Cause, written by Dr. Daniels, were issued outside the usual or acceptable course of professional medical practice and were not issued for legitimate medical purposes. Tr. 191–92, 206, 220, 231, 238, 244, 255, 261, 266, 278–83, 372–73. As a rebuttal witness, Dr. Kennedy slightly modified his testimony concerning Dr. Daniels' treatment of patient TC. Tr. 601–04. While Dr. Kennedy's opinion had not changed as to whether the prescription that Dr. Daniels issued to TC was outside the standard of care, and outside the usual course of professional practice, Tr. 602–03, he testified that Dr. Daniels may have believed he had a legitimate medical purpose to issue the prescription. Tr. 602. Concerning the question of ''whether or not it was issued for a legitimate medical purpose,'' Dr. Kennedy testified that he ''would have to go over everything again to make a final decision . . . .'' Tr. 602.[*D]

[*C] Despite not raising objections at the hearing, Dr. Daniels suggests in his posthearing brief that Dr. Kennedy's testimony should be considered in light of the fact that he ''has never practiced medicine in the State of Louisiana.'' Respondent's Posthearing, at 4. In this case, I find that Dr. Kennedy primarily relied on Louisiana law and regulations to formulate his opinion regarding the standard of care and usual course of professional practice and the laws provide extremely strong support for his testimony. *See infra* Analysis.V.

[*D] Ultimately, I find that the distinction that Dr. Kennedy makes here with regard to whether the prescription had a legitimate medical purpose is not entirely relevant considering Louisiana law and the CSA regulations. As explained below, Louisiana law mirrors the DEA regulations in providing that ''[a]n order purporting to be a prescription issued

Dr. Kennedy presented his testimony in a professional, candid, and straightforward manner. He also presented his testimony in an objective manner, and as a witness who had no stake in the outcome of the case. In addition, the testimony of Dr. Kennedy was sufficiently detailed, plausible, and internally consistent. Furthermore, Dr. Kennedy's testimony went unrebutted.[1] Therefore, I merit it as fully credible in this Recommended Decision.

II. Respondent's Witnesses

Respondent presented his case through the testimony of two witnesses. The Respondent's first witness was LW (''LW''). Tr. 418–69. LW was the owner of the Medical Clinic (''the Clinic'') where Dr. Daniels worked. Tr. 419. The Clinic closed on October 3, 2017. *Id.* While in operation, the Clinic provided services for patients who had low, to mid-level incomes, and who were being treated for some kind of opioid addiction. Tr. 421–22. Between January 2016 and April 24, 2017, LW was at the Clinic one evening a week. *Id.* On April 24, 2017, LW started working at the Clinic full time and oversaw its day-to-day operations. Tr. 420. LW is a medical assistant. Tr. 445.

LW provided testimony about how the Clinic operated after April 24, 2017. Tr. 430–31. After that date, Dr. Daniels worked at the Clinic just one evening a week and saw about 25 patients a week. Tr. 424–25. He was the only doctor who worked at the Clinic. Tr. 427. In addition to Dr. Daniels and LW, the Clinic employed five other individuals. Tr. 425–26. LW testified about the duties of those employees. Tr. 428–29, 431–34, 436–41. Each of the employees played a part in assembling the patients' medical records. Tr. 427, 438. LW testified that each new patient submitted to a urine drug screen and that the Clinic checked the patient's PMP. Tr. 442–43, 446. Information about the results of the drug screening and the PMP were provided to Dr. Daniels. Tr. 443. Although LW testified that after she started working at the Clinic full-time, Clinic employees always checked the PMP, she did not know if that information was placed into a patient's medical record. Tr. 448.

In general, I found LW to be a sincere and credible witness who testified about how she thought the Clinic was running after she took over the day-to-day operations. It was also obvious that she has a sincere interest in providing health services to an underserved community. For someone who was overseeing the day-to-day operations of the Clinic, however, her testimony was less than clear about when and how PMPs were run, and how the results of the PMP search and of the urine drug screens were provided to Dr. Daniels. Although she testified that the PMP report was run for each patient, Tr. 442, it was not clear when the clinic ran PMP's on patients. She testified it was run when the patient came in, and it was run after they saw the social worker, ''it was run constantly.'' Tr. 457–59. Further, LW was not clear on what information from the PMP was shared with Dr. Daniels. Tr. 460–465. In that her testimony about running PMP reports on every patient is directly contradicted by Government Exhibit 30,[2] I give little weight to this testimony. Further, while LW testified that urine drug screens were taken for each patient, Tr. 443, she also testified that the Clinic discovered that the results of those tests were not always in the patients' charts. Tr. 427, 439. I find that LW's testimony about having patients submit to urine drug screening is generally consistent with other evidence of record, namely the large number of drug screening reports that are in the patients' medical records. Thus, with the exception of LW's testimony about PMPs, I give credit to LW's testimony.

Next, Dr. Larry Daniels, M.D., testified on his own behalf. Tr. 475–586. Dr. Daniels worked at the Shreveport Job Corps Center, the Diabetes Management Center, and the Clinic. Tr. 475. Dr. Daniels has practiced medicine in Louisiana since 1983. Tr. 476. He practiced for one year in Houston, Texas, from 1999 to 2000. Tr. 476–77. Dr. Daniels received compensation for his services at the Clinic from the Clinic itself, and not from patients. Tr. 480. Throughout his career, Dr. Daniels has worked for multiple clinics that provide medical services to low-income patients, and he has treated patients who had chemical dependencies. Tr. 482–84. Dr. Daniels worked at the Clinic on Wednesday evenings. Tr. 488. He would normally see about 10–20 patients on those evenings. *Id.*

The Clinic was located in Minden, Louisiana, which is a rural area. Tr. 480. Dr. Daniels worked at the David Raines Community Health Center (''Community Health Center'') at the same time that he worked at the Clinic. *Id.* Before working at the Clinic, Dr. Daniels had experience in private practice and at the Community Health Center in treating chemical dependency. Tr. 482.

Dr. Daniels acknowledged that there is information missing from the patients' charts. Tr. 487. Dr. Daniels testified that the patient charts in this case do not include sticky notes and other notes that would have been on the inside of the manila folder that held the charts. Tr. 488. Dr. Daniels testified that a doctor learns the patient's medical history by talking to the patient about his or her past medical conditions and any current problems, to include the patient's chief complaint. Tr. 491. He stated that a doctor also acquires the patient's medical history by discussing the patient's family and social history. *Id.*

Dr. Daniels acknowledged that he did not always document the justification for the prescriptions he wrote. Tr. 523. When Dr. Daniels saw a patient at the Clinic, some of the patient's medical history was available on forms that the patient completed before the visit. Tr. 492. He explained that because he has worked in several mental health-counseling clinics, he has gained familiarity and experience in treating certain conditions. *Id.* Dr. Daniels also noted that the Clinic saw an increase in patients when it received its waiver to treat 100 patients. Tr. 489. Previously it only held a waiver for 30 patients. *Id.*

Dr. Daniels agreed with Dr. Kennedy's testimony about physical examinations. Tr. 492. Dr. Daniels testified that in situations where there is limited staff and when other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing the waiting patients. Tr. 493. In those situations, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493. Dr. Daniels also testified that a doctor can perform an examination by observing the patient,

not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act.'' La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); *see also* 21 CFR 1306.04(a) (same). Therefore, the fact that Dr. Kennedy had concluded that this prescription was issued outside the usual course of professional treatment and beneath the standard of care, Tr. 602–03, demonstrates that there was a violation of law for the purpose of consideration under Factor Four of the public interest factors. *See infra* Analysis.V (Patient TC); *infra* n.27; *see also Ester Mark, M.D.,* 16,760, 16,778 (citing *Wesley Pope, M.D.,* 82 FR 14,944, 14,967 n.38 (2017) (explaining ''there is no material difference between'' the dual criteria of Section 1306.04(a).'') Prescribing a controlled substance outside the course of professional practice is enough to violate DEA's prescription requirement. *Id.*

[1] ''When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge.'' *Zvi H. Perper, M.D.,* 77 FR 64131, 64140 (2012) (citing *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966)).

[2] Government Exhibit 30, however, gives some support to Dr. Daniels' position that he was checking the PMP, *[at least with respect to two of the patients].

and noting the patient's demeanor, activity, mood, and physical appearance. Tr. 493–94. Sometimes, Dr. Daniels decided to do a more thorough physical examination. Tr. 512.

Dr. Daniels testified that in general he would ask each patient: About his or her medication; whether the medication was working; who initially prescribed it; and how long the patient had been taking it. Tr. 517. Similarly, Dr. Daniels testified that the purpose of checking a patient's PMP report was to see which medications, if any, the patient has received before, when the patient received those medications, and the doctors who prescribed them. Tr. 495. Although there is no requirement to print out a copy of a patient's PMP report, Dr. Daniels testified that it would be ideal to obtain a printout. Tr. 496.

Dr. Daniels testified that when searching for a patient on the PMP, he was mostly concerned with looking at the past 30 days. Tr. 496–97. It is normal to delegate the duty to check the PMP to someone other than the doctor. Tr. 497. Normally, a staff member of the Clinic would run a PMP report and provide the results to Dr. Daniels. Tr. 514, 522. The Clinic did not document the results of the PMP report. Tr. 522.

With respect to urine drug screens, Dr. Daniels testified that in most cases he addressed abnormalities with the patient but did not document that fact in the patient's chart. Tr. 498, 502. He acknowledged it would be best practice to document efforts to address an abnormal urine drug screen. Tr. 501. He also acknowledged that ''a couple of patients'' tested negative for their prescribed medications. Tr. 502. It is unclear, however, whether he was referring to the patients in this case. Testing negative for a prescribed controlled substance raises the concern of diversion. *Id.* When this occurred, he would refer it to the clinical social worker. Tr. 503. These actions, in his opinion, should have been better documented. *Id.*

Dr. Daniels testified that the current standard is not to discharge a noncompliant patient. Tr. 499–500. It was unclear from his testimony when this standard began. For example, Dr. Daniels made an analogy to a diabetic patient whose sugars are elevated after not complying with his or her prescribed diet. *Id.* Dr. Daniels said that a doctor would not discharge this patient simply because the patient failed to comply with his or her diet. Tr. 500. According to Dr. Daniels, the same is true for doctors treating patients for chemical dependency. *Id.* He explained that it is better for a patient in the long-term to be kept on medication than to discharge the patient. *Id.* Discharging a patient could lead to a relapse or to the patient taking dangerous street drugs. *Id.* In Dr. Daniels' opinion, none of the patients in this case should have been discharged because of a urine drug screen. Tr. 501–02.

Some of the patients who presented with opioid addiction also had other issues, such as anxiety and depression, and Dr. Daniels had to formulate a treatment plan for those issues as well. Tr. 506. Most of the patients also needed counseling. Tr. 501, 504, 506. If Dr. Daniels was not going to be at the Clinic, he would sometimes write a prescription for the patient and have the staff check the patient's vitals and take a urine drug screen. Tr. 508–10. If the patient was taking Suboxone, Dr. Daniels would discuss the Suboxone treatment regimen plan with the patient. Tr. 516. He would also ask the patient if he or she signed the treatment contract, and whether the patient understood it. Tr. 516. He would only address specific provisions of the treatment contract if he believed there might be a particular issue with the patient's ability to comply with the contract. Tr. 516.

When asked about the physical examination he conducted of patient AK, at AK's first visit on January 18, 2017, Dr. Daniels said he checked-off neat and clean on the record, and noted AK had a depressed affect. Tr. 512; GE–6, at 25. Patient AK also took a urine drug screen at this first visit. Tr. 514; GE–6, at 29. AK's initial urine drug screen was positive for methamphetamine, but not when he returned to the next visit. Tr. 515; GE–6, at 29. It was also positive for marijuana. *Id.* Dr. Daniels testified that he was not concerned when a patient tested positive for THC because ''it's so ubiquitous in this population that I see,'' and he did not believe it would be unsafe for AK to take marijuana. Tr. 515. Dr. Daniels' treatment plan for AK at the first visit was to conduct monthly and random urine drug screens, provide AK counseling, prescribe Subutex 8 mg TID and Klonopin 2 mg, and have AK return to the Clinic in one month. Tr. 515, 518.

Dr. Daniels could not remember what was found on AK's PMP report, if anything, because AK's PMP results are not documented. Tr. 514. Dr. Daniels testified that he was able to conclude that AK had an opioid addiction based on AK's medical history, the physical examination that Dr. Daniels described, and AK's urine drug screen. Tr. 515. AK also had an anxiety disorder and pain. Tr. 517–18. Dr. Daniels did not see pain recorded in AK's chart. Tr. 517. Dr. Daniels did not see AK's counseling records in his chart. Tr. 515–16. Dr. Daniels testified that the Food and Drug Administration has advised that patients should not be denied Subutex simply because the patient is also taking a benzodiazepine. Tr. 518. In Dr. Daniels' opinion, he believed it was justified to prescribe Subutex and Klonopin to AK because AK had pain and had taken opioids and Klonopin before. Tr. 518. Dr. Daniels acknowledged, however, that AK's chart does not document that AK had taken opioids before *[for a pain condition]. *Id.* Dr. Daniels believed prescribing a higher dose of Subutex to AK was warranted because in addition to opioid addiction AK also had pain, and Subutex can be used to relieve pain. Tr. 517–18. In Dr. Daniels' opinion, the prescriptions in Stipulation 17 were written to treat AK's substance abuse disorder, anxiety, and chronic pain. Tr. 520.

On June 22, 2016, patient CA presented with an opioid addiction, and history of abdominal pain, hand fracture, arthritis, anxiety, ADHD, and TMJ. Tr. 521. CA had received Subutex from another doctor for opioid addiction, as well as Adderall for ADHD and Klonopin for anxiety. Tr. 521–22. When asked about the physical examination he conducted of CA, Dr. Daniels testified that he looked at CA's person, place, and orientation; noted that CA's affect was ''blunted and flat''; and observed that he was ''depressed and anxious.'' Tr. 521. Dr. Daniels testified that CA's history, his answers, and his demeanor were consistent with ADHD. Tr. 523. Based on CA's history and Dr. Daniels' examination of CA, he was able to diagnose CA with an opioid addiction, anxiety disorder, and ADHD. Tr. 522. Dr. Daniels testified that CA had received treatment from another provider before CA had seen him. Tr. 528.

Dr. Daniels' treatment plan for CA included monthly urine drug screens, counseling, Subutex at his current dosage, Klonopin 1 mg TID, and Adderall 30 mg. Tr. 523. In Dr. Daniels' opinion, the prescriptions in Stipulation 22 were written to treat CA's diagnosed conditions of opioid addiction, anxiety, chronic abdominal pain, ADHD, and TMJ. Tr. 524; GE–10, at 53.

Patient MN's chief complaint was an addiction to Subutex. Tr. 526. After talking with her, he learned that she had been addicted to other medications as well. *Id.* MN had already been prescribed Subutex for opioid dependence by other doctors before seeing Dr. Daniels. Tr. 528–29. MN also had anxiety. Tr. 529. Dr. Daniels' chart for MN included a note that Suboxone

gave her migraines. Tr. 527; GE–14, at 29. Dr. Daniels described it as ''a very limited note,'' but explained that ''sometimes with interruptions in the clinic, you get limited information to put in the chart.'' Tr. 527.

When asked whether he physically encountered MN, Dr. Daniels said that he did not ''see a document of physical encounter.'' Tr. 527. Dr. Daniels testified, however, that he did see MN, and he did conduct a physical examination. Tr. 527–28. MN's chart includes some medical history collected by the Clinic's staff and the counselor. Tr. 528. When asked whether he was able to diagnose MN, he stated that he diagnosed her with an opioid addiction based on her history. Tr. 528–29. Dr. Daniels' treatment plan for MN included Subutex 8 mg TID and Klonopin. Tr. 529. In Dr. Daniels' opinion, the prescriptions in Stipulation 24 were written to treat MN's opioid dependency and anxiety. Tr. 529–30.

Patient JD presented with a history of back pain and opioid abuse. Tr. 531. JD had been prescribed Lortab for his back pain by another physician, but he later began taking Percocet and methadone, which he bought on the street. *Id.* A previous physician had also prescribed Subutex to JD for an opioid addiction, and his urine drug screen was ''consistent with having [taken] Subutex.'' Tr. 532.

Dr. Daniels' treatment plan for JD included Subutex 8 mg TID, monthly drug screens, and counseling. *Id.* He additionally testified that JD remained in the Clinic past this initial visit and that the Subutex prescription was meant to address JD's back pain as well as his addiction. Tr. 533.

Patient SB's chief complaint was panic attacks and a history of recreational drug abuse. Tr. 534. SB had been treated by another physician with Suboxone, but after experiencing side effects was treated with Subutex instead. *Id.* In addition to taking vitals, height, and weight, Dr. Daniels ordered a urine drug screen for SB. *Id.* SB tested positive for methamphetamine, marijuana, and Subutex. *Id.* While he did not make a note of it in SB's file, Dr. Daniels testified that in this situation, his general recommendation would have been for more frequent counseling. Tr. 535–36. However, he prescribed SB with Subutex for addiction, and with Klonopin for panic attacks. Tr. 535.

Patient CM came to the Clinic with a history of abusing oxycodone and roxycodone. Tr. 537. CM had previously been prescribed Subutex by another physician. *Id.* Dr. Daniels took CM's vitals, recorded height and weight, and made some other notes about CM's appearance and habits. *Id.* CM did a urine drug screen, which came back positive for marijuana and Suboxone. Tr. 538. Dr. Daniels also noted that CM ''appeared to have an anxiety disorder.'' Tr. 540.

Dr. Daniels' treatment plan for CM included Subutex for ''chemical dependencies,'' and Klonopin for anxiety. *Id.* When pressed about the Klonopin prescription, Dr. Daniels testified that Klonopin is what is usually prescribed for anxiety. Tr. 542. He also recommended counseling. Tr. 540. According to Dr. Daniels, CM remained a patient with the clinic for some time and was making progress. Tr. 539–40.

In detailing his treatment of patient JW, Dr. Daniels noted that JW was a professional colleague of his who owned the Clinic before Ms. LW took it over. Tr. 543. JW is a professional counselor who has known Dr. Daniels since 2003. *Id.* Dr. Daniels testified that JW began developing chronic pain in 2013, and a local physician was treating him with methadone. Tr. 544. JW had been referred to a pain specialist in Shreveport who was unable to see him because of an insurance issue. *Id.* Dr. Daniels agreed to see JW temporarily because he was in terrible pain and ''almost unable to ambulate.'' *Id.* Though he says it was not his intent to treat JW long term, he treated him until 2017. *Id.*

Dr. Daniels determined that JW had hypertension, lumbar disc disease, chronic back pain, a history of carpal tunnel syndrome, and multiple surgeries in the past. Tr. 547. The initial plan was to follow up on medical records. *Id.*

Dr. Daniels prescribed OxyContin to JW because he had just had knee surgery, and he was complaining of severe knee pain. Tr. 548. He chose OxyContin because JW had developed a tolerance to other pain medications. Tr. 549. He claims that he wrote the prescription for every 4–6 hours by mistake and that the usual dose is every 12 hours. *Id.* He also believes that JW was taking it ''correctly,'' meaning every 12 hours. Tr. 550. Dr. Daniels also prescribed Percocet to JW so that he could ''rotate [the pain medications] around'' for ''different options on pain relief,'' because JW described being able to take certain medications on some days, but not on others. *Id.* Dr. Daniels saw JW as a patient at least once per week, but sometimes two or three times per week, in addition to encountering him professionally on a regular basis. Tr. 550–51. On cross-examination, Dr. Daniels agreed that five of the prescriptions he wrote to JW for OxyContin were written with the wrong dosing instructions. Tr. 577–79.

When Dr. Daniels first saw the undercover agent (''TC'') as a patient, TC initially told him that he was taking 4–5 pain pills per day that he had bought off of the street, presuming them to be Lortab. Tr. 552. Dr. Daniels believed that TC would benefit from counseling. *Id.* From further conversation, Dr. Daniels got the impression that TC was actually taking more pills than he was letting on and that he was not completely sure that the pills were, in fact, Lortab. Tr. 553. TC also ''indicated that he was taking Suboxone off the street'' and ''taking maybe Adderall.'' Tr. 554. This led Dr. Daniels to prescribe Suboxone. *Id.*

TC took a urine drug screen which tested negative. Tr. 556. However, based on his understanding of ''the local people that [he] had been treating for so many years'' and TC's history, Dr. Daniels felt that the dose of Suboxone he prescribed was appropriate because he believed it to be one that would prevent a relapse. Tr. 557. Dr. Daniels testified that the reason why some of his discussions with TC did not get documented in the medical record was ''because it was cumbersome.'' Tr. 506.

As to his licensing history, Dr. Daniels testified that he had never been denied a COR. Tr. 560. Regarding his state authority, Dr. Daniels entered into a consent order with the state medical board, and he testified that there had been concerns that he was not properly monitoring patients or supervising staff. *Id.* *[He stated that the state medical board ''felt like that [he], as an individual practitioner, trusted people too much, that I gave too much confidence in the people when I would ask them to do things or expect them to bring things to me.'' Tr. 561.] Citing personal stress, Dr. Daniels testified that he ''had not be[en] able to really take full advantage of the opportunity to see these patients'' leading to potential risks given the areas he was practicing in. Tr. 561. At the state medical board's recommendation, Dr. Daniels attended continuing medical education seminars on controlled substance prescribing, ethics, and boundaries. Tr. 562. After completing these recommendations, the medical board restored his license, but he was not allowed to practice in the areas of managing: Addiction; chronic pain; or obesity. Tr. 563.

Dr. Daniels re-applied for a COR once his state license was reinstated. Tr. 564. In filling out the form, he claims he did not realize that he ''would have to be more complete'' and that he ''wasn't aware that the high risk practice areas

was where they were restricting [him].'' Tr. 565. His understanding was that the state medical board had fully reinstated his controlled substance prescribing authority. *Id.* Dr. Daniels claims that he did not intend to be evasive or misleading. *Id.* He additionally testified that he has been struggling professionally without a COR because he currently works at a diabetes management clinic where Lyrica, a Schedule V controlled substance, is an important part of treatment. Tr. 568–69.

* [Dr. Daniels testified that he felt ''like he had made every attempt to make sure that these patients were getting proper evaluations, and that the medicines that [he] was prescribing were safe and effective, and that [he] admit[s] some of the records fall short. [He] failed. But [he] feel[s] that still the overall diagnoses were correct, and the treatment plans were good.'' Tr. 570.]

Despite being the witness with the most at stake in these proceedings, and thus the witness with the strongest motive to fabricate, Dr. Daniels presented generally as candid and sincere. However, there were notable inconsistencies between his descriptions of his prescribing history to various patients and objective data such as the PMP report for the relevant period. * [Additionally, I note that regarding the undercover TC, Dr. Daniels stated, ''[a]nd he did tell me about alcohol and he was drinking. And we talked about some of the things that needed to be understood about the contract that he signed that he would not drink alcohol when taking these medicines.'' Tr. 555. However, the transcript of their recorded conversation does not reflect any mention of the contract that TC signed or not drinking alcohol when taking the medicines, despite TC bringing up his alcohol use twice in the conversation. *See* GE–25, at 3; *see also* Tr. Tr. 82–84. I find this statement to weigh against Dr. Daniels' credibility and to be an attempt to minimize the egregiousness of his actions.] Thus, I generally credit Dr. Daniels' testimony, but where his testimony conflicts with that of other witnesses or record evidence, I consider it with close scrutiny.

The Facts

I. Stipulations

The Parties agree to 49 stipulations (''Stip.''), which the Parties have accepted as facts in these proceedings. Tr. 10.

Background

1. Dr. Daniels is a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners in the State of Louisiana.

2. Dr. Daniels was previously registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. AD2802937 at 1514 Doctors Drive, Bossier City, Louisiana 71111.

3. Dr. Daniels surrendered DEA COR No. AD2802937 for cause on September 29, 2017.

4. Government Exhibit No. 1 is a true and correct copy of Dr. Daniels' signed surrender of his DEA COR No. AD2802937, dated September 29, 2017.

5. On September 20, 2017, the Louisiana State Board of Medical Examiners (''LSBME'') issued a notice partially suspending Dr. Daniels' medical license and prohibiting him from ''prescribing, dispensing or administering controlled substances to any patient, effective September 21, 2017.''

6. Government Exhibit No. 2 is a true and correct copy of the notice issued by the LSBME on September 20, 2017.

7. Dr. Daniels filed a new application for a DEA COR on or about March 16, 2018.

8. Government Exhibit No. 3 is a true and correct copy of Dr. Daniels' March 16, 2018 application for a DEA COR.

9. Government Exhibit No. 4 is a true and correct copy of the Certification of Registration History showing Dr. Daniels' answers to the liability questions in his March 16, 2018 application for a DEA COR.

Consent Order

10. On March 12, 2018, the LSBME issued a Consent Order for Reprimand to Dr. Daniels that, among other things, did the following:

a. The Consent Order recalled the suspension of Dr. Daniels' authority to prescribe, dispense, or administer controlled substances issued on September 20, 2017.

b. The Consent Order accepted Dr. Daniels' representations to the LSBME that he would permanently refrain from prescribing controlled substances for chronic pain or obesity and refrain from associating himself with a drug treatment clinic.

c. The Consent Order imposed continuing restrictions on Dr. Daniels' authority to prescribe, dispense, or administer controlled substances, namely that it required Dr. Daniels to meet with the LSBME or a designee in advance and to abide by any suggestions or conditions the LSBME might recommend if Dr. Daniels ever wished to resume the acts he promised to discontinue.

11. Government Exhibit No. 5 is a true and correct copy of the Consent Order for Reprimand issued by the LSBME on March 12, 2018.

12. Dr. Daniels referenced the Consent Order, a public document, in his application for the COR.

Patient AK

13. Government Exhibit No. 6 is a true and correct copy of Dr. Daniels' patient file for Patient AK.

14. Government Exhibit No. 7 is a true and correct copy of a DEA subpoena issued to the CVS Pharmacy located at 2735 Beene Boulevard, Bossier City, Louisiana, regarding Dr. Daniels' prescriptions to Patient AK.

15. Government Exhibit No. 8 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patient AK and that DEA obtained from the CVS Pharmacy located at 2735 Beene Boulevard, Bossier City, Louisiana.

16. Government Exhibit No. 9 is a true and correct copy of a DEA subpoena issued to Super One Pharmacy located at 745 Shreveport Barksdale Highway, Shreveport, Louisiana, regarding Dr. Daniels' prescriptions to Patient AK, and the response that DEA received from Brookshire Grocery Company, Pharmacy Operations, 1600 WSW Loop 323, Tyler, Texas, containing copies of prescriptions Respondent issued to Patient AK

17. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex (buprenorphine) and Klonopin (clonazepam), to Patient AK on at least the following occasions:

Date issued	Prescription
1/16/2017	15 units of Subutex 8 mg.
1/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
2/23/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
3/22/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
4/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
5/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.

Date issued	Prescription
7/28/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
8/25/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.

Patient CA

18. Government Exhibit No. 10 is a true and correct copy of Dr. Daniels' patient file for Patient CA.

19. Government Exhibit No. 11 is a true and correct copy of a DEA subpoena issued to Benzer Pharmacy located at 2951 E. Texas Street, Bossier City, Louisiana, regarding Dr. Daniels' prescriptions to Patient CA.

20. Government Exhibit No. 12 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patient CA and that DEA obtained from Benzer Pharmacy located at 2951 E. Texas Street, Bossier City, Louisiana.

21. Government Exhibit No. 13 is a true and correct copy of a response to a DEA Subpoena from Walgreen's Pharmacy located at 9209 Mansfield Road, Shreveport, Louisiana, containing a prescription that Dr. Daniels issued to Patient CA.

22. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex, Klonopin, and Adderall (amphetamine-dextroamphetamine mixture), to Patient CA on at least the following occasions:

Date issued	Prescription
6/9/2016	90 units of Subutex 8 mg; 30 units of Klonopin 1 mg.
6/22/2016	90 units of Klonopin 1 mg; 30 units of Adderall 30 mg.
7/6/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
8/31/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
9/28/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
10/26/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
11/16/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
12/14/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
1/11/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
2/8/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
3/8/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
4/5/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
5/3/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
5/31/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
6/29/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
7/26/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
8/23/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
9/13/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.

Patient MN

23. Government Exhibit No. 14 is a true and correct copy of Dr. Daniels' patient file for Patient MN.

24. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient MN on at least the following occasions:

Date issued	Prescription
5/3/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
5/31/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
6/28/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
7/28/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
8/29/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.

Patient JD

25. Government Exhibit No. 15 is a true and correct copy of Dr. Daniels' patient file for Patient JD.

26. Government Exhibit No. 16 is a true and correct copy of a response to a DEA Subpoena from Brookshire's Pharmacy located at 1125 Highway 80, Haughton, Louisiana, containing prescriptions that Dr. Daniels issued to Patient JD.

27. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex, to Patient JD on at least the following occasions:

Date issued	Prescription
8/3/2016	90 units of Subutex 8 mg.
8/31/2016	90 units of Subutex 8 mg.
9/28/2016	90 units of Subutex 8 mg.
10/26/2016	90 units of Subutex 8 mg.
11/16/2016	90 units of Subutex 8 mg.
12/14/2016	90 units of Subutex 8 mg.
1/18/2017	90 units of Subutex 8 mg.
2/8/2017	90 units of Subutex 8 mg.
3/8/2017	90 units of Subutex 8 mg.

Date issued	Prescription
4/5/2017	90 units of Subutex 8 mg.
5/3/2017	90 units of Subutex 8 mg.
6/7/2017	90 units of Subutex 8 mg.
7/5/2017	90 units of Subutex 8 mg.
8/2/2017	90 units of Subutex 8 mg.
8/30/2017	90 units of Subutex 8 mg.

Patient SB

28. Government Exhibit No. 17 is a true and correct copy of Dr. Daniels' patient file for Patient SB.

29. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient SB on at least the following occasions:

Date issued	Prescription
1/18/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
2/15/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
3/15/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
4/12/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
5/10/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
6/24/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
7/19/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.

Patient CM

30. Government Exhibit No. 18 is a true and correct copy of Dr. Daniels' patient file for Patient CM.

31. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient CM on at least the following occasions:

Date issued	Prescription
5/4/2016	90 units of Subutex 8 mg.
6/1/2016	90 units of Subutex 8 mg.
6/29/2016	90 units of Subutex 8 mg.
7/27/2016	90 units of Subutex 8 mg.
8/24/2016	90 units of Subutex 8 mg.
9/21/2016	90 units of Subutex 8 mg.
10/19/2016	90 units of Subutex 8 mg.
11/16/2016	90 units of Subutex 8 mg.
12/14/2016	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
1/11/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
2/22/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
3/20/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
4/19/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
5/17/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
6/14/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
7/12/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
8/9/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
9/5/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.

Patient JW

32. Government Exhibit No. 19 is a true and correct copy of Dr. Daniels' patient file for Patient JW.

33. Government Exhibit No. 20 is a true and correct copy of a DEA subpoena issued to the CVS Pharmacy located at 1118 Homer Road, Minden, Louisiana, regarding Dr. Daniels' prescriptions to Patients CA, JD, CM, and JW.

34. Government Exhibit No. 21 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patients CA, JD, CM, and JW, and that DEA obtained from the CVS Pharmacy located at 1118 Homer Road, Minden, Louisiana.

35. As listed below, Dr. Daniels issued prescriptions for controlled substances, including methadone, Percocet (oxycodone-acetaminophen), OxyContin (oxycodone extended release), and Lortab (hydrocodone-acetaminophen), to Patient JW on at least the following occasions:

Date issued	Prescription
7/5/2013	90 units of methadone 10 mg.
7/22/2013	150 units of methadone 10 mg.
8/9/2013	30 units of Percocet 10/325 mg.
8/16/2013	150 units of methadone 10 mg.
8/23/2013	60 units of Percocet 10/325 mg.

Date issued	Prescription
9/6/2013	60 units of Percocet 10/325 mg.
9/13/2013	150 units of methadone 10 mg.
10/11/2013	150 units of methadone 10 mg.
10/18/2013	60 units of Percocet 10/650 mg.
11/8/2013	150 units of methadone 10 mg; 60 units of Percocet 10/325 mg.
12/6/2013	150 units of methadone 10 mg; 60 units of Percocet 10/325 mg.
12/20/2013	60 units of Percocet 10/325 mg.
1/3/2014	150 units of methadone 10 mg; 90 units of Percocet 10/325 mg.
1/17/2014	90 units of Percocet 10/325 mg.
1/31/2014	150 units of methadone 10 mg; 90 units of Percocet 10/325 mg.
2/14/2014	90 units of Percocet 10/325 mg.
2/28/2014	90 units of Percocet 10/325 mg.
3/14/2014	30 units of OxyContin 10 mg.
3/19/2014	90 units of Percocet 10/325 mg.
3/21/2014	150 units of methadone 10 mg.
3/28/2014	20 units of OxyContin 10 mg; 90 units of Percocet 10/325 mg.
4/11/2014	20 units of OxyContin 10 mg; 90 units of Percocet 10/325 mg.
4/17/2014	150 units of methadone 10 mg.
4/25/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/9/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/16/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/23/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
6/6/2014	120 units of Percocet 10/325 mg.
6/20/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/10/2014	60 units of Lortab 10/325 mg.
7/16/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/8/2014	120 units of Percocet 10/325 mg.
8/22/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
9/5/2014	120 units of Percocet 10/325 mg.
9/19/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/17/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/14/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
12/5/2014	120 units of Percocet 10/325 mg.
12/12/2014	150 units of methadone 10 mg.
12/23/2014	120 units of Percocet 10/325 mg.
1/5/2015	120 units of Percocet 10/325 mg.
1/12/2015	150 units of methadone 10 mg.
1/23/2015	120 units of Percocet 10/325 mg.
2/6/2015	120 units of Percocet 10/325 mg.
2/20/2015	120 units of Percocet 10/325 mg.
3/6/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
3/20/2015	120 units of Percocet 10/325 mg.
4/2/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
4/17/2015	120 units of Percocet 10/325 mg.
5/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
5/15/2015	120 units of Percocet 10/325 mg.
6/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
6/15/2015	120 units of Percocet 10/325 mg.
7/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/30/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/14/2015	120 units of Percocet 10/325 mg.
8/31/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
9/14/2015	120 units of Percocet 10/325 mg.
9/26/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/14/2015	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/24/2015	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
12/9/2015	120 units of Percocet 10/325 mg.
12/19/2015	120 units of Percocet 10/325 mg.
12/30/2015	180 units of methadone 10 mg.
1/12/2016	120 units of Percocet 10/325 mg.
1/27/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
2/24/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
3/16/2016	120 units of Percocet 10/325 mg.
3/23/2016	180 units of methadone 10 mg.
4/6/2016	120 units of Percocet 10/325 mg.
4/27/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
5/18/2016	120 units of Percocet 10/325 mg.
5/25/2016	180 units of methadone 10 mg.
6/8/2016	120 units of Percocet 10/325 mg.
6/22/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/20/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/10/2016	120 units of Percocet 10/325 mg.
8/24/2016	180 units of methadone 10 mg.
8/31/2016	120 units of Percocet 10/325 mg.

Date issued	Prescription
9/21/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/5/2016	120 units of Percocet 10/325 mg.
10/26/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/9/2016	120 units of Percocet 10/325 mg.
12/14/2016	120 units of Percocet 10/325 mg.
12/21/2016	180 units of methadone 10 mg.
1/4/2017	120 units of Percocet 10/325 mg.
1/6/2017	30 units of OxyContin 10 mg.
1/18/2017	180 units of methadone 10 mg.
1/30/2017	120 units of Percocet 10/325 mg.
2/13/2017	120 units of Percocet 10/325 mg.
2/21/2017	180 units of methadone 10 mg.
3/1/2017	120 units of Percocet 10/325 mg.
3/22/2017	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
4/5/2017	120 units of Percocet 10/325 mg.

Patient TC

36. Government Exhibit No. 23 is a true and correct copy of Dr. Daniels' patient file for Patient TC.

37. On September 13, 2017, Dr. Daniels issued a prescription to Patient TC for 60 units of Suboxone (buprenorphine/naloxone) 8/2 mg.

38. Government Exhibit No. 24 is a true and correct video recording of Dr. Daniels' interaction with Patient TC on September 13, 2017.

39. Government Exhibit No. 25 is a true and correct transcript of Dr. Daniels' interaction with Patient TC on September 13, 2017.

40. Government Exhibit No. 27 is a true and correct video recording of Patient TC's visits to Dr. Daniels' office on September 12 and 13, 2017.

Controlled Substances

41. DEA lists Subutex (buprenorphine) as a Schedule III controlled substance under 21 CFR 1308.13(e)(2)(i).

42. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(11).

43. DEA lists Adderall (amphetamine-dextroamphetamine mixture) as a Schedule II controlled substance under 21 CFR 1308.12(d)(1).

44. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15).

45. DEA lists Percocet (oxycodone-acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

46. DEA lists OxyContin (oxycodone extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

47. DEA lists Lortab (hydrocodone-acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vi).

48. DEA lists Suboxone (buprenorphine/naloxone) as a Schedule III controlled substance under 21 CFR 1308.13(e)(2)(i).

49. Respondent's Exhibit No. 2 is a true and correct copy of a March 9, 2018 letter from Dr. Daniels' counsel to Cecilia Mouton, M.D., the Director of Investigations for the Louisiana State Board of Medical Examiners, and which is countersigned by Cecilia Mouton, M.D., on behalf of the Louisiana State Board of Medical Examiners.

II. Findings of Fact

The Application

1. Dr. Daniels has never been denied a COR. Tr. 560.

2. Dr. Daniels entered into a consent order with the State Medical Board (''the Board''), following concerns that he was not properly monitoring patients or supervising staff. Tr. 560.

3. At the Board's recommendation, Dr. Daniels attended continuing medical education seminars on controlled substance prescribing, ethics, and boundaries. Tr. 562. After completing those seminars, the Board restored Dr. Daniels' medical license, but he was not allowed to practice in the areas of managing: Addiction; chronic pain; or obesity. Tr. 563.

4. Dr. Daniels re-applied for a COR once his license was reinstated. Tr. 564. In filling out the application, he did not realize that he ''would have to be more complete'' and that he was not ''aware that the high risk practice areas was where they were restricting [him].'' Tr. 565. His understanding was that the Board and the State Pharmacy Board had fully reinstated his controlled substance prescribing authority. *Id.*

5. The application for a COR does not inform an applicant to provide the detailed information that the DEA asserted was missing from Dr. Daniels' application. Tr. 70.

6. The information Dr. Daniels provided on his application placed the DEA on notice that it should not summarily approve Dr. Daniels' application, but rather that DEA should investigate it. Tr. 70–71.

7. Dr. Daniels did not intend to be evasive or misleading when he submitted his application for a Certificate of Registration. Tr. 565.

8. Dr. Daniels is struggling professionally without a COR because he currently works at a diabetes management clinic where Lyrica, a Schedule V controlled substance, is an important part of treatment. Tr. 568–69.

The Clinic

9. The Clinic was located in Minden, Louisiana, which is a rural area. Tr. 480.

10. LW had full control of the Clinic from April 2017 to September 2017. Tr. 479.

11. The Clinic provided services for low, to mid-level, income individuals, but it focused its service on those with low incomes. Tr. 421. The Clinic provided services to a wide array of patients including those suffering from drug addiction and those with mental health problems. Tr. 421–22. Most of the patients had some type of opioid addiction. Tr. 424. The Clinic stayed open late on Wednesdays to make it convenient for patients to seek treatment. Tr. 422–23.

12. Dr. Daniels would see patients at the Clinic one day a week, arriving around 5:00 p.m., and staying until 9:00 to 10:00 p.m. Tr. 424–25. Dr. Daniels was scheduled to see 25 patients a week, but sometimes he saw more. Tr. 425.

13. Dr. Daniels was the only physician who worked at the Clinic. Tr. 425. Most of the patients he saw had some kind of opioid addiction. Tr, 427.

14. The Clinic also employed a licensed practical nurse, a registered nurse, a licensed clinical social worker, a receptionist, and a phlebotomist. Tr. 425–26.

15. The Clinic struggled with establishing a reliable system for

ensuring the patients' charts were complete and accurate. Tr. 486–87.

16. The entire staff of the Clinic worked on medical records, but the Clinic brought in an RN to work on the records because the Clinic had seen a lot of deficiencies in the records. Tr. 427. These changes were made after LW began working full-time in the Clinic. Tr. 428. As of April 2017, the Clinic was attempting to organize and re-structure. Tr. 435.

17. Various employees at the Clinic inserted documents into the patients' charts as well as taking the patient's vital signs. Tr. 437–38. The office staff as a whole was responsible for making sure the documents got into the patient's medical record. Tr. 438.

18. The registered nurse was hired to audit the medical records, and she was also in the office with Dr. Daniels when he saw patients. Tr. 436.

19. When a patient came into the Clinic, the licensed clinical social worker would conduct a clinical/behavioral assessment to determine whether the patient met the criteria to be treated at the Clinic. Tr. 429, 443.

20. Most of the Clinic's patients had previously been seen at other clinics. Tr. 429.

21. All new patients were required to submit urine samples for drug screening. Tr. 432, 443. The results of the screening were passed on to the licensed clinical social worker. *Id.*

22. The phlebotomist did the urine drug screens and bloodwork. Tr. 441.

23. If a patient met the Clinic's requirements, the patient was scheduled to see Dr. Daniels. Tr. 432.

24. Dr. Daniels wanted to see the patients' vitals, as well as their drug screens. Tr. 438.

25. The work that the Clinic employees performed was at Dr. Daniels' request. Tr. 441. Information gathered in the assessments was provided to Dr. Daniels. Tr. 441–42.

26. Generally, PMPs were tracked for each patient and if anything was out of line Dr. Daniels was informed. Tr. 442, 446. Of the patients named in the Order to Show Cause, however, Dr. Daniels' PMP account was used to check the prescriptions filled by only two patients, CA and TC. Tr. 597–99; GE–30. The PMP was checked for both of these patients on September 13, 2017, which was the last day CA received a prescription from Dr. Daniels, and the only time he issued a prescription to TC. Tr. 598; GE–30, at 2; Stip. 22, 37.

27. The Clinic's default setting used for reviewing PMPs was one year, but Dr. Daniels was more concerned about what a patient had received within the last 30 days. Tr. 496–97.

28. Normally a staff member of the Clinic would run a PMP report and provide the results to Dr. Daniels. Tr. 448, 497, 514, 522. The results of the PMP report would not be documented. Tr. 522.

29. Ideally, a doctor gets a print-out of a patient's PMP report, but there is no requirement to print it out. Tr. 496.

30. The Clinic did not check a patient's PMP when the patient came in to pick up a prescription. Tr. 451.

Dr. Daniels' Clinic Practices

31. Dr. Daniels used Suboxone and Subutex to treat opioid addiction. Tr. 506.

32. Dr. Daniels did not put together the patient charts at the Clinic. Tr. 485–86.

33. Dr. Daniels acknowledged that there is information missing from the patients' charts. Tr. 487. Dr. Daniels testified that the patient charts in this case do not include sticky notes and other notes that would have been on the inside of the manila folder that held the charts. Tr. 488.

34. When Dr. Daniels saw a patient at the Clinic, some of the patient's medical history was available on forms that the patient completed before the visit. Tr. 492.

35. In general, Dr. Daniels would ask each patient: About his or medication; whether the medication was working; who initially prescribed it; and how long the patient had been taking it. Tr. 517.

36. Dr. Daniels testified that a doctor can perform an examination by observing the patient, and noting the patient's demeanor, activity, mood, and physical appearance. Tr. 493–94. Sometimes Dr. Daniels decided to do a more thorough physical examination. Tr. 512.

37. Dr. Daniels testified that in situations where there is limited staff and other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing waiting patients. Tr. 493. In that situation, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493.

38. With respect to urine drug screens, Dr. Daniels testified that he was provided the results of the screens. Tr. 510. He testified that in most cases he addressed abnormalities with the patient, but did not document that fact in the patient's chart. Tr. 498, 502, 510. He acknowledged it would be best practice to document efforts to address an abnormal urine drug screen. Tr. 501.

39. Dr. Daniels testified that the current standard is to not discharge a patient who is noncompliant with the treatment plan. Tr. 499–500.

40. In Dr. Daniels' view, it is better to keep a long-term patient on medication than to discharge the patient. Tr. 500. Discharging a patient could lead to a relapse, or to the patient taking dangerous street-drugs. *Id.*

41. If the new patient was already taking Suboxone, Dr. Daniels would discuss the Suboxone treatment regimen plan with the patient. Tr. 516. He would also ask the patient if he or she signed the treatment contract, and whether the patient understood it. *Id.* He would only address specific provisions of the treatment contract if he believed there might be a particular issue with the patient's ability to comply with the contract. *Id.*

42. Dr. Daniels reviewed the PMP to: See what medications a patient has been on; determine previous providers; and, determine when the patient received medications. Tr. 495.

43. When one of Dr. Daniels' substance-abuse patients tested positive for marijuana he did not address the issue with the patient because it was ''so ubiquitous in the population'' that Dr. Daniels treated. Tr. 515.

44. While working at the Clinic, Dr. Daniels was under quite a bit of personal stress and he ''had not be[en] able to really take full advantage of the opportunity to see these patients,'' which lead to potential risks given the areas in which he was practicing. Tr. 561.

General Facts Derived From Expert Testimony

45. Klonopin (clonazepam) is a benzodiazepine. Tr. 177.

46. To prescribe controlled substances in Louisiana for the treatment of chemical dependency, the standard of care requires the treating physician to: conduct an adequate physical examination; obtain past medical records; obtain PMP reports; conduct drug screening; and maintain medical records. Tr. 141–42, 492.

47. The standard of care requires that a patient's medical record be ''complete and accurate.'' Tr. 151.

48. A doctor need not document everything that occurred during a patient encounter, but the doctor should document the important, pertinent information that will give an objective viewer a picture of what happened during the encounter. Tr. 151–52.

49. Changes in medical treatment, and the reasons for those changes, must be documented. Tr. 150. The treatment plan is updated over time. *Id.*

50. When there is a consistent absence of pertinent information in a patient's medical records such as: PMP reports; a credible physical examination; past medical records; resolution of abnormal drug screens, the records reach a point where it is not possible to say that the treatment has been within the scope of acceptable medical practice or that the prescriptions are legitimate. Tr. 154; *see also* Tr. 384.

51. Because the application of medicine needs to be individualized, a sufficiently adequate physical examination would not necessarily be the same for every patient. Tr. 144–45, 492.

52. In conducting a physical examination for a patient who has chemical dependency the doctor should: Look for track marks; note how the patient's pupils look and whether the patient's mucous membranes are dry; look for goosebumps; look for signs of withdrawal such as whether the patient is sweaty and/or shaky, and/or whether the patient is obtunded. Tr. 143, 289, 492. Much of this information can be obtained through a discussion with the patient. Tr. 290, 492. If the chemical dependency originated following treatment of an injury to a part of the body, the physical examination should also include an examination of that body part. Tr. 388–89, 492.

53. As part of a physical examination for a patient who has a chemical dependency, a doctor should ask the patient questions such as: What are you using?; How long have you been using?; Why did you start using?; Are you around people who are using?; and, How do the drugs affect your life? Tr. 144, 492.

54. It is possible to treat a patient even without obtaining prior medical records; however, contained within the patient's medical records should be a documented good-faith effort to obtain the prior records, and an explanation of why treatment has begun without those prior records. Tr. 292.

55. Obtaining past medical records is important because such records contain an abundance of information that a treating doctor needs to know. Tr. 145. Obtaining past medical records is mandatory. Tr. 146. Even if the patient presents with medical documentation, the physician is not relieved of the obligation to attempt to obtain past medical records. Tr. 291.

56. A physician also needs to take a medical history and/or look for past medical records upon the patient's initial visit. Tr. 146. It is also important to update the patient's medical history. Tr. 147.

57. The failure to take a medical history, and/or to obtain past medical records, makes it difficult to argue that the doctor knows what he or she is doing at any particular instance of the patient's care. Tr. 147.

58. In Louisiana, the treatment plan must talk about what is being done for a patient, and why. Tr. 148, 503. The treatment plan allows another physician to pick up the patient's record and understand the treatment. Tr. 148–49. The treatment plan assists with continuity of care. Tr. 149.

59. For a patient with a chemical dependency, the treatment plan is dependent on what has been done in the past, and where the medical treatment is intended to take the patient. Tr. 149. *[For opioid addiction, Dr. Kennedy testified that in a treatment plan, he ''would expect there to be goals as far as where it is that we're heading with this. In other words, is this somebody that we expect that we're going to wean and discharge from this medication eventually? What are the likelihood of doing dosage adjustments if it works or if it doesn't work? What are we going to do if the patient has problems with some social issue . . . . All of the other kind of things that would go into any treatment record, where you're hoping that the patient is going to have an improved life.'' Tr. 301]

60. Informed consent is not obtained by having a signature on a form. Tr. 306. Informed consent is obtained by a conversation between the physician and the patient in which the doctor explains the dangers, the side effects of treatment, and that the treatment might not work. *Id.*

61. A prescription itself is not sufficient documentation of medical treatment. Tr. 234.

62. In Louisiana, a doctor who is treating a patient for addiction or chemical dependency is required to document the results of an abnormal urine drug screen, and the actions the physician took in response to it. Tr. 173, 225–26. If the test is abnormal, the results must be documented, as well as documenting the type of action that was taken in response to the abnormal test. Tr. 310–11, 318, 336, 378. Ignoring an abnormal urine drug screen, or saying nothing about it, is outside the course of acceptable medical practice in Louisiana. Tr. 378. *[Regarding the standard of care for chemical dependency, Dr. Kennedy stated, ''If we're talking about treating patients with chemical dependency, with the way that the regulations, the way the systems are designed, there's a reason we have to check PDMP reports and there's a reason that we have to get drug screens and there's a reason that we have to get past medical records and all of these other things, and it's not because we're counting on the patients being compliant, it's because of the likelihood of patients being noncompliant.'' Tr. 299.]

63. For a doctor to treat a diagnosis there must be supporting information. Tr. 323. A diagnosis alone is not sufficient to support a prescription for controlled substances. Tr. 371.

64. A clinical licensed social worker cannot make a diagnosis. Tr. 408. Thus, the diagnosis made by the social worker contained in Government Exhibit 14, pages 31–39, is not a valid diagnosis. *See also* Tr. 380 (no evidence that Dr. Daniels reviewed the diagnosis).

65. Prior to 2018, doctors in Louisiana were not required to check a patient's PMP before writing a prescription for a controlled substance, but it was considered the standard of care. Tr. 393.

66. The use of multiple pre-signed medical forms and/or identical copied handwritten treatment notes do not support a finding of legitimate medical care and are not credible in medical records. Tr. 190, 196; *cf.* GE–6 at 12, GE–14, at 14, and GE–18, at 26; and GE–6, at 26, and GE–10, at 57.

67. Signed forms do not provide sufficient advice concerning the dangers of combining alcohol with buprenorphine when the patient had a history of abusing drugs, and an abnormal urine drug screen. Tr. 400. A discussion needs to occur because the patient is starting a program of regular scheduled medications. Tr. 401. If, later, it is determined that the patient is still abusing drugs, it is clear the original discussion was not enough, and the doctor needs to revisit the issue with the patient. *Id.*

68. Signed forms are not sufficient to constitute a treatment plan. Tr. 374.

69. A Patient Treatment Contract does not establish a physician/patient relationship. Tr. 304.

70. None of the patients' medical records in the Administrative Record contained sufficient documentation to support a prescription for Klonopin. Tr. 399–400.

The Patients

Patient AK

71. On January 16, 2017, AK signed a Patient Treatment Contract with Dr. Daniels. Tr. 161, 303–04; GE–6, at 30. In paragraph one of that contract, AK agreed to keep, and be on time, for all of his scheduled appointments, and in paragraph two he agreed to the payment policy of Dr. Daniels' office. *Id.* In paragraph 13 of the contract, AK agreed

to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.* This contract was signed by Dr. Daniels on January 18, 2017. Tr. 162; GE–6, at 30.

72. Paragraph 10 of the Patient Treatment Contract that AK signed on January 16, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–6, at 30.

73. On January 16, 2017, AK signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 161, 308; GE–6, at 31. At the end of each paragraph is a space for the patient's initials, but there are no initials there. Tr. 308; GE–6, at 31.

74. On January 16, 2017, AK signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–6, at 41. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

75. The prescription that Dr. Daniels wrote for AK on January 16, 2017, for 15 tablets of 8 mg Subutex predates any written documentation of Dr. Daniels actually seeing AK. Tr. 160–61; GE–9, at 10; Stip. 17. Because this prescription was written prior to Dr. Daniels initially seeing AK, this prescription was issued outside of the course of medical practice in the state of Louisiana, and it was not issued for a legitimate medical purpose. Tr. 162–63, 401–02.

76. The initial Physician Intake Note for AK, dated January 18, 2017, indicates that AK had a history of multiple fractures, secondary to a fight and a motor vehicle accident. Tr. 162, 511; GE–6, at 25. The Note also indicates that AK had an opioid addiction issue, and that he previously took prescriptions for 8 mg Subutex, three times a day, and for 2 mg Klonopin, once a day. Tr. 165, 302, 511; GE–6, at 25; *see also* GE–6, at 43. The treatment history indicated that AK had previously been treated by another provider. Tr. 165, 511; GE–6, at 25. It does not appear that Dr. Daniels obtained treatment records from that provider. Tr. 165–66; GE–6. The Authorization to Release Healthcare Information in AK's file was not completed. Tr. 167; GE–6, at 47.

77. Dr. Daniels testified that he was able to conclude that AK had an opioid addiction based on AK's medical history, the physical examination that Dr. Daniels described, and AK's urine drug screen. Tr. 515.

78. Dr. Daniels testified that, even though the documentation is limited, AK also had an anxiety disorder and pain, and that the pain was related to AK's fractures. Tr. 517–18. Dr. Daniels did not see pain recorded in AK's chart.[3] Tr. 517.

79. Dr. Daniels testified that the Food and Drug Administration has advised that patients should not be denied Subutex simply because the patient is also taking a benzodiazepine. Tr. 518. In Dr. Daniels' opinion, he believed it was justified to prescribe Subutex and Klonopin to AK because he had pain and had taken opioids and Klonopin before. Tr. 518. Dr. Daniels acknowledged, however, that AK's chart does not document that AK had taken opioids before *[for a pain condition]. *Id.*

80. Dr. Daniels believed prescribing a higher dose of Subutex to AK was warranted because in addition to opioid addiction, AK also had pain and Subutex can be used to relieve pain. Tr. 517–19.

81. The initial Physician Intake Note for AK, dated January 18, 2017, contains a treatment plan that reads, ''Monthly and random drug screens. Counseling with LW Medical Multi Care Clinic 801 Shreveport Rd. Minden, La. One group monthly 6:00–7:30 p.m. Meet with LPC 20 minutes prior to doctor visit.''[4] Tr. 169, 302–03; GE–6, at 25. The treatment plan also includes the medications prescribed, but it does not include a rationale as to why the medications were prescribed. *Id.* Dr. Daniels testified that AK's treatment plan developed on January 18, 2017, was to conduct monthly and random urine drug screens, provide AK counseling, prescribe Subutex 8 mg TID and Klonopin 2 mg, and have AK return to the Clinic in one month. Tr. 515, 518; GE–6, at 25.

82. Contained in AK's medical file is a Physician Assessment form dated January 18, 2017. Tr. 164; GE–6, at 45–46. Although this assessment is contained in AK's patient file, his name is not on the form, and the form is not signed by a doctor. *Id.* The form also does not document that Dr. Daniels performed a physical examination of AK. *Id.*

83. The only portion of a physical examination documented in AK's medical record for his first visit on January 18, 2017, was that AK appeared neat and clean, and that he had a depressed affect. Tr. 512; GE–6, at 25.

84. Dr. Daniels did not know whether the Klonopin AK reported he had been taking had been prescribed to him, or if he was taking it ''off the street.'' Tr. 511–12.

85. AK's PMP was not checked at the Clinic. Tr. 168, 597–99; GE–30.

86. On January 18, 2017, AK's urine drug screen was positive for benzodiazepines, methamphetamine, THC, and Subutex. Tr. 169–70, 514; GE–6, at 29. In his ''MD Notes'' for that day, Dr. Daniels wrote that AK's drug screen was positive for Subutex and negative for opioids.[5] *Id.* at 26. This was an abnormal drug screen because it was positive for methamphetamine and THC (''marijuana''). Tr. 170–72. In that AK had indicated that he had not used crystal methamphetamine, the results of the urine drug screen should make a physician very suspicious that AK was lying. Tr. 171–72; GE–6, at 39. There is no indication in AK's medical record that Dr. Daniels took any action in response to AK's abnormal drug screen. Tr. 174.

87. On February 23, 2017, and March 22, 2017, AK's urine drug screens were positive for benzodiazepines, THC and Subutex. GE–6, at 27–28. In his treatment notes for those days, Dr. Daniels wrote that AK's drug screen was positive for Subutex and negative for opioids. *Id.* at 26.

88. On a Pharmacy Prior Authorization Form, dated April 3, 2017, Dr. Daniels notes that AK had reported adverse reactions to Suboxone. GE–6, at 24.

89. On June 20, 2017, AK's urine drug screen was positive for benzodiazepines and Subutex. Tr. 309; GE–6, at 6.

90. On September 25, 2017, Dr. Daniels discharged patient AK for failing to keep agreed appointments every 28 days, and/or for not paying in full for his office visits in a timely manner. GE–6, at 6.

91. A review of Dr. Daniels' medical records of AK reveals no documentation that Dr. Daniels ever conducted a physical examination of AK, and those records provide no justification for Dr.

[3] Assuming that AK was in pain, a physical examination should have included an examination of AK's body parts that had been fractured. Tr. 388–89, 492. No such examination, however, is documented in AK's medical record. GE–6.

[4] This treatment plan will be referred to as the ''boilerplate treatment plan'' throughout the remainder of this Recommended Decision.

[5] This note makes little sense, however, because Subutex is an opioid. Tr. 177.

Daniels' prescription of Klonopin to AK. Tr. 396–97; GE–6, at 1–49.

92. The prescriptions that Dr. Daniels wrote for AK on January 18, 2017, for Klonopin and Subutex were not issued for a legitimate medical purpose because: action taken on the abnormal urine drug screen, if any, was not documented; the PMP was not checked; there were no past medical records; and there was no documentation of a significant physical examination. Tr. 177; GE–30.

93. A Physician Intake Note dated June 20, 2017, is contained in AK's patient file. Tr. 180; GE–6, at 12. This is the only other intake note contained in AK's patient file. Tr. 182; GE–6, at 12. Prior to this date, Dr. Daniels issued prescriptions to AK on six occasions, and after this date on two more occasions. Tr. 181; Stip. 17.

94. The Physician Intake Note of June 20, 2017, does not document: A physical examination; AK's response to prior treatment; a rationale for the prescriptions; or the response to abnormal drug screens. Tr. 182–84; GE–6, at 11, 12, 27–28.

95. Although the Physician Intake Note of June 20, 2017, is signed, it is not dated, and the signature is identical to that contained on an intake note of patient MN, dated June 28, 2017, and an intake note of patient CM, dated August 9, 2017, and the signatures on both of those intake forms are not dated. Tr. 186–89; GE–6 at 12; GE–14, at 14; GE–18, at 26.

96. Dr. Daniels also used identical copied handwritten ''boilerplate'' notes concerning patients' monthly counseling appointments. Tr. 193–95; *cf.* GE–6, at 26, and GE–10, at 57. Such notes are not credible in medical records. Tr. 196.

97. The prescriptions that Dr. Daniels issued to AK between January 16, 2017 and August 25, 2017, identified in Stipulation 17, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose because Dr. Daniels did not: conduct a sufficient medical history of AK; conduct a physical examination of AK; formulate a treatment plan with a rationale that supported the prescriptions; document resolution of abnormal urine drug screens; obtain prior medical records or conduct a review of AK's PMP; or maintain accurate medical records. Tr. 191–92.

Patient CA

98. On June 9, 2016, CA signed a Patient Treatment Contract with Dr. Daniels. GE–10, at 56. In paragraph 13 of the contract, CA agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

99. Paragraph 10 of the Patient Treatment Contract that CA signed on June 9, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–10, at 55.

100. On June 9, 2016, CA signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–10, at 76. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

101. On June 9, 2016, CA's urine drug screen tested positive for only buprenorphine. GE–10, at 93–95. This was abnormal based on the medications that CA reported he was taking. Tr. 217–18.

102. The prescriptions that Dr. Daniels wrote for CA on June 9, 2016, for Klonopin and Subutex predate any written documentation of Dr. Daniels actually seeing CA. Tr. 204; Stip. 22. Because these prescriptions were written prior to Dr. Daniels initially seeing CA, these prescriptions were issued outside of the course of medical practice in the State of Louisiana, and they were not issued for legitimate medical purposes. Tr. 204, 401–02.

103. On June 22, 2016, an assessment was completed for CA. Tr. 196; GE–10, at 51–53. The assessment indicates that CA had an opioid (oxycodone) addiction, and that another doctor had given CA a prescription for Subutex. Tr. 197, 521; GE–10, at 51. The assessment indicates that CA became addicted to oxycodone while being treated for abdominal pain, a hand fracture, and arthritis. Tr. 196, 521; GE–10, at 51. The assessment also indicates that CA had a history of ADHD for which he was taking Adderall, and he was taking Klonopin for anxiety. Tr. 196, 521–22, 524; GE–10, at 51. CA also had a history of TMJ. Tr. 521; GE–10, at 51. The assessment does not document a physical examination that would support prescriptions for controlled substances. Tr. 196–97; GE–10, at 53. The assessment also does not document a rationale for the controlled substances that Dr. Daniels prescribed. Tr. 198–99; GE–10, at 51–53. Because CA's chart does not support a diagnosis of ADHD, there is nothing in CA's chart that justified a prescription for Adderall. Tr. 322, 377.

104. The comments' section of the June 22, 2016 assessment is a handwritten partial treatment plan.[6] Tr. 406–07; GE–10, at 51–53. What is missing is a notation of follow-up, anticipated reaction to things that may go wrong or if the patient needs more medication. Tr. 407; *see also* Tr. 503. In addition, Louisiana law details specific information that must be contained in a treatment plan. *See* La. Admin. Code tit. 46, Pt. XLV, § 6921(A)(3).

105. Although the June 22, 2016 assessment indicated that another doctor had treated CA, there are no prior medical records in CA's medical file, nor was there a request for those records in the file. Tr. 197–98.

106. Dr. Daniels viewed CA's history, his answers, and his demeanor as being consistent with ADHD. Tr. 523. Based on CA's history and Dr. Daniels' examination of CA, he diagnosed CA with an opioid addiction, anxiety disorder, and ADHD. Tr. 522.

When asked about the physical examination he conducted of CA, Dr. Daniels testified that he looked at CA's person, place, and orientation; noted that CA's affect was ''blunted and flat''; and observed that he was ''depressed and anxious.'' Tr. 521. This information was obtained from CA's mental status examination, however, not from a physical examination. Tr. 582; GE–10, at 52.

107. Dr. Daniels' treatment plan for CA included monthly urine drug screens, counseling, Subutex at his current dosage, Klonopin 1 mg TID, and Adderall 30 mg. Tr. 523; GE–10, at 53. Dr. Daniels acknowledged, however, that the justification for these prescriptions is not contained in CA's medical records. *Id.* He further testified these prescriptions were written to treat CA's medical condition he had diagnosed: Opioid addiction, anxiety, chronic abdominal pain, TMJ, and ADHD. Tr. 524; GE–6, at 53.

108. CA's medical file contains a Physician Intake Note dated July 26, 2017. Tr. 199; GE–10, at 34. The intake note contains the boilerplate treatment plan. GE–10, at 34. The intake note does not document: A physical examination; CA's responses to past treatment; or a

[6] This partial treatment plan is the same plan that is preprinted on Physician Intake Forms–the boilerplate treatment plan. *See, e.g.,* GE–6, at 25; GE–10, at 23.

rationale for the prescriptions that Dr. Daniels issued to CA. Tr. 199; GE–10, at 34. In addition, the length of time between this documented encounter with CA and the previous documented encounter (more than a year), during which CA continued to get the same three prescriptions every month, is not consistent with the standard of care. Tr. 205–06; Stip. 22.

109. CA's medical file contains a Physician Intake Note dated September 13, 2017. Tr. 200; GE–10, at 23. The intake note contains the boilerplate treatment plan. GE–10, at 23. The intake note does not document: A physical examination,*E or a rationale for the prescriptions that Dr. Daniels issued to CA. Tr. 201; GE–10, at 23. It does have a comment that CA reported zero problems with current meds. *Id.* That comment, however, does not provide sufficient follow-up or history of his prior treatment with Dr. Daniels. Tr. 201–202.

110. On June 9, 2016, CA's urine drug screen was positive for only buprenorphine. Tr. 217; GE–10, at 93–94. This was an abnormal urine drug screen because it was inconsistent with the medications he told the doctor he had been previously prescribed. Tr. 217–18.

111. On September 29, 2016, CA's urine drug screen was positive for only Subutex. Tr. 212; GE–10, at 87. This was an abnormal urine drug screen because it was inconsistent with the medications he was prescribed, whereas earlier tests were positive for those same medications. Tr. 212–13.

112. On October 18, 2016, November 16, 2016, December 7, 2016, and January 4, 2017, CA's urine drug screens were positive for benzodiazepines, Subutex, and methamphetamine. Tr. 208–212; GE–10, at 72–74, 97. *[Although CA was taking amphetamines, Dr. Kennedy testified that this would not make the urine drug test positive for methamphetamines. Tr. 209. Additionally, he testified that ''this is an inconsistent result and we have to send it out to disprove that notion.'' Tr. 210.]

113. A treatment note of January 11, 2017, indicates that CA was receiving a prescription of Adderall for ADHD, and a prescription of Klonopin for anxiety. GE–10, at 64. Someone other than Dr. Daniels signed this note. *Id.*

114. On May 2, 2017, CA's urine drug screen was positive for Subutex, but negative for Adderall and Klonopin. Tr. 216; GE–10, at 18. CA had received prescriptions for all of these medications on April 5, 2017. GE–10, at 6. The results of this urine drug screen were abnormal. Tr. 216. On May 3, 2017, an unsigned, handwritten treatment note for CA indicates that his drug screen was positive, but does not indicate what it was positive for. GE–10, at 57. The treatment note also incorrectly indicates that the drug screen was negative for opioids. *Id.*

115. On July 26, 2017, CA's urine drug screen was positive for buprenorphine, but negative for amphetamines and benzodiazepines. Tr. 216–17; GE–10, at 28, 30. CA had received prescriptions for all types of these medications on June 29, 2017. GE–10, at 3. The results of this urine drug screen were abnormal. Tr. 216–17.

116. On August 23, 2017, CA's urine drug screen was positive for buprenorphine, but it was negative for amphetamines and benzodiazepines. Tr. 214; GE–10, at 11–12. CA had received prescriptions for all types of these medications on July 26, 2017. GE–10, at 2. The results of this test were not normal. Tr. 214–15.

117. A review of Dr. Daniels' medical records of CA reveals no documentation that Dr. Daniels ever conducted a physical examination of CA, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to him, other than CA's claim that he had a history of ADHD and anxiety, which was unsupported by any records. GE–10, at 1–97, 51; Tr. 322. *[The record does contain vital signs for CA, which Dr. Kennedy described as ''part'' of the physical examination. Tr. 316; GE–10, at 51.]

118. There are no discussions of any abnormal urine drug screens in CA's medial file. Tr. 214–15, 220. The failure to respond or document that response to abnormal urine drug screens makes it very difficult to conclude that the physician is engaged in ''legitimate medical management in a patient who's receiving scheduled medications for any reason.'' Tr. 219.

119. Between June 2016 and September 2017, Dr. Daniels was issuing CA prescriptions for Subutex, Klonopin, and Adderall, an opioid, a benzodiazepine, and an amphetamine. Tr. 203; Stip. 22.

120. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels wrote for CA, identified in Stipulation 22, were issued outside the course of medical practice and were not issued for a legitimate medical purpose. Tr. 206–07, 220.

Patient MN

121. On May 2, 2017, MN presented to the Clinic needing help with withdrawal symptoms due to a history of opioid dependence. GE–14, at 19. She stated that she was addicted to Subutex, which she claimed to have been taking for two years. *Id.* MN also reported that she had taken Klonopin in the past for depression and anxiety and was requesting a refill. *Id.*

122. On May 2, 2017, MN signed a Patient Treatment Contract with Dr. Daniels. Tr. 327–28; GE–14, at 43. In paragraph 13 of the contract, MN agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. GE–14, at 43. Although MN signed this contract, it was not signed by Dr. Daniels or anyone else. *Id.*

123. Paragraph 10 of the Patient Treatment Contract that MN signed on May 2, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–14, at 43.

124. MN's medical file contains an assessment completed by a licensed clinical social worker on May 2, 2017. GE–14, at 19–28, 31–39.

125. On May 3, 2017, MN's urine drug screen was positive for ecstasy, THC, and Subutex. Tr. 222, 327; GE–14, at 41. The presence of ecstasy and marijuana indicates that MN was abusing drugs. Tr. 222.

126. On May 3, 2017, Dr. Daniels entered a ''very limited note'' [7] in MN's medical record that Suboxone gave MN headaches. Tr. 527, 583–84; GE–14, at 29. The note does not include a subjective complaint, any objective findings, any assessment of MN's conditions, or a medical treatment plan. GE–14, at 29. That same day, Dr. Daniels wrote prescriptions to MN for 8 mg Subutex TID, and 2 mg Klonopin BID. Stip. 24; GE–14, at 5. Then on May 31, 2017, Dr. Daniels again wrote a prescription to MN for 8 mg Subutex TID, but he modified the prescription for 2 mg Klonopin to TID. GE–14, at 4; Stip. 24. Because these prescriptions were written prior to Dr. Daniels documenting sufficient information into MN's medical record, these prescriptions were issued outside of the usual course of professional practice in

*E Although vital signs were taken for CA, Dr. Kennedy testified that they are not adequate to support the provision of controlled substances. Tr. 376–77; GE–10, at 51.

[7] Dr. Daniels explained that it was a limited note because ''sometimes with interruptions in the clinic, you get limited information to put in the chart.'' Tr. 527.

the State of Louisiana, and not for a legitimate medical purpose. Tr. 163, 401–02.

127. MN's medical file contains a Physician Intake Note dated June 28, 2017. Tr. 221; GE–14, at 14. The intake note contains the boilerplate treatment plan. GE–14, at 14. The intake note does not document: A physical examination; MN's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to MN. GE–14, at 14. The MD note of May 3, 2017, and this intake note are the only notes in MN's file that document an encounter between Dr. Daniels and MN. Tr. 221; GE–14.

128. When asked whether he had a physical encounter with MN, Dr. Daniels testified that he did not ''see a document of physical encounter.'' Tr. 527. Although there is no documentation of a physical encounter, he testified that he did see her and he did conduct a physical examination.[8] Tr. 527–28. Dr. Daniels also testified, however, that he diagnosed MN as having an opioid addiction based on her history. Tr. 528–29.

129. There is nothing in Dr. Daniels' medical record concerning MN that documents that Dr. Daniels diagnosed MN's medical condition. Tr. 582.

130. A treatment plan for MN would have included a discussion of how Dr. Daniels was going to wean MN off of Subutex, the substance she claimed she was addicted to. Tr. 408–09. As of May 3, 2017, Dr. Daniels' treatment plan for MN only included Subutex 8 mg TID and Klonopin. Tr. 529; GE–14, at 29.

131. On June 28, 2017, MN's urine drug screen was positive for only Subutex. Tr. 223; GE–14, at 10. This drug screen was abnormal because it should have been positive for a benzodiazepine, having received a prescription for Klonopin on May 31, 2017. Tr. 223–24; Stip. 24.

132. On July 28, 2017, MN's urine drug screen was positive for ecstasy, Subutex, and methamphetamines, and negative for benzodiazepines. Tr. 224; GE–14, at 8. This is a ''wildly abnormal'' drug screen. Tr. 224–25. *[Dr. Kennedy testified that ''to have a drug screen like this, and to make absolutely no comment in the medical record, did not make any comment with addressing the patient about it, or what you plan to do about this, is in my view, inexcusable.'' Tr. 226. Further, he stated that ''to continue providing this patient with scheduled medications without comment, in my view, is not medically legitimate.'' *Id.*]

133. On August 29, 201[7]*, MN received prescriptions for Subutex and Klonopin, written by Dr. Daniels, but there is no documentation in MN's medical file of an encounter with Dr. Daniels that day. Tr. 228; GE–14, at 1; Stip. 24. *[Dr. Kennedy testified that ''every single prescription for a scheduled medication, in my opinion, must be accounted for.'' Tr. 233. He clarified that when writing new prescription, there must be something documenting that prescription in the medical record. *Id.*]

134. There are no discussions of any abnormal urine drug screen in MN's medical file. Tr. 226–27; GE–14. The failure to respond or document a response to abnormal urine drug screens makes it very difficult to conclude that the physician is engaged in ''legitimate medical management in a patient who's receiving scheduled medications for any reason.'' Tr. 219.

135. A review of Dr. Daniels' medical records of MN reveals no documentation that Dr. Daniels ever conducted a physical examination of MN, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to her, other than that she had been prescribed it in the past, and she had requested a refill. GE–14, at 1–47, 19.

136. In Dr. Kennedy's opinion, all the prescriptions identified in Stipulation 24, issued to MN, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 231. Dr. Kennedy's opinion was based upon: The absence of drug screening documentation; the absence of medical records; no documentation that MN's PMP was reviewed; no evidence of a credible physical examination; and the absence of any documented discussions with MN that would establish a valid doctor-patient relationship. Tr. 231–32.

Patient JD

137. On August 3, 2016, JD signed a Patient Treatment Contract with Dr. Daniels. GE–15, at 30. In paragraph 13 of the contract, JD agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

138. Paragraph 10 of the Patient Treatment Contract that JD signed on August 3, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–15, at 30.

139. On August 3, 2016, JD signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–15, at 32. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

140. On August 3, 2016, JD signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 332; GE–15, at 29. At the end of each paragraph is a space for the patient's initials, but there are no initials there. *Id.* Dr. Daniels did not sign the Agreement; a counselor signed it instead. GE–15, at 29.

141. On August 3, 2016, JD presented to Dr. Daniels with a history of back pain, and indicated that he had a prior prescription for Lortab. Tr. 235, 531; GE–15, at 22. JD also reported that he had taken Percocet and methadone off the streets, and that he had used Subutex for two years. *Id.* Dr. Daniels signed and dated this handwritten assessment on August 10, 2016. Tr. 235; GE–15, at 22–23. This is the only documented encounter between JD and Dr. Daniels. Tr. 235; GE–15.

142. A review of Dr. Daniels' medical records of JD reveals no documentation: That he obtained JD's prior medical records; that Dr. Daniels ever conducted a physical examination of JD; [*F] or that he developed an appropriate treatment plan for JD. Tr. 235–36; GE–15, at 1–35.

143. Dr. Daniels' assessment of JD does not document a treatment plan (other than the boilerplate treatment plan) and it does not provide a rationale for the controlled substances prescribed to JD. Tr. 236, 330, 532; GE–15, at 22–23.

144. On August 3, 2016, JD's urine drug screen was positive for only Subutex. Tr. 532; GE–15, at 26. A counselor signed this urine drug screen. Tr. 330; GE–15, at 26. A physician should have signed the urine drug screen. Tr. 331, 380–81.

145. Over the 13 months that Dr. Daniels treated JD, there is only one encounter note. Tr. 235, 237; GE–15. Dr. Kennedy testified that one encounter followed by a year's worth of the maximum dosage of buprenorphine, is clearly outside the course of acceptable

[8] Earlier, however, Dr. Daniels testified that, ''After looking at the notes, I just remember the encounter. I don't remember from just my memory though.'' Tr. 525.

[*F] The JD file does include vital signs, which Dr. Kennedy testified is part of the physical examination, but not adequate by itself to meet the standard of care and usual course of professional practice. Tr. 329; GE–15, at 22.

medical practice anywhere in the United States. Tr. 238–39.

146. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels issued to JD, identified in Stipulation 27, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 238. Dr. Kennedy's opinion was based upon the absence of follow-up care after the initial encounter. *Id.*

Patient SB

147. On January 17, 2017, SB signed a Patient Treatment Contract with Dr. Daniels. Tr. 340; GE–17, at 17. In paragraph 13 of the contract, SB agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. GE–17, at 17.

148. Paragraph 10 of the Patient Treatment Contract that SB signed on January 17, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–17, at 17.

149. On January 17, 2017, SB signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 337–38; GE–17, at 18. At the end of each paragraph is a space for the patient's initials, but only half of the spaces were initialed. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. GE–17, at 18.

150. On January 17, 2017,[*G] SB signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–17, at 31. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

151. On a January 18, 2017 Physician Intake Note, Dr. Daniels noted that SB had a history of recreational drug abuse, heroin abuse, and severe panic attacks. Tr. 239, 333, 533–34; GE–17, at 15. The Note states that SB had previously been treated with Suboxone, but developed hives as a side effect. Tr. 534; GE–17, at 15. This Note is the only documentation of Dr. Daniels' assessment of SB, other than an undated, unsigned ''Physician Assessment'' in SB's medical file that does not bear the name of a patient. Tr. 239–40; GE–17, at 27–28. Neither the Note nor the Assessment documents a physical examination of SB. Tr. 240, 333; GE–17, at 15, 27–28. In addition, neither the Note nor the Assessment documents a rationale for the medications Dr. Daniels prescribed to SB. Tr. 243; GE–17, at 15, 27–28.

152. Although the Intake Note indicates that SB was treated with Suboxone in Dallas, the medical records request form was not completed and there are no prior medical records in SB's medical file. Tr. 241; GE–17, at 29.

153. On January 18, 2017, SB's urine drug screen tested positive for methamphetamine, THC and Subutex. Tr. 336, 534; GE–17, at 16. Dr. Daniels did not document any discussions with SB about this abnormal urine drug screen. Tr. 243. In light of this abnormal drug screen, Dr. Daniels should have provided a rationale for his decision to treat SB. Tr. 337. On July 14, 2017, SB's urine drug screen tested positive for Klonopin, Subutex, fluoxetine, norfluoxetine, and cTHC. GE–17, at 8, 10–11. The lab report indicates that a source for fluoxetine includes Prozac. *Id.* at 8. On her patient intake form, SB indicated that she had previously taken Prozac. *Id.* at 24–25.

154. While Dr. Daniels did not make a note of it in the file, he testified that the general recommendation for a drug screening that was positive for marijuana and methamphetamine would have been more frequent counseling.[9] Tr. 534–35.

155. A review of Dr. Daniels' medical records of SB reveals no documentation that Dr. Daniels ever conducted a physical examination of SB, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to her, other than that she had a history of severe panic attacks. GE–17, at 1–32, 15.

156. In Dr. Kennedy's opinion, all the prescriptions issued to SB, identified in Stipulation 29, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 244. Dr. Kennedy's opinion was based upon SB being a young woman of reproductive age, who had a history of heroin abuse, issues with alcohol, an abnormal drug screen, and an absence of documentation to explain treatment. *Id.* *[Dr. Kennedy testified that, ''there was, in essence, in [his] view, no medical care here, simply the provision of scheduled prescriptions.'' *Id.*]

Patient CM

157. On May 2, 2016, CM's urine drug screen tested positive for buprenorphine and cTHC. GE–18, at 34, 36.

158. On May 3, 2016, CM signed a Patient Treatment Contract with Dr. Daniels. GE–18, at 45. In paragraph 13 of the contract, CM agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

159. Paragraph 10 of the Patient Treatment Contract that CM signed on May 3, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–18, at 45.

160. On May 3, 2016, CM signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–18, at 41. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. *Id.*

161. On May 3, 2016, CM signed a Patient Agreement to Participate in Suboxone Treatment. GE–18, at 42. At the end of each paragraph is a space for the patient's initials, but there are no initials there. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. *Id.*

162. A May 4, 2016 nursing assessment indicates that CM had been abusing oxycodone and Roxicodone, and he had been taking Subutex 8 mg for three years. Tr. 341, 537; GE–18, at 49. The individual who completed this

[*G] It appears that the patient mistakenly marked this with the year 2016 and so I have edited the RD to reflect 2017. In GE–17, at 17, the patient's signature year of ''16'' is crossed out and hand-edited to state ''17'' and the physician's signature lists 2017. *See* GE–17, at 17 and 18. The record demonstrates that SB first came to the clinic in January 2017. It is logical, based on these other records, that the patient was simply confused about the new year in signing this form.

[9] The medical records in this case, however, do not document an instance where Dr. Daniels increased the frequency of counseling based upon an abnormal urine drug screen. Further, although SB had an abnormal urine drug screen on January 18, 2017, GE–17, at 13, *see supra* FF 154, SB's treatment plan with respect to counseling is identical to those of other patients who had not initially tested positive for marijuana or methamphetamines. GE–10, at 34; GE–17, at 15; GE–23, at 8. In fact, Dr. Daniels' medical records concerning SB do not document that she ever returned to the Clinic for follow-up treatment or counseling, though she did receive monthly prescriptions of Subutex and Klonopin for another six months after her initial appointment. GE–17; Stip. 29.

nursing assessment did not sign or date it.[10] Tr. 251; GE–18, at 50. This nursing assessment is not sufficient to support issuing prescriptions for controlled substances to CM. Tr. 250–51. The nursing assessment indicates that a different provider had previously treated CM. Tr. 253, 537–38; GE–18, at 49. The assessment does not contain any diagnoses or a treatment plan. GE–18, at 50.

163. The prescriptions that Dr. Daniels wrote for CM on May 4, 2016, through May 17, 2017, for Subutex and Klonopin predate any written documentation of Dr. Daniels actually seeing CM. GE–18; Stip. 31. These prescriptions were issued outside the usual course of medical practice in the state of Louisiana. Tr. 401–02.

164. On December 14, 2016, Dr. Daniels began prescribing Klonopin to CM. Tr. 254; Stip. 31. Nothing in Dr. Daniels' medical records concerning CM supports prescribing Klonopin to him. Tr. 254, 542; GE–18. In fact, there are no treatment notes concerning CM dated December 14, 2016. GE–18.

165. CM's medical file contains a Physician Intake Note, dated June 14, 2017. Tr. 251, 343; GE–18, at 26. Although the intake note is signed by Dr. Daniels, the signature appears to be photocopied, and it is not dated. Tr. 251. The note contains the boilerplate treatment plan. GE–18, at 26. The note does not document: A physical examination; CM's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to CM. Tr. 252–54; GE–18, at 26.

166. CM's medical file contains a Physician Intake Note, dated August 9, 2017. Tr. 251–52; GE–18, at 20. This note reports that the patient was doing well on medications. GE–18, at 20. Although Dr. Daniels signed the note, the signature appears to be a photocopy, and it is not dated. Tr. 252, 340. The note contains the boilerplate treatment plan. GE–18, at 20. The intake note does not document: A physical examination; CM's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to CM. Tr. 252–54; GE–18, at 20.

167. There is no completed medical records' release form contained in CM's medical file. Tr. 253–54; GE–18. There are no prior medical records contained in CM's medical file. Tr. 253–54; GE–18.

168. On May 17, 2017, July 12, 2017, and September 5, 2017, CM's urine drug screens tested positive for THC (tetrahydrocannabinol) and Subutex. Tr. 538–39; GE–18, at 19, 23, 32. Although counseling would have been Dr. Daniels' normal response, he did not indicate that it was done, nor is it documented. Tr. 539; GE–18.

169. On September 9, 2017, CM's urine drug screen tested positive for benzodiazepines, THC, and Subutex. GE–18, at 21.

170. Dr. Daniels testified that CM was prescribed 8 mg Subutex TID, for his substance abuse issues, and he was eventually prescribed Klonopin for his anxiety. Tr. 540.

171. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels issued to CM, identified in Stipulation 31, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 255. Dr. Kennedy's opinion was based upon: The lack of PMP reports in CM's file; the lack of prior medical records, the failure to document responses to abnormal urine drug screen, as well as ''other modalities'' he previously testified about. Tr. 255–56.

Undercover Patient TC

172. A DEA Task Force Officer (''TFO'') conducted two undercover visits with Dr. Daniels. Tr. 76–77, 80. The TFO presented himself to Dr. Daniels as patient TC. *Id.*

173. TC first visited Dr. Daniels' practice on September 12, 2017. Tr. 77. TC made an audio and video recording of the visit. *Id.*; GE–24, 27.

174. When TC went to the Clinic on September 12, 2017, a nurse instructed him to provide a urine sample. Tr. 77. After TC provided a urine sample, the nurse checked his vitals, and TC's blood pressure was found to be about 190/120. Tr. 78. That was the only physical examination conducted of TC. *Id.*

175. TC's urine drug screen was negative. Tr. 89; GE–23, at 9. TC reported he had not used any controlled substances in the prior two-three weeks. Tr. 89–90; GE–23, at 9; GE–25, at 1–2.

176. After TC's vitals were taken, he met with a counselor for 10 to 15 minutes. Tr. 78–79. The counselor asked him questions about his family and alcohol/substance use. *Id.* TC did not record this portion of the visit to the Clinic. *Id.* Following the interview with the counselor, the counselor indicated there was no problem. Tr. 79–80.

177. TC told the counselor that he had an addiction to Lortab and he wanted to get off it right away. Tr. 87; GE–23, at 2. TC also informed the counselor that about four years ago he began buying Lortabs off the street. Tr. 87–88; GE–23, at 2.

178. On September 12, 2017, TC signed a Patient Treatment Contract with Dr. Daniels. Tr. 90–91; GE–23, at 16. In paragraph 13 of the contract, TC agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. Tr. 91, 104; GE–23, at 16. No one at the Clinic discussed the content of the contract with TC, he was just told to sign it. Tr. 102–03.

179. Paragraph 10 of the Patient Treatment Contract that TC signed on September 12, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' Tr. 90; GE–23, at 16.

180. On September 12, 2017, TC signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. Tr. 91–92; GE–23, at 17. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.* No one from the Clinic signed this form. *Id.* No one at the Clinic discussed the content of the form with TC, they just told him to sign it. Tr. 102–03.

181. On September 12, 2017, TC signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 348–49; GE–23, at 19. At the end of each paragraph is a space for the patient's initials, and TC initialed each space. GE–23, at 19. Although the form was witnessed, Dr. Daniels did not sign as the witness. *Id.*

182. On September 12, 2017, Dr. Daniels' Clinic completed a Behavioral Health Assessment of TC. GE–23, at 2. The assessment was conducted by Akee Jackson. *Id.* at 6. TC's chief complaint was that he was addicted to Lortab and he wanted to get off it right away. *Id.* at 2. TC reported that he had last used Lortab two weeks prior to the assessment. *Id.*

183. On September 12, 2017, TC's urine drug screen tested negative for all drugs. Tr. 257, 556; GE–23, at 9. Based on when TC reported that he had last used an opioid, he would have been an opioid naïve patient on September 12, 2017. Tr. 258.

184. TC returned to the Clinic on September 13, 2017. Tr. 80–81. When

[10] Dr. Daniels testified, however, that this was the encounter note for the initial visit. Tr. 537. There is no Physician Intake Note concerning CM in the medical file contemporaneous with Dr. Daniels' initiation of care for CM.

TC entered Dr. Daniels' office, he asked to step out for a second. Tr. 81. He momentarily stepped out of Dr. Daniels' office to turn on his recording devices. *Id.*

185. On his second visit to the Clinic, no one took TC's vitals or conducted a physical examination of him before he saw Dr. Daniels. Tr. 81.

186. On September 13, 2017, the Clinic checked the PMP concerning TC. Tr. 598; GE–30, at 2. The medical records that Dr. Daniels maintained on TC did not contain a PMP report concerning TC. Tr. 261; GE–23. Dr. Daniels did not mention the PMP report when he met with TC on that date. GE–25.

187. On September 13, 2017, Dr. Daniels completed a Physician Intake Note concerning TC. Tr. 256; GE–23, at 8. Dr. Daniels noted that TC had a history of recreational drug abuse, and that he had positive signs of withdrawal, to include: Migraine headaches, elevated blood pressure, and sweating. GE–23, at 8; *see also* GE–25, at 4. The Intake Note does not reflect a diagnosis for TC, or document that Dr. Daniels conducted a physical examination of TC. Tr. 256–57; GE–23, at 8. In addition, a review of the video recording of this visit by TC with Dr. Daniels shows that TC met with Dr. Daniels for 8 minutes, 36 seconds, and that no physical examination [*H] was conducted, TC and Dr. Daniels just talked. Tr. 84; GE–27.

188. During the September 13, 2017 office visit, TC informed Dr. Daniels that he had provided a drug screen and that he drinks alcohol. Tr. 82. TC also informed Dr. Daniels that he had taken Suboxone or Subutex before and that he had taken it ''from people.'' Tr. 82–83; GE–25, at 2. Dr. Daniels responded by saying ''okay.'' *Id.* TC told Dr. Daniels that he had been taking 8 mg Suboxone off the street, and that he had not had any adverse reaction. Tr. 83; GE–25, at 2.

189. During the September 13, 2017 office visit, TC informed Dr. Daniels that he had been taking Lortabs, but he had not taken any for several weeks. Tr. 82, 552; GE–23, at 8; GE–25, at 1. TC also informed Dr. Daniels that he had taken Adderall before. Tr. 84; GE–25, at 3.

190. During the September 13, 2017 office visit, Dr. Daniels informed TC several times that he did not think TC's condition was very severe and that he would like to get TC some counseling. Tr. 93–94, 552; GE 25, at 3–4. TC then gave Dr. Daniels indications that his condition was more serious than he had previously been telling Dr. Daniels. Tr. 94–95, 554.

191. During the September 13, 2017 office visit, Dr. Daniels did not counsel TC about the dangers of using alcohol while taking Suboxone. GE–25. Combining alcohol with Suboxone could be dangerous. Tr. 263–64; GE–23, at 17.

192. During the September 13, 2017 office visit, Dr. Daniels did not counsel TC about the dangers of obtaining drugs off the street, or the dangers of mixing controlled substances. Tr. 83–84.

193. On September 13, 2017, Dr. Daniels issued TC a prescription for 60 tablets of 8/2 mg Suboxone, to be taken twice a day. Tr. 261–62; GE–23, at 1; Stip. 37. *[''8 milligrams twice daily, that would be, as you said, 16 milligrams a day.'' Tr. 262]

194. Dr. Daniels did not document a rationale for the prescription for the Suboxone he issued to TC. Tr. 260. Dr. Daniels did, however, ask TC appropriate questions when he met with him on September 13, 2017. Tr. 261, 349; GE–25.

195. Dr. Daniels testified, however, that based on his understanding of ''the local people that [he] had been treating for so many years,'' and TC's history, Dr. Daniels felt that the dose of Suboxone he prescribed to TC was appropriate because he believed it to be one that would prevent a relapse. Tr. 556–57.

196. Because TC was opioid naïve, if he took the Suboxone as it had been prescribed to him by Dr. Daniels, TC could have become quite sick. Tr. 262–63, 399.

197. None of the records that Dr. Daniels maintained concerning TC document a physical examination of TC. Tr. 257; GE–23. Concerning TC, Dr. Daniels should have documented a physical examination that included: Checking heart and lungs, checking for tremors in the eyes, and checking peripheral pulses for tachycardia. Tr. 389–90.

198. The medical records that Dr. Daniels maintained on TC did not contain any medical records from TC's prior doctors, but TC also told Dr. Daniels that he did not have a primary care doctor, and that he had never been treated for substance abuse. Tr. 261; GE–23; GE–25, at 3–4.

199. In Dr. Kennedy's opinion, the prescription Dr. Daniels issued to TC, identified in Stipulation 37, was issued outside the course of acceptable medical practice and was not issued for a legitimate medical purpose. Tr. 261, 266. Dr. Kennedy's opinion was based upon: The lack of PMP reports in CM's file; the lack of prior medical records; the failure to perform a physical examination; giving a high dose of Suboxone to an asymptomatic patient who has a history of recreational substance abuse; *[the lack of actual counseling regarding the dangers of mixing alcohol and Suboxone] and the deficiency of Dr. Daniels' medical records concerning TC. Tr. 261, 264–66, 386–87, 602.

200. Upon learning that TC's PMP report was checked, and after listening to Dr. Daniels' testimony, Dr. Kennedy stated that he still believes that the prescription of 16 mg of Suboxone to an opioid naïve patient was outside the standard of care, however, as to the question of ''whether or not it was issued for a legitimate medical purpose, that I would have to go over everything again to make a final decision on.'' Tr. 602.

Patient JW [11]

201. JW owned the Clinic before LW took it over. Tr. 543. JW is a professional counselor who Dr. Daniels had known and worked with since 2003. *Id.*

202. In 2013, JW developed chronic pain and a local physician treated him with methadone. Tr. 544. JW was referred to a pain specialist in Shreveport who was unable to see him because of an insurance issue. *Id.* Dr. Daniels agreed to see JW on a temporary basis because JW was in terrible pain and was ''almost unable to ambulate.'' *Id.* Although Dr. Daniels did not intend to treat JW long term, he treated JW until 2017. *Id.*

203. On July 5, 2013, JW presented to Dr. Daniels with complaints of back, arm, hand, knee, and leg pain. GE–19, at 11, 21.

204. On July 5, 2013, Dr. Daniels conducted a physical examination of JW. GE–19, at 9–10, 21. JW rated his pain as 8/10, and reported that he had surgeries performed on his back, shoulder, and a hernia. *Id.* at 21. JW reported that he was taking 10 mg methadone five times a day for chronic pain and carpal tunnel syndrome. *Id.* Following the physical examination, Dr. Daniels reached the following clinical impressions concerning JW's conditions: Hypertension; lumbar disc

[*H] Dr. Kennedy testified that although he thought that the interview of TC was appropriate, the physical examination needed to be done, and that would have included generally ''a heart and lung exam, and the doctor look in his eyes and notice if there is any kind of tremoring going on and maybe check peripheral pulses and see if he's tachycardic, and if not a complete and in-depth physical exam, at least a checking over of the patient before you embark on this program of long-term scheduled medications.'' Tr. 389–90.

[11] With respect to patient JW, the Government's only concern is with the OxyContin prescriptions that Dr. Daniels issued to JW. Tr. 547–48. Therefore, the facts concerning JW will focus on just those prescriptions.

disease; chronic back pain; history of carpal tunnel syndrome; and a history of multiple surgeries. Tr. 547; GE–19, at 9–10, 21; *see also* Patient Questionnaire, *Id.* at 26–32.

205. On July 5, 2013, Dr. Daniels placed a note in JW's medical file indicating that JW was the former patient of another doctor, but JW was well-known to Dr. Daniels. Tr. 545–46; GE–19, at 83. The note indicated that JW needed follow up for medical problems including knee and leg pain, back pain, and carpal tunnel syndrome, with the pain rating of 8/10. *Id.* Dr. Daniels noted that JW's activities of daily living were poor. *Id.*

206. A progress note for JW, dated January 31, 2014, indicates that JW presented with complaints of constant right knee pain, which he rated as 8/10. GE–19, at 103. Upon examination, Dr. Daniels noted that JW's pulse was 80, and his blood pressure was 130/82. *Id.* Dr. Daniels noted that JW's right knee was swollen, that there was increased pain with motion, and that JW was walking with a noticeable limp. *Id.* Dr. Daniels refilled prescriptions for JW for 90 tablets of 10/325 mg Percocet, and 150 tablets of 10 mg methadone. *Id.*

207. On February 20, 2014, JW had a total knee replacement of his right knee. GE–19, at 101.

208. On March 14, 2014, JW complained of very intense knee pain, which he numerically rated a 9 out of 10. GE–19, at 99. Upon examination, Dr. Daniels noted no swelling but a reduced range of motion, status-post knee surgery. *Id.* On that date, Dr. Daniels issued JW a prescription for 30 tablets of OxyContin, to be taken twice a day. *Id.*

209. Progress notes from March 28, 2014, for JW reveal complaints of occasional severe knee pain for which he needs 10 mg OxyContin, but his routine chronic pain was relieved by 10/325 mg Percocet. Tr. 548–49; GE–19, at 100. Upon physical examination, JW's pulse was 84, and his blood pressure was 146/90. *Id.* JW's knee surgery was healing well, but there was increased limited range of motion. *Id.* There was tenderness over the medial collateral ligament, and the strength was 4/5. *Id.* Dr. Daniels gave JW prescriptions for 90 tablets of 10 mg OxyContin, and 90 tablets of 10/325 mg Percocet. *Id.; see also* Stip. 35.

210. Dr. Daniels prescribed OxyContin to JW because he had just had knee surgery and was complaining of severe knee pain. Tr. 548. He chose OxyContin because JW had developed a tolerance to other pain medications. Tr. 549. Dr. Daniels claims that he wrote the dosing instructions for the prescription, to be taken every 4–6 hours, by mistake, and that he knows that the usual dose is every 12 hours. *Id.* Dr. Daniels also believed that JW was taking the OxyContin ''correctly,'' meaning every 12 hours.[12] Tr. 550, 577–79.

211. While JW was taking the OxyContin, Dr. Daniels encountered JW, either professionally or as a patient, almost daily. Tr. 550–51.

212. OxyContin is a long-acting continuous release medication indicated for patients who need around-the-clock pain management. Tr. 268. It is not appropriate to prescribe OxyContin to be taken ''as needed.'' Tr. 272. It is not appropriate to prescribe OxyContin for breakthrough pain. Tr. 272–73, 372. OxyContin has a ''Black Box Warning'' that it is not intended to be taken ''as needed,'' and that it could be dangerous to take it that way. Tr. 273. Any physician prescribing OxyContin should know that it is not to be prescribed to be taken ''as needed.'' Tr. 274.

213. The prescription that Dr. Daniels issued to JW on March 14, 2014, for OxyContin, was issued with instructions to take them as the medications are intended to be used, one tablet every 12 hours. Tr. 275–76; GE–19, at 99; Stip. 35.

214. The prescriptions that Dr. Daniels issued to JW on March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, May 16, 2014, and January 6, 2017, for OxyContin were issued with instructions that the OxyContin was to be taken every four to six hours for severe breakthrough pain. Tr. 277–82; GE–19, at 94–97, 174; GE–21, at 75. A prescription for OxyContin should never be written like this. Tr. 278. It would be dangerous to issue a patient a prescription like this. *Id.* These prescriptions were not issued within the usual course of professional practice and were not issued for a legitimate medical purpose. Tr. 278–83, 372–73.

[12] The timing of JW obtaining new prescriptions for OxyContin lends support to this belief. On March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, and May 16, 2014, JW received prescriptions for 20 tablets of OxyContin. Stip. 35. If JW had been taking the tablets four to six times a day, he would have run out of the medication before he returned to Dr. Daniels for a new prescription. The intervals between these appointments are 13 days, 14 days, 14 days, and 7 days. Furthermore, the dosing instructions of the March 14, 2014 prescription of 30 tablets, were to take one tablet twice a day. GE–19, at 99. Thus, that prescription was a fifteen-day supply. JW returned 14 days later to obtain a new prescription. Stip. 35. There are, however, no treatment notes concerning the stand-alone prescription for 30 tablets of OxyContin on January 6, 2017. On January 17, 2016, Dr. Daniels noted that JW ''takes meds appropriate.'' GE–19, at 60.

Analysis

To deny an application for a COR, the Government must prove, by a preponderance of the evidence, that the requirements for registration are not satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR 1301.44(d). Under 21 U.S.C. 823(f), the DEA may deny a COR application if the ''issuance of such registration . . . would be inconsistent with the public interest.'' The DEA considers the following five factors to determine whether granting a registration is in the public interest:

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

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

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

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

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

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

The DEA considers these public interest factors separately. *Ajay S. Ahuja, M.D.,* 84 Fed Reg. 5479, 5488 (2019); *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76–77 (4th Cir. 1988). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094–95 (2009) (basing sanction on all evidence of record).

The Government bears the initial burden of proof, and must justify denial by a preponderance of the evidence. *Steadman,* 450 U.S. at 100–03. If the Government presents a *prima facie* case for denying a COR application, the burden of proof shifts to the applicant to show that such action would be inappropriate. *Med. Shoppe—Jonesborough,* 73 FR 364, 387 (2008); *see, e.g., Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078, 10,081 (2009). An applicant may prevail by successfully attacking the veracity of the OSC's allegations or the Government's evidence. *Superior Pharmacy I &*

Superior Pharmacy II, 81 FR 31,310, 31,340 n.68 (2016); *see Hatem M. Ataya, M.D.,* 81 FR 8221, 8224 (2016). Alternatively, an applicant may rebut the Government's *prima facie* case for denial of the application 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). When assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of an applicant's offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38,363, 38,385 (2013).

In this case, the Government alleged that Dr. Daniels materially falsified his application for a Certificate of Registration by failing to disclose a restriction on his Louisiana state controlled substance license that was imposed on him by a Consent Order issued by the Louisiana Medical Board, *[which would constitute a ground for revocation or denial of an application under 21 U.S.C. 824(a)(1). *See Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45 (collecting cases) (DEA has consistently used the grounds for revocation in section 824 as a basis for denial of an application)]. The Government also alleges that Factors Two and Four of the public interest standard set forth in 21 U.S.C. 823(f) weigh against the Respondent's registration. *See* ALJ–18. Additionally, evidence introduced by the Respondent merits consideration under Factor One.

I. The Government's Position

The Government presented its position in an opening statement, Tr. 16–19, and in its Post-Hearing Brief, which it submitted on January 10, 2020.[13] I have read and considered the Government's opening statement, and its Brief, in preparing this Recommended Decision. In its Brief, the Government's proposed findings of fact are essentially the same as the Findings of Fact set forth in this Recommended Decision. ALJ–18, at 4–22. The Findings of Fact in this Recommended Decision differ from those proposed by the Government, where I have found the Government's proposed findings to be in error or not relevant to resolve the issues in this case. [Omitted] *[I][14]

With respect to the public interest considerations, the Government argues that it is relying ''on the testimony of Dr. Kennedy to show that [Dr. Daniels] issued prescriptions . . . outside the usual course of professional practice, beneath the standard of care in the State of Louisiana, . . . and without a legitimate purpose.'' ALJ–18, at 29. The Government noted that Dr. Kennedy's opinion was informed by numerous Louisiana Regulations. *Id.* Informed by those regulations, Dr. Kennedy testified that the standard of care in Louisiana for the treatment of addiction patients requires that a physician: Conduct an adequate physical examination; obtain an adequate medical history through past medical records or the PMP; create a treatment plan that includes a rationale for treatment; maintain adequate treatment records; conduct urine drug screening; and document the response to abnormal screenings within the patient's medical record. *Id.* at 30. The Government also noted that Dr. Daniels did not dispute Dr. Kennedy's testimony concerning the standard of care. *Id.* at 30–31.

The Government argues that I should not credit the testimony of Dr. Daniels, or his witness LW. ALJ–18, at 31–35. It also argues that Dr. Daniels' evidence concerning the Clinic's use of PMP reports is ''demonstrably false.'' *Id.* at 35. I note that I have addressed the credibility of both Dr. Daniels and LW earlier in this Recommended Decision. Concerning the PMP reports, Government Exhibit 30 demonstrates that the Clinic viewed the PMP concerning only two of the eight patients identified in the Order to Show Cause. *See* FF 26. Nevertheless, that same exhibit shows that between June 18, 2016, and September 20, 2017, Dr. Daniels checked the PMP 497 times. GE–30.

Next, the Government summarized the evidence it presented with respect to each allegation contained in the Order to Show Cause, and argued it had proven its *prima facie* case for denial of Dr. Daniels' application. ALJ–18, at 36–40. Finally, the Government argues that Dr. Daniels has not accepted responsibility, and, thus, his application should be denied. *Id.* at 40–41.

II. The Respondent's Position

Dr. Daniels presented his position in an opening statement, Tr. 20–22, and in his Post-hearing Brief, which he submitted on January 10, 2020.[15] I have read and considered Dr. Daniels' opening statement, and his Brief, in preparing this Recommended Decision. In his Brief, Dr. Daniels' proposed findings of fact are essentially the same as the Findings of Fact set forth in this Recommended Decision. ALJ–19, at 3–21. The Findings of Fact in this Recommended Decision differ from those proposed by the Respondent, where I have found the Respondent's proposed findings to be in error or not relevant to resolve the issues in this case.

Regarding the allegation of material falsification, Dr. Daniels points out that when submitting his application he ''specifically referenced the Consent Order issued by the [California Board of Medicine] as further explanation of the suspension.'' *Id.* at 3. He also notes that the Government acknowledged that his affirmative answer to the liability question and his reference to the Consent Order in his application ''certainly put the DEA on notice to investigate the application and not to summarily approve it.'' *Id.*

With respect to whether his registration would be inconsistent with the public interest, Dr. Daniels argues that the ''case must rest on the question of whether [he] knowingly prescribed drugs for other than a medical purpose, and not whether [he] used good judgment or bad judgment in trying to actually treat a patient.'' *Id.* at 4. Dr. Daniels also calls into question the lack of Louisiana specific experience of the Government's expert, as well as the ''miniscule sampling of six charts,'' when compared to the number of patients he had treated at the Clinic. *Id.* at 4–5.

Dr. Daniels notes that the Government's expert testified that the standard of care requires that the treating physician: 1. Obtain a history from the patient; 2. Conduct a physical examination of the patient; 3. Obtain the patient's past medical records and review the patient's PMP; 4. Conduct drug screening of the patient; and 5. Develop a treatment plan for the patient. *Id.* at 5. Dr. Daniels then proceeds to review the evidence, patient by patient, arguing that ''the treatment provided by [him] to each of the subject patients met this test.'' *Id.* at 6. Dr. Daniels does acknowledge that ''[r]egarding the patient charts . . . some information was missing.'' *Id.* With respect to reviewing the patient's PMP, Dr. Daniels noted that ''Dr. Kennedy testified that prescription monitoring as an accepted practice requirement became effective in 2018. (Trans., pg. 393). The charts reviewed were for patient visits between 2016 thru 2017 when prescription

[13] The Government's Brief has been marked as ALJ–18.

[*I] I am omitting the paragraph where the ALJ discussed the Government's position on the material falsification charge, because the Government abandoned its allegations related to material falsification in its Exceptions, and therefore, I find that this issue is no longer relevant. *See also infra* III.

[14] [Footnote omitted. *See* n.I.]

[15] Respondent's post-hearing brief has been marked as ALJ–19.

monitoring was more of a recommendation.'' *Id.* at 8.

Dr. Daniels argued that when presented with the results of an abnormal urine drug screen, ''he reacted to the information with directives for his staff to carry out.'' *Id.* Dr. Daniels states that ''[c]ounseling to the patient was always appropriate.'' *Id.* Furthermore, the Patient Treatment Agreements required drug screening as part of the recovery plan. *Id.* Dr. Daniels than addressed each of the subject patients, essentially reviewing their case files as he did when he testified. *Id.* at 9–21. For each patient, except JW and TC, Dr. Daniels argues that the Government had presented no evidence suggesting that the patients were somehow engaged in diversion.[16] *Id.* at 11, 13, 15, 16, 17, 19.

In conclusion, Dr. Daniels acknowledges that ''the patient files needed much improvement.'' *Id.* at 22. He adds, however, that ''poor documentation is not evidence that prescriptions were written for illegitimate purposes.'' *Id.* Of note, Dr. Daniels does not address acceptance of responsibility or remedial steps he may have taken.

III. Material Falsification

The DEA alleged that on March 12, 2018, the Louisiana State Board of Medical Examiners (''the Board'') issued a Consent Order that ''imposed a continuing restriction on [Dr. Daniels'] ability to practice medicine and to prescribe controlled substances for pain management or addiction treatment.'' ALJ–1, at 3–4, para. 8(c). The DEA further alleged that Dr. Daniels' application for a DEA certificate of registration, dated March 16, 2018, failed to disclose the restriction imposed by the Board's Consent Order on his Louisiana state controlled substance license. *Id.* at 3–4, paras. 8–9. *[I am omitting the RD's discussion of material falsification,[17] [18] because the Government in its Exceptions abandoned the allegation. *See* Government Exceptions, at 1 (stating that the Government does not ''take exception to the ALJ's finding that Respondent did not materially falsify his DEA COR application.''). Accordingly, I am not including an analysis of whether the facts here would have amounted to a material falsification, but instead, I am removing the RD's legal analysis per the Government's request for me to ''decline to adopt those limited portions of the Recommended Decision.'' *Id.* at 8. I find, as did the ALJ, that there is more than enough support in the record without the material falsification allegations that Dr. Daniels' registration is inconsistent with the public interest and that the appropriate sanction is denial of his application, as further explained below.]

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

*[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. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020); *see also Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002).]

In this case, it is undisputed that Dr. Daniels holds a valid state medical license in Louisiana. Tr. 476; Stip. 1; GE–3. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20,011, 20,018 (2011). It is well established that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chien* v. *DEA,* 533 F.3d 828 (DC Cir. 2008).*[J]

The record contains no evidence of a recommendation *[to the Agency regarding whether or not Dr. Daniels' DEA controlled substance registration application should be granted] by a relevant state licensing board or professional disciplinary authority. *[*See John O. Dimowo, M.D.,* 85 FR 15,810. However, as previously discussed, the State Board issued Consent Order for Reprimand, which was reached following a notice of Summary Suspension in Part of Dr. Daniels' Medical License filed by the Louisiana State Board of Medical Examiners (the Board) against Dr. Daniels based on ''information that he prescribed controlled substances without sufficient documentation.'' GE–5 and RE–1 (Consent Order); GE–2 (Summary Suspension). Neither the Consent Order, nor the Summary Suspension Order details the allegations against Dr. Daniels, so it is difficult to determine whether the State Board considered the same allegations and the extent of violations that DEA is considering herein. However, the Consent Order states that ''Dr. Daniels has surrendered his controlled dangerous substance registration to federal authorities.'' GE–5, at 1. Therefore, at the time the Board made its decision, Dr. Daniels was without a DEA registration and the Board had no reason to know whether he would receive one again. The Consent Order also included restrictions, which were proposed by Dr. Daniels, on Dr. Daniels' ability ''to prescribe controlled substances for chronic pain or obesity, associating himself with a drug treatment clinic, or serving in any position of responsibility for the health care services provided by others.'' *Id.* at 1–2. Therefore, the Consent Order does not indicate that the Board has a substantial amount of trust in Dr. Daniels' prescribing. For all of these reasons, the terms of the Board's Consent Order are not dispositive of the public interest inquiry in this case, and although I have considered it slightly in favor of Respondent, it is also minimized by the circumstances described above. *See John O. Dimowo,* 85 FR 15,810–11 (citing *Brian Thomas Nichol, M.D.,* 83 FR 47,352, 47,362–63 (2018)).] *[K]

[16] The Government, however, is not required to prove that diversion resulted from the unauthorized issuance of prescriptions. *Arvinder Singh, M.D.,* 81 FR 8247, 8249 (2016) *[(parentheticals omitted). In fact, Agency decisions have made clear that ''diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .'" *Id.* (citing *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014)). In this case, I have found that Respondent issued prescriptions without complying with his obligations under the CSA and Louisiana law. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010).].

[17] [Footnote omitted regarding material falsification.]

[18] [Footnote omitted regarding material falsification.]

*[J] I moved the three sentences preceding this footnote from the RD to provide further analysis of Factor 1 in accordance with Agency decisions.

*[K] It is noted that the ALJ found that this Factor weighed neither for nor against Dr. Daniels. *See* RD, at 69. Although I am weighing the factor slightly in his favor, it does not outweigh the egregious violations of law and misconduct in prescribing that I am considering under Factors 2 and 4.

V. Public Interest Factors Two & Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

[*L] [ ] Here, the Government alleges that denying Dr. Daniels' COR application is appropriate under Factors Two and Four because Dr. Daniels improperly prescribed controlled substances to: Six addiction treatment patients; a pain patient; and an undercover patient. ALJ–1, at 4–8, paras. 10–19.

It is unlawful for a practitioner to distribute controlled substances except as authorized under the CSA. 21 U.S.C. 841(a)(1). To combat abuse and diversion 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, a DEA registrant may prescribe a controlled substance only by writing a valid prescription. *Carlos Gonzalez, M.D.,* 76 FR 63,118, 63,141 (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)). * [According to the CSA's implementing regulations, a lawful] controlled substance prescription is valid only when 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.* Furthermore, 21 U.S.C. 842(a)(1) establishes that it is illegal for a person to distribute or dispense controlled substances without a prescription, as is required under 21 U.S.C. 829. [ ][*M]

The Government presented the expert testimony of Dr. Kennedy, who testified that Dr. Daniels' prescriptions to the patients in this case were not issued for legitimate medical purposes and were issued outside the usual course of professional practice. Second, the Government has shown through the testimony of its expert witness that Dr. Daniels violated the Louisiana standard of care *[and Louisiana law]. [ ][*N]

[Furthermore, Agency decisions highlight the Agency's interpretation that '''[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.' '' *Mark A. Wimbley, M.D.,* 86 FR 20,713, 20,726 (2021) (quoting *Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,464 (2011)); *[*see also Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,686 (2020) (''DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.''). Here, Respondent's sparse documentation made it impossible to evaluate his prescribing practices in any meaningful way.]

In fact, several of the regulatory provisions cited by the Government and Dr. Kennedy impose specific requirements on practitioners when practitioners obtain evidence that a patient is abusing or diverting controlled substances. In addition, Louisiana's controlled substance regulations also require practitioners to conduct urine drug screens and check the PMP, precautionary actions designed to check for abuse and diversion.

Because Dr. Daniels practices medicine in Louisiana, and because the OSC cites to specific provisions of Louisiana law and regulations, it is important to review the requirements of Louisiana law as they relate to professional conduct and the maintenance of medical records.

Louisiana Law

Louisiana law imposes requirements on controlled substance prescriptions similar to those imposed by the Controlled Substances Act and its implementing regulations. For example, under Louisiana law, ''[a] prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). Louisiana law further provides that ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act.'' *Id.*

Louisiana law provides that treating chronic pain not related to cancer with controlled substances ''constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record.'' La. Admin. Code tit. 46, Pt. XLV, § 6919. Louisiana law imposes several limitations on the use of controlled substances in the medical treatment of non-cancer related chronic pain. Specifically, Louisiana law requires that the medical practitioner evaluate the patient; diagnose the patient; establish a treatment plan; and obtain informed consent. *Id.* at § 6921(A)(1)–(4).

To comply with Louisiana law, a medical evaluation must include ''relevant medical, pain, alcohol and substance abuse histories''; assessment of the pain's impact ''on the patient's physical and psychological functions''; review of past diagnostic tests; previously utilized therapies; ''assessment of coexisting illnesses, diseases, or conditions''; and ''an appropriate physical examination.'' *Id.* at § 6921(A)(1).

With respect to the requirement to diagnose the patient, Louisiana law provides that ''[a] medical diagnosis shall be established and fully documented in the patient's medical record.'' *Id.* at § 6921(A)(2). The patient's medical record must indicate ''the presence of noncancer-related chronic or intractable pain'' and ''the nature of the underlying disease and pain mechanism,'' if possible for the practitioner to determine. *Id.*

In addition to the requirement to document a diagnosis, Louisiana law also requires the practitioner to document in the patient's medical record a treatment plan that provides medical justification for the use of controlled substances. *Id.* at § 6921(A)(3). The treatment plan must be tailored to each patient's individual needs. *Id.* The treatment plan must also ''include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success.'' *Id.* In addition, the treatment plan must ''specify the intended role of

[*L] Omitted content for clarity.

[*M] I am omitting some of the ALJ's analysis related to 21 CFR 1306.04(a) for brevity and clarity.

[*N] Omitted. *See* supra n.M

controlled substance therapy within the overall plan.'' *Id.*

Lastly, with respect to informed consent, Louisiana law requires the practitioner to ensure the patient is informed of the risks and benefits of controlled substance therapy. *Id.* at § 6921(A)(4). Louisiana law requires that ''[d]iscussions of risks and benefits should be noted in some format in the patient's record.'' *Id.*

Once a practitioner determines that controlled substance therapy is justified, Louisiana law imposes several additional requirements, to include the requirement that the practitioner: Monitor and assess the treatment's efficacy; conduct urine drug screens if appropriate; assume primary responsibility for the patient's controlled substance therapy; refer the patient for further evaluation and treatment if necessary; document the need for prescribing more than one controlled substance; maintain complete and accurate medical records; and document specific information concerning the controlled substance therapy. *Id.* at § 6921(B)(1)–(7).

Specifically, the practitioner must see the patient ''at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects.'' *Id.* at § 6921(B)(1). The requirement to monitor and assess the efficacy of controlled substance therapy includes the requirement to evaluate any ''[i]ndications of substance abuse or diversion.'' *Id.* In addition, the practitioner ''should seek evidence of under treatment of pain'' and assess ''the possibility of decreased function or quality of life as a result of controlled substance treatment.'' *Id.*

With respect to urine drug screens, Louisiana law requires that if the practitioner ''reasonably believes'' the patient is abusing or diverting controlled substances, the practitioner ''shall obtain a urine drug screen on the patient.'' *Id.* at § 6921(B)(2). In addition, Louisiana law requires that ''[a] single physician shall take primary responsibility'' for a patient's controlled substance therapy. *Id.* at § 6921(B)(3).

In addition, a practitioner treating a patient with controlled substances ''should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.* at § 6921(B)(4). Using controlled substances to treat patients with a history of substance abuse or with psychiatric disorders ''may require extra care, monitoring, documentation, and consultation with or referral to an expert.'' *Id.* Louisiana law specifically instructs practitioners to pay special attention to patients who are at-risk for misusing or diverting their controlled substances. *Id.*

Louisiana law also requires that if a practitioner prescribes more than one controlled substance to a patient, the practitioner must ''document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance.'' *Id.* at § 6921(B)(5).

Furthermore, Louisiana law imposes several specific requirements concerning the information that a practitioner must document in a patient's medical record. Specifically, Louisiana law provides that with respect to medical records:

> A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

Id. at § 6921(B)(6).

With respect to controlled substance prescriptions, a Louisiana practitioner must also document in the patient's medical record: ''The date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.'' *Id.* at § 6921(B)(7).

Louisiana law also provides that if a practitioner obtains evidence of, or if a patient's behavior indicates, abuse or diversion of controlled substances, the practitioner should taper the patient's prescriptions and discontinue controlled substance therapy. *Id.* at § 6921(C). The practitioner should only reinitiate controlled substance therapy after an addiction or pain management specialist, or psychiatrist, provides written support for ''the medical necessity of continued controlled substance therapy.'' *Id.*

Louisiana law also imposes requirements on behavioral health service providers, which includes practitioners who provide substance abuse or addiction treatment services. La. Admin. Code tit. 48, Pt. I, § 5603. Among those requirements include the requirement to maintain a client record ''according to current professional standards'' and to ensure medical records contain, at minimum, the treatment provided to the patient; the patient's response to treatment; initial assessment, diagnosis, and referral information; treatment plan; results of diagnostic and laboratory tests; and progress notes. *Id.* at § 5637(A)–(B). In addition, a practitioner must document in the patient's medical record the results of the patient's five most recent urine drug screens, as well as the action the practitioner took ''for positive results.'' *Id.* at § 5731(A)(2). Providers operating an opioid treatment program must ''conduct at least eight random monthly drug screen tests on each'' patient per year. *Id.* at § 5723(A)(4).

Behavioral Health Service [*O] providers must also conduct an initial assessment of a patient admitted for behavioral health services, to include a physical examination and drug screening. *Id.* at § 5647(C)(4)(b)–(c). In addition, the initial assessment must also contain a biopsycho-social evaluation, which covers, among other information, the reason for the patient's admission to behavioral health services; medical history and past treatment; family and social history; living situation; education level; employment status; and functioning level. *Id.* at § 5647(C)(4)(b). A practitioner may only admit a patient to behavioral health services if the practitioner has verified that ''treatment is medically necessary,'' and if the patient has had a complete physical evaluation before admission, and a full medical examination within 14 days of admission. *Id.* at § 5725(A)(3)–(5).[*P]

[*O] I made a slight correction here to the RD, because the regulation appears to apply to all Behavioral Health Service providers, including outpatient substance abuse or addiction treatment service providers, such as the Clinic where Dr. Daniels worked at the time of the allegations. I find that the substantial record evidence supports a finding that the Clinic was a Behavioral Health Service provider and that, therefore, these provisions of Louisiana regulations apply. Tr. 126, 421; La. Admin. Code tit. 48, Pt. I, § 5603 (defining a Behavioral Health Service provider as a clinic that ''provides behavioral health services, presents itself to the public as a *provider* of behavioral health services.'')

[*P] In this case, the requirement to adequately address and document aberrant results of the urine drug screens has been fully established by Louisiana law and the standard of care as testified to by Dr. Kennedy, whose expert testimony is unrebutted. *See* La. Admin. Code tit. 48, Pt. I, § 5731(A)(2). As discussed herein, Dr. Kennedy testified that many of the urine drug screens were aberrant and there was no documentation of their resolution in violation of state regulations and the usual course of professional practice. *See infra* AK, CA, MN, JD, SB, and CM. The ALJ added a section in the RD here regarding other DEA decisions that considered a practitioner's failure to address aberrant urine drug screens in assessing whether a registration was inconsistent with the public interest. *See Hatem M. Ataya, M.D.,* 81 FR 8221, 8227 (2016); *Jacobo Dreszer, M.D.,* 76 FR at 19,388, 19,394 (2011); ''[A] practitioner's failure to properly

Addiction Treatment

The Government alleged that between May 2016 and September 2017, Dr. Daniels prescribed controlled substances to patients AK, CA, MN, JD, SB, and CM, outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4, paras. 10–12. Specifically, the Government alleged that Dr. Daniels' prescriptions to these patients exhibited several deficiencies, to include Dr. Daniels' failure to conduct physical examinations; failure to request the patients' past medical records; failure to obtain PMP reports; failure to resolve aberrant urine drug screens; and failure to document the rationale for his medical treatment. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels prescribed patients AK, CA, MN, SB, and CM, prescriptions for both buprenorphine (Subutex) and clonazepam. The Government further alleged that both of these controlled substances were respiratory depressants, and that Dr. Daniels failed to document in the patients' medical records any rationale that justified prescribing buprenorphine and clonazepam at the same time. ALJ–1, at 5, para. 13. Dr. Daniels also failed to document in the patients' medical records that he discussed with them the risks of taking these controlled substances at the same time. *Id.*

During his testimony, Dr. Kennedy provided guidance concerning the standard of care in Louisiana. For example, to prescribe controlled substances in Louisiana for the treatment of chemical dependency, the standard of care requires the treating physician to: Conduct an adequate physical examination; obtain past medical records; obtain PMP reports; conduct drug screening; and maintain medical records. FF 46. In addition, the standard of care requires that a patient's medical record be ''complete and accurate.'' FF 47. With respect to the Louisiana PMP, prior to 2018, doctors in Louisiana were not required to check a patient's PMP before writing a prescription for a controlled substance, but it was considered the standard of care. FF 65.

Patient AK

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient AK, between May 2016 and September 2017,[19] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to AK, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of AK, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request AK's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for AK, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in AK's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in AK's medical records his rationale for his medical treatment of AK, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to AK at the same time. Because Dr. Daniels failed to document in AK's medical record any rationale that justified prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with AK the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of AK. FF 78, 82, 83, 91, 92, 94, 97. Dr. Daniels also failed to obtain past medical records concerning AK. FF 76, 92, 97; Tr. 198. Although the standard of care dictated that Dr. Daniels check AK's PMP, he did not do so. FF 26, 85, 92, 97. Although Dr. Daniels did conduct some urine drug screens of AK, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 86, 87, 92, 94, 97. Finally, Dr. Daniels did not document within AK's medical record a rationale for the controlled substances he prescribed to AK. FF 81, 94, 97. Accordingly, *[I find based on the unrebutted, credible testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to AK were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 97.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on AK, failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution AK of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, AK's medical records include a Patient Treatment Contract that AK signed that specifically warned AK of the dangers of taking buprenorphine and Klonopin together. FF 72. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 17 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 97.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued

supervise his patients to prevent them from personally abusing controlled substances or selling them to others constitutes conduct 'inconsistent with the public interest' and can support the denial of an application for registration, or the revocation of an existing registration.'' *Bienvenido Tan, M.D.,* 76 FR 17,673, 17,689 (2011) (quoting *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601 (1998)); *Mireille Lalanne, M.D.,* 78 FR 47,750, 47,766–68 (2013) (finding that failing to confront a patient about inconsistent drug screens by itself is sufficient evidence to show that the registrant acted outside the scope of professional practice). I have omitted this section of the RD, but included some of the cited decisions herein. *See Kaniz Khan-Jaffery,* 85 FR 45,667, n.71 (2020) (''Even though these Agency decisions are not essential or controlling in determining the standard of care in New Jersey that applies to this case, the fact that other medical experts in other states have testified regarding the importance of documenting inconsistent urine screens to their applicable standard of care and that DEA has long highlighted the importance of this aspect of the standard of care in those states to maintaining registrations under the CSA lends further support to the findings herein.'') It is noted that, the decisions cited in the RD and this footnote, relied on expertise regarding the applicable standard of care and usual course of professional practice to those particular registrants, as does this decision.

[19] This includes all of the prescriptions listed in Stipulation 17.

prescriptions to Patient AK in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants, and because the number of prescriptions alleged in the Order to Show Cause to have been issued by Dr. Daniels to AK is inconsistent with the Government's proof, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning AK are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for AK, including those for buprenorphine and Klonopin, identified in Stipulation 17, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient CA

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient CA, between May 2016 and September 2017,[20] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to CA, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of CA, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request CA's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for CA, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in CA's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in CA's medical records his rationale for his medical treatment of CA, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to CA at the same time. Because Dr. Daniels failed to document in CA's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with CA the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15. The Government also alleged that Dr. Daniels failed to document any rationale for prescribing Adderall to CA. ALJ–1, at 6, para. 14.b.i.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of CA. FF 103, 107, 109, 110, 118. Dr. Daniels also failed to obtain past medical records concerning CA. FF 105; Tr. 198. The evidence shows, however, that Dr. Daniels checked CA's PMP, but he did not do so until more than a year after he first prescribed controlled substances to CA. FF 26. Although Dr. Daniels did conduct some urine drug screens of CA, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 101, 102, 111–13, 115–17, 119. Finally, Dr. Daniels did not document within CA's medical record a rationale for the controlled substances he prescribed to CA. FF 103, 108–10, 118. Accordingly, *[I find, based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to CA were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 121.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on CA failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution CA of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, CA's medical records include a Patient Treatment Contract that CA signed that specifically warned CA of the dangers of taking buprenorphine and Klonopin together. FF 99. *[Additionally, both Dr. Daniels and Dr. Kennedy testified that prescribing both Klonopin and buprenorphine is not outside the usual course of professional practice. Tr. 315, 518.] Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 22, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 121. With respect to the prescriptions for Adderall that Dr. Daniels prescribed to CA, the Government established Dr. Daniels did not document a rationale for prescribing Adderall to CA. FF 103. In fact, during his testimony, Dr. Daniels acknowledged that the justification was not contained in CA's medical records. FF 108.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient CA in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants, and because the number of prescriptions alleged in the Order to Show Cause to have been issued by Dr. Daniels to CA is inconsistent with the Government's proof, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning CA are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for CA, identified in Stipulation 22, including those for buprenorphine and Klonopin, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Furthermore, the allegation contained in ALJ–1, at 6, para. 14.b.i., that Dr. Daniels failed to document a rationale for prescribing Adderall to CA is not documented in CA's medical record in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), is SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient MN

The Government alleged that all of the prescriptions for controlled substances

[20] This includes all of the prescriptions listed in Stipulation 22.

that Dr. Daniels issued to Patient MN, between May 2016 and September 2017,[21] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to MN, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of MN, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request MN's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for MN, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in MN's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in MN's medical records his rationale for his medical treatment of MN, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to MN at the same time. Because Dr. Daniels failed to document in the MN's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with MN the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of MN. FF 128–29, 136–37. Dr. Daniels also failed to obtain past medical records concerning MN. FF 137; Tr. 198. Although the standard of care dictated that Dr. Daniels check MN's PMP, he did not do so. FF 26, 137. Although Dr. Daniels did conduct some urine drug screens of MN, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 126–27, 132–33, 135, 137. Finally, Dr. Daniels did not document within MN's medical record a rationale for the controlled substances he prescribed to MN. FF 128, 137. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to MN were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 137.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on MN failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution MN of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, MN's medical records include a Patient Treatment Contract that MN signed that specifically warned MN of the dangers of taking buprenorphine and Klonopin together. FF 124. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 24 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 137.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient MN in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that both buprenorphine and Klonopin (clonazepam) are respiratory depressants, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning MN are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for MN, including those for buprenorphine and Klonopin, identified in Stipulation 24, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient JD

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient JD, between May 2016 and September 2017,[22] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to JD, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of JD, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request JD's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for JD, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in JD's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in JD's medical records his rationale for his medical treatment of JD, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of JD. FF 143. Dr. Daniels also failed to obtain past medical records concerning JD. FF 143; Tr. 198. Although the standard of care dictated that Dr. Daniels check JD's PMP, he did not do so. FF 26. Although Dr. Daniels conducted a urine drug screen of JD, due to the length of time he treated JD, Dr. Daniels should have conducted additional urine drug screens of JD. FF 145; La. Admin. Code tit. 48, Pt. I § 5723(A)(4). Finally, Dr. Daniels did not document within JD's medical record a rationale for the controlled

[21] This includes all of the prescriptions listed in Stipulation 24.

[22] This includes all of the prescriptions listed in Stipulation 27.

substances he prescribed to JD. FF 177. Accordingly, I *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to JD were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 147. Of significance, Dr. Kennedy's opinion concerning the prescriptions that Dr. Daniels issued to JD was based on the fact that there was no documented follow-up care of JD after his initial visit with Dr. Daniels, though JD continued to obtain prescriptions from Dr. Daniels for more than a year after obtaining his first prescription from Dr. Daniels. FF 147; Stip. 27.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient JD in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient SB

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient SB, between May 2016 and September 2017,[23] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to SB, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of SB, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725.

Second, Dr. Daniels failed to request SB's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for SB, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in SB's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in SB's medical records his rationale for his medical treatment of SB, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to SB at the same time. Because Dr. Daniels failed to document in SB's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed the risks of taking these controlled substances at the same time with SB, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of SB. FF 152, 156. Dr. Daniels also failed to obtain past medical records concerning SB. FF 153; Tr. 198. Although the standard of care dictated that Dr. Daniels check SB's PMP, he did not do so. FF 26. Although Dr. Daniels did conduct some urine drug screens of SB, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 154–55, 157. Finally, Dr. Daniels did not document within SB's medical record a rationale for the controlled substances he prescribed to SB. FF 152, 154, 157. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to SB were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 157.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on SB failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution SB of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, SB's medical records include a Patient Treatment Contract that SB signed that specifically warned SB of the dangers of taking buprenorphine and Klonopin together. FF 149. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 29 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 157.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient SB in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning SB are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for SB, including those for buprenorphine and Klonopin, identified in Stipulation 29, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient CM

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient CM, between May 2016 and September 2017,[24] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to CM, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of CM, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request CM's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for CM, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in CM's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for

[23] This includes all of the prescriptions listed in Stipulation 29.

[24] This includes all of the prescriptions listed in Stipulation 31.

substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in CM's medical records his rationale for his medical treatment of CM, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to CM at the same time. Because Dr. Daniels failed to document in CM's medical record any rationale that justified prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with CM the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15. During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of CM. FF 166–67. Dr. Daniels also failed to obtain past medical records concerning CM. FF 168, 172; Tr. 198. Although the standard of care dictated that Dr. Daniels check CM's PMP, he did not do so. FF 26, 172. Although Dr. Daniels did conduct some urine drug screens of CM, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 158, 169, 170, 172. Finally, Dr. Daniels did not document within CM's medical record a rationale for the controlled substances he prescribed to CM. FF 166–67. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to CM were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 172.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on CM failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution CM of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, CM's medical records include a Patient Treatment Contract that CM signed that specifically warned CM of the dangers of taking buprenorphine and Klonopin together. FF 160. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 31 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 172.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient CM in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning CM are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for CM, including those for buprenorphine and Klonopin, identified in Stipulation 31, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Undercover Patient TC

The Government alleged that Dr. Daniels issued a prescription to TC for 60 tablets of 8/2 mg Suboxone on September 13, 2017. ALJ–1, at 7, para. 18. It also alleges that this prescription was issued beneath the standard of care for the practice of medicine in Louisiana, and outside the usual course of professional practice in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). ALJ–1, at 7–8, paras. 18–19. The Government alleged that the prescription was issued outside the usual course of professional practice and was beneath the standard of care for the following reasons. First, Dr. Daniels failed to conduct a physical examination of TC. Second, Dr. Daniels failed to request TC's medical records concerning prior substance abuse or past treatment of substance abuse. Third, Dr. Daniels failed to obtain a PMP report concerning TC. Fourth, Dr. Daniels prescribed a high dose of Suboxone to TC who presented as an opioid naïve patient. Fifth, Dr. Daniels' medical record for TC failed to provide an adequate evaluation of TC's condition or a treatment plan. ALJ–1, at 7–8, para. 19.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of TC. FF 175, 186, 188, 198, 200. Dr. Daniels also failed to obtain past medical records concerning TC. FF 199, 200. Contrary to the Government's allegation, Dr. Daniels did obtain a PMP report concerning TC. FF 26. The results of the PMP report, however, are not contained in TC's medical record. FF 187. Dr. Daniels conducted a urine drug screen of TC, which did not reveal any controlled substances in his body. FF 175–76. During TC's first appointment with Dr. Daniels, he prescribed 60 tablets of 8/2 mg of Suboxone, one tablet to be taken twice a day. FF 194. Because TC was an opioid naïve patient, had TC taken the Suboxone as it was prescribed, *[Dr. Kennedy testified that] he could have become quite sick. FF 197. Finally, Dr. Daniels' treatment notes for TC do not document his rationale for the manner in which he initiated his treatment of TC. FF 195. Therefore, I *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescription that Dr. Daniels issued to TC was issued outside the standard of care. FF 200–01.

Accordingly, the allegations contained in Paragraph 18–19 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient TC in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) are SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Pain Management Patient JW

Lastly, the Government alleged that Dr. Daniels' issuance of controlled substance prescriptions for pain management to JW exhibited several deficiencies, to include: The lack of a doctor-patient relationship; therapeutic duplication; failure to justify co-prescribing; and failure to justify increasing his methadone dosage. ALJ–1, at 6–7, paras. 16–17. At the hearing, however, the Government stated that with respect to Patient JW, it was only concerned with the prescriptions that Dr. Daniels wrote to JW for OxyContin.[25] Tr. 547–48.

[25] Testimony in support of the Government's position is consistent with the summarization of Dr.

Continued

The Government presented evidence that OxyContin is a long-lasting continuous release medication indicated for patients who need around-the-clock pain management. FF 213, 268. It is not appropriate to prescribe OxyContin to be taken ''as needed.'' *Id.* It is also not appropriate to prescribe OxyContin for break-through pain. *Id.* In fact, taking OxyContin for break-through pain or on an ''as needed'' basis could be dangerous. *Id.*

Dr. Daniels issued seven OxyContin prescriptions to JW. Stip. 35. The prescription that Dr. Daniels issued to JW on March 14, 2014, for OxyContin, was issued with instructions to take them as the medications are intended to be used, one tablet every 12 hours. FF 214. The prescriptions that Dr. Daniels issued to JW on March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, May 16, 2014, and January 6, 2017, for OxyContin were issued with instructions that the OxyContin was to be taken every four to six hours for severe breakthrough pain. FF 215. Dr. Daniels acknowledges when he wrote instructions for JW to take the OxyContin every four to six hours, he did so by mistake. Tr. 211. Nevertheless, he did so five times in 2014, and once again in 2017. FF 215; Stip. 35. Even though Dr. Daniels acknowledges it was a mistake to issue the OxyContin in the manner that he did, [*Q] [''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28,643, 28,662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998).]

In light of the six separate prescriptions that Dr. Daniels wrote to JW for OxyContin, with instructions to take the medication once every four to six hours, *[I find based on the unrebutted, credible expert testimony of Dr. Kennedy, and as supported by the evidence] that these six prescriptions were not issued within the usual course of professional practice and were not issued for a legitimate medical purpose. Accordingly, the allegation that Dr. Daniels issued these six prescriptions beneath the standard of care in Louisiana and outside the usual course of professional practice in violation of Federal and State laws and regulations is SUSTAINED. Because the Government did not present evidence to support the specific allegations contained in Paragraphs 16–17 of the Order to Show Cause, those allegations are NOT SUSTAINED. The sustained allegation, however, weighs in favor of denying Dr. Daniels' current application.

Discussion and Conclusions of Law [*R]

Based upon my review of the evidence in this case, I have sustained the allegations that all of the prescriptions that Dr. Daniels issued to patients AK, CA, MN, JD, SB, CM, and TC, and six of the prescriptions Dr. Daniels wrote to patient JW, were issued outside the usual course of professional practice, and therefore were not issued for legitimate medical purposes. While these prescriptions were issued to only eight patients, Dr. Daniels wrote over 140 prescriptions to these patients during a 17-month period. My independent review of the medical records that Dr. Daniels maintained on all of these patients, except for JW, allows me to adopt fully Dr. Kennedy's testimony concerning the adequacy of those records. *[Based on Dr. Kennedy's expert testimony and the record evidence in this case] where there is a consistent absence of pertinent information in a patient's medical records, such as: PMP reports; a credible physical examination; past medical records; resolution of abnormal drug screens, the records reach a point where it is not possible to say that the treatment has been within the scope of acceptable medical practice or that the prescriptions are legitimate. FF 50.

Issues Raised by the Respondent

In explaining this Recommended Decision, it is appropriate to address two issues that Dr. Daniels raised both at the hearing and in his Post-Hearing Brief. In that Brief, Dr. Daniels repeatedly asserts that ''the Government presented no evidence that [the patient] was obtaining the same or similar prescriptions from multiple sources or obtaining those medications for illicit purposes.'' ALJ–19, at 11, 13, 15, 16, 17, 19. In addition, in his Brief, Dr. Daniels notes that Dr. Kennedy's opinions were based upon his review of a few charts and that ''[t]his miniscule sampling of six (6) charts hand picked by DEA should raise serious questions as to the legitimacy of any 'pattern' that may be deduced therefrom.'' *Id.* at 4–5.

Meaning of Diversion

Some of Dr. Daniels' arguments in his Brief reflect a misunderstanding of the DEA's definition of diversion. Dr. Daniels essentially contends that the Government did not present evidence of diversion. ALJ–19, at 11, 13, 15, 16, 17, 19. One of the CSA's primary purposes is to protect against ''the diversion of drugs from legitimate channels to illegitimate channels.'' *United States* v. *Moore,* 423 U.S. 122, 135 (1975). To ensure that controlled substances remain in legitimate channels, the CSA creates a ''closed regulatory'' scheme. *Gonzales* v. *Oregon,* 546 U.S. 243, 250 (2006). The DEA has explained that diversion occurs whenever controlled substances leave ''the closed system of distribution established by the CSA . . . .'' *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014). Thus, ''when prescriptions are issued outside of the usual course of professional practice and lack a legitimate medical purpose, . . . the drugs are deemed to have been diverted.'' *George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010).

Contrary to Dr. Daniels' suggestion, the Government does not need to prove that a patient was seeking medications from multiple sources or was abusing controlled substances for a finding of diversion. Rather, when a practitioner violates the CSA's prescription requirement, set forth in 21 CFR 1306.04(a), by issuing a prescription without a legitimate medical purpose and outside the course of professional practice, the DEA [essentially] considers the prescription to have been diverted. *Mathew,* 75 FR at 66,146. *[Omitted for brevity.]

Although the DEA has occasionally considered such evidence,[26] the Government is not obligated to show, as the Respondent would suggest, that a patient died, overdosed, or illegally disposed of prescription medication.

Kennedy's testimony contained in the Government's Prehearing Statement, ALJ–5, at 25–26, and the Government's Supplemental Prehearing Statement. ALJ–9, at 3–4.

[*Q] Altered for clarity.

[*R] I am omitting the RD's discussion of material falsification because, as noted above, the Government has explicitly abandoned that allegation. *See supra* Analysis.III.

[26] *See, e.g. Lawrence E. Stewart, M.D.,* 81 FR 54,822, 54,832, 54847 (2016) (discussing registrant's treatment of patient who overdosed on prescriptions issued by the registrant); *Ibem R. Borges, M.D.,* 81 FR 23,521, 23,523 (2016) (suggesting that registrant's prescribing which caused overdose deaths could result in ''total revocation based on public interest grounds'', but deciding the case differently in accord with the allegations premised on lack of state authority); *Samuel Mintlow, M.D.,* 80 FR 3630, 3646 (2015) (noting expert testimony that respondent prescribed at such high dosages as to risk '''acute narcotic overdose'''); *Richard D. Vitalis, D.O.,* 79 FR 68,701, 68,701, 68,707 (2014) (considering evidence that respondent's patient died of overdose attributable to respondent's over-prescribing); *Darryl J. Mohr, M.D.,* 77 FR 34,998, 35,010–11 (2012) (discussing three patients who died due to registrant's prescribing).

Waiting for a controlled substance to be found coursing through a person's bloodstream before holding the registrant accountable is wholly at odds with the DEA's responsibility to protect the public interest under 21 U.S.C. 823(f). For these reasons, I reject Dr. Daniels' suggestion that the Government has not provided enough evidence to justify denying his application.

Size of the Sample

The DEA has made it clear that the Government may proceed to hearing with only a few allegations. ''[W]here the Government has seized files, it can review them and choose to present at the hearing only those files which evidence a practitioner's most egregious acts.'' *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,387 (2011); *see also Cleveland J. Enmon, Jr., M.D.,* 77 FR 57,116, 57,126 (2012) (rejecting argument that the respondent's practice could not be judged based upon a review of only 19 files). Furthermore, the DEA has held that ''even though the patients at issue are only a small portion of [a] [r]espondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding his ability to responsibly handle controlled substances in the future.'' *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,600 (1998).

With respect to consideration given to a practitioner's positive experience in prescribing, the DEA assumes that all of the prescriptions a registrant has issued were issued lawfully, except for those prescriptions that the Government alleges were issued unlawfully. *Wesley Pope, M.D.,* 82 FR 14944, 14,984 (2017). *[The violations I have found demonstrate that Dr. Daniels repeatedly violated the applicable standard of care and state law and that his conduct was not an isolated occurrence, but occurred with multiple patients and in multiple contexts over a period of years. *See Kaniz Khan-Jaffery M.D.,* 85 FR 45,667, 45,685 (2020).]

Prima Facie Showing and Balancing

The Government can meet its burden for revocation or denial by proving ''only a few instances of illegal prescribing.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 464 (2009). DEA precedent asserts in no uncertain terms that the public interest inquiry is not a numbers game in which the Government must prove a certain number of violations.[27] For instance, in *Alan H. Olefsky, M.D.,* the DEA imposed a revocation based on evidence of only two fraudulent prescriptions.[28] 57 FR 928, 928–29 (1992). In *James Clopton, M.D.,* the DEA denied the respondent's application on evidence that he wrote only four unlawful prescriptions. 79 FR 2475, 2475–77 (2014). Although the record contained additional evidence of recordkeeping violations, the Administrator viewed the unlawful prescriptions as ''reason alone to deny [respondent's] application.'' *Id.* at 2478.

Additionally, in *Jose Gonzalo Zavaleta, M.D.,* the Administrator denied an application where the evidence showed a total of six unlawful prescriptions written on four occasions. 77 FR 64,128, 64,129–30 (2012). In *Gabriel Sanchez, M.D.,* the DEA based revocation on a total of seven prescriptions issued to two undercover officers who each had one appointment with the respondent. 78 FR 59,060, 59,060–61 (2013). In *Clair L. Pettinger, M.D.,* the Administrator revoked the registrant's COR based on evidence that he issued nine prescriptions in violation of 21 CFR 1306.04(a), and authorized one prescription while his COR was suspended. 78 FR at 61,600. In *MacKay* v. *DEA,* the Tenth Circuit affirmed revocation based on 14 unlawful prescriptions. 664 F.3d 808, 811–14, 822 (10th Cir. 2011). In *Wesley Pope, M.D.,* the Administrator deemed denial the appropriate sanction where the Government proved violations stemming from 19 unlawful prescriptions. 82 FR at 14,985. In *Lynch* v. *DEA,* the Eleventh Circuit upheld revocation based on evidence of 19 unlawful prescriptions. 480 Fed. App'x 946, 948 (11th Cir. 2012) (unpublished) (per curium) (reviewing *Ronald Lynch, M.D.,* 75 FR 78,745 (2010)).

These cases represent only a sampling of DEA final orders, but they illustrate the point that the Administrator has imposed the DEA's harshest sanction—revocation or denial—based on evidence of only 2 to 19 unlawful prescriptions. The present case involves over 140 prescriptions.[*S]

Summary of Factors One, Two and Four

Specifically, the Government bases its case on evidence that implicates Factors Two and Four of 21 U.S.C. 823(f). The Government did not advance any evidence under Factors One, Three, and Five. As the DEA has explained, ''findings under a single factor are sufficient to support the revocation or suspension of a registration.'' *Syed Jawed Akhtar-Zaidi, M.D.,* 80 FR 42,962, 42,967 (2015). While I consider all the factors, the central inquiry ''focuses on protecting the public interest,'' and misconduct relevant to only one factor can be sufficient to support a finding that a practitioner's continued registration threatens the public interest. *Id.*

[I have found that there is substantial evidence in the record before me that Dr. Daniels issued controlled substance prescriptions to eight individuals, including for Schedule II controlled substances, for no legitimate medical purpose and outside the usual course of professional practice, that Respondent failed to maintain medical records pertaining to his prescribing of controlled substances in violation of state law and the state standard of care. Accordingly, I conclude that it would be ''inconsistent with the public interest'' for Dr. Daniels to be granted a registration due to the substantial evidence of his violations of the CSA and its implementing regulations and state law. 21 U.S.C. 823(f).]

Based on the evidence in this case, *[I have found that Factor One weighs slightly] against denying Dr. Daniels' application. Factors Two and Four, however, weigh for denying his application. Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that Dr. Daniels' registration would be inconsistent with the public interest.

[*T] Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Dr. Daniels' application for a registration is inconsistent with the public interest due to his violations of federal and state law pertaining to controlled substance prescribing, the burden shifts to the Dr. Daniels to show why he can be entrusted with a new

[27] *See Lawrence E. Stewart, M.D.,* 81 FR 54,822, 54,848 (2016) (stressing that even though the respondent committed ''far more than one'' violation, proving only one instance of knowing diversion is enough to make a *prima facie* case for revocation); *T.J. McNichol, M.D.,* 77 FR 57,133, 57,145 (2012) (''[P]roof of a single act of intentional or knowing diversion is sufficient to satisfy the Government's *prima facie* burden . . . .''); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009) (emphasizing that ''what matters is the seriousness'' of the misconduct rather than a tallying up of violations).

[28] Additionally, in the *Olefsky* case, the registrant argued in his exceptions to the ALJ's recommended ruling that suspension of his license was disproportionate to the proven misconduct, which was limited to two fraudulent prescriptions presented on one occasion. 57 FR at 929. The Administrator rejected the registrant's exception and ruled that ''[r]evocation [was] an acceptable remedy.'' *Id.*

[*S] Omitted for brevity.

[*T] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same. I will also address Dr. Daniels' Exceptions herein as noted.

registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. at 259. A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that [she] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23,853; *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).]

Dr. Daniels may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,228 (2003). To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *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 26,208, 26,211 (1996). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013).

Notwithstanding the fact that the Government has made a *prima facie* case for sanction, imposing a sanction is a matter of discretion. *See* 21 U.S.C. 824(a) (''A registration . . . *may* be suspended or revoked by the Attorney General . . . .'') (emphasis added); *Martha Hernandez, M.D.,* 62 FR 61,145, 61,147 (1997) (referring to Administrator's authority to exercise discretion in issuing the appropriate sanction).[*T]

[*U] [Respondent argues in his Exceptions that he ''acknowledged responsibility throughout the proceedings.'' Resp Exceptions, at 2. In support of this statement, he cites to the record [*V] where he ''agreed with DEA's expert, Dr. Kennedy's testimony about the importance of physical examinations.'' *Id.* (citing Tr. 492). Although I credit Dr. Daniels for agreeing with the Government's expert regarding the standard of care, he then went on to state that in situations where there is limited staff and when other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing the waiting patients. Tr. 493. In those situations, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493. After agreeing with the Government's expert that ''a physical examination is certainly very important,'' Tr. 492, which in this case is required by state law, Dr. Daniels then proceeded to try to minimize his misconduct in not conducting the required, self-described ''very important'' physical examinations by implying that a practitioner could ignore a legal requirement for one patient in order to not ''inconvenience other patients who may be waiting.'' Tr. 493. Not only do I find this statement to minimize any acceptance of responsibility, I find it to be in blatant disregard of the ''importan[ce]'' of a physical examination.[*W] *See Stein,* 84 FR at 46,972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility); *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (Respondent did not accept responsibility noting that he ''repeatedly attempted to minimize his [egregious] misconduct''); *Michael White, M.D.,* 79 FR 62,957, 62,967 (2014) (finding that Respondent's ''acceptance of responsibility was tenuous at best'' and that he ''minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict.''). It does not instill confidence in me that Dr. Daniels could be entrusted with a registration when he could so casually dismiss a legal requirement based on a perception of inconvenience to other patients.

Further, when explaining the reasons for his Consent Agreement with the Medical Board, Dr. Daniels stated that the Board ''felt like that [he], as an individual practitioner, trusted people too much, that [he] gave too much confidence in the people when [he] would ask them to do things or expect them to bring things to [him].'' Tr. 561. If the violations before the Medical Board were similar to the ones before me, as the record suggests, I find this to be an outrageously minimized characterization of his wrongdoing. Dr. Daniels subtly passes the blame onto his co-workers at the clinic and characterizes himself as too trusting. Based on this statement, it does not appear to me that Dr. Daniels

[*T] Omitted for brevity.

[*U] The ALJ found that thee was ''no evidence that Dr. Daniels has accepted any responsibility for the 141 prescriptions he issued to eight different patients. The closest he came to accepting responsibility was an acknowledgement that 'some of the records fell short.' Tr. 570.'' RD, at 98. Although I agree with the ALJ that ultimately Respondent did not adequately accept responsibility, Respondent has taken exception to this finding and therefore I am evaluating Respondent's additional citations to the record in support of his statement that he ''acknowledged responsibility throughout the proceedings.'' Resp Exceptions, at 2.

[*V] Dr. Daniels also cited to page 11 of the Transcript to support that he had ''acknowledged that he did not always document the justification for the prescriptions that he wrote,'' but I could not find what he was referencing. Resp Exceptions, at 2.

[*W] I also found above that Dr. Daniels misstated his conversations with TC regarding alcohol use that he had counseled TC not to drink alcohol, TR. 555, despite the fact that the record directly contradicts this statement. Again, I find that this is an attempt to minimize the egregiousness of his interaction with TC and weighs against a finding of acceptance of responsibility.

comprehends the full extent of his wrongdoing in order for me to find acceptance of responsibility. Furthermore, it demonstrates that, thus far, he has not learned from his mistakes in order to be deterred from repeating them.]

[The ALJ found that the] closest [Dr. Daniels] came to accepting responsibility was an acknowledgment that ''some of the records fell short.'' Tr. 570. Then in his Brief, Dr. Daniels admits that ''the documentation of the patient files needed much improvement.'' ALJ–19, at 22. He adds, however, that ''poor documentation is not evidence that the prescriptions were written for illegitimate purposes.'' [29] *Id.* *[Again, Dr. Daniels minimizes his misconduct, and additionally, this statement critically understates the egregiousness of his found wrongdoing, which is more serious than poor documentation, as explained below. I agree with the ALJ that these admissions do not amount to acceptance of responsibility. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021) (''Respondent's admission that she failed to maintain adequate medical records was not a sufficient acceptance of responsibility.''); *see also Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,686 (2020) (''Respondent's assertion that she 'should have written more' barely scrapes the surface of these issues, and seems to be an attempt to minimize the severity of her actions by so lightly characterizing a substantive documentation requirement.'')

I further find that the additional cites to the transcript that Dr. Daniels references in his Exceptions, also do not amount to adequate acceptance of responsibility. *See Hoxie* v. *Drug Enf't Admin.,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician'' and ''admitting fault'' is an ''important factor[ ] in determining whether the physician's registration should be revoked''). Although Dr. Daniels admitted that he made a ''mistake'' on the instructions for JW's OxyContin prescriptions, Tr. 549, he also stated that he thought JW ''was taking it correctly,'' Tr. 550, based on the fact that he did not run out between visits; however, Dr. Daniels never acknowledged the severity of the consequences that could have occurred had JW taken them pursuant to his mistaken instructions. Tr. 273 (Dr. Kennedy's testimony that taking OxyContin pursuant to Dr. Daniels instructions would be ''very dangerous'' and that the controlled substance had a ''black box'' warning regarding those dangers.)

Further, even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust him with a registration. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021). Dr. Daniels stated that as a result of the Consent Order, he took ''a controlled substance prescribing course in Cleveland, Ohio at Case Western Reserve University, ethics, boundaries, those were recommended. I did complete those,'' Tr. 562, however, he did not submit any documentation regarding these courses, and I do not find that he presented any meaningful evidence regarding actual or proposed remedial measures, other than the possibility of limiting his registration to Schedule V controlled substances. *See infra* n.30.]

''[E]ven though the Government has made out a *prima facie* case'' for sanction, the registrant remains free to argue that ''his conduct was not so egregious as to warrant revocation.'' *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,387–88 (2011). ''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Richard J. Settles, D.O.,* 81 FR 64,940, 64,945 n.17 (2016) (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009)).

*X [ ] The Administrator has noted that ''there may be some instances in which the proven misconduct is not so egregious as to warrant revocation . . . and a respondent, while offering a less than unequivocal acceptance of responsibility[,] nonetheless offers sufficient evidence of adequate remedial measures to rebut the Government's proposed sanction.'' *Roberto Zayas, M.D.,* 82 FR 21410, 21429 (2017). This is not such an instance.

*[In this case, the ALJ found, and I agree, that there was substantial record evidence that over 140 prescriptions issued by Respondent were issued outside the usual course of professional practice and beneath the standard of care. Specifically, the Government's credible expert witness testified that certain conduct was particularly egregious. For example, he described one of the urine drug screens for Patient MN, which was positive for ecstasy, as ''wildly abnormal,'' Tr. 225, and he stated that ''to have a drug screen like this, and to make absolutely no comment in the medical record, did not make any comment with addressing the patient about it, or what you plan to do about this, is in my view, inexcusable.'' Tr. 226. Further, Dr. Kennedy testified regarding Patient SB's records that ''there was, in essence, in [his] view, no medical care here, simply the provision of scheduled prescriptions.'' Tr. 244. Dr. Kennedy also testified several times that there was no medical diagnosis at all in the records to support controlled substance prescriptions. *See e.g.,* Tr. 396–97; GE–6, at 1–49 (no justification for Klonopin to AK); Tr. 322, 377 (no justification for Adderall to CA). Dr. Daniels prescribed controlled substances to AK and CA without maintaining any records on his visits with them, if they occurred. He repeatedly failed to conduct physical examinations, address urine drug screens, and counsel patients about risks. The Government's expert, Dr. Kennedy, testified that in addiction treatment, these accountability measures were of particular importance, ''not because we're counting on the patients being compliant, it's because of the likelihood of patients being noncompliant.'' Tr. 299. Although I find Dr. Daniels to be sincere and laudable in his wish to help an underserved population, it does not excuse his repeated failure to follow the laws designed to keep these patients safe.]

In addition to the severity of the proven misconduct, DEA also considers its interest in specific and general deterrence when determining the appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). Deterrence is an appropriate consideration, and is consistent with the CSA's purpose of protecting the public interest and the DEA's broad grant of authority to consider acts inconsistent with the public interest. *Southwood Pharm., Inc.,* 72 FR 36,487, 36,504 (2007). General deterrence concerns DEA's

[29] This statement demonstrates Dr. Daniels' lack of understanding of the need to maintain adequate medical records. First, the State of Louisiana requires it. La. Admin. Code tit. 46, Pt. LIII, § 6921(B)(6); La. Admin. Code tit. 48, Pt. I, § 5637 (A)–(B). Second, when a practitioner fails to maintain adequate medical records that practitioner is not acting within the usual course of professional practice. Third, as noted earlier in this Recommended Decision, a controlled substance prescription is valid only when 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) (emphasis added).

*X Omitted for brevity.

responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Glick,* 80 FR at 74,810. Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.*

Having considered all of the evidence, I find that Dr. Daniels' violations of federal and state laws and regulations concerning the prescribing of controlled substances were egregious. I concur with Dr. Kennedy's assessment of the adequacy of Dr. Daniels' medical records concerning patients, AK, CA, MN, JD, SB, CM, and TC, not only because his expert testimony went unrebutted, but also *[because a review of the sparse medical records demonstrates obvious deficiencies, to include no records at all related to some of the prescriptions]. I also find Dr. Daniels' statement that poor documentation is not evidence of illegitimate prescriptions to be a further indication demonstrating his continuing lack of understanding of the responsibilities of an individual who holds a Certificate of Registration.

Further, I find it appropriate to consider both general and specific deterrence. In light of the extremely poor quality of the medical records that Dr. Daniels maintained, which were non-existent in some instances, and the fact that he continues to attempt to portray his records as adequate to support his prescriptions for controlled substances, to include Schedule II and III substances, granting his application would send the wrong message to other medical practitioners. In addition, granting a Certificate of Registration to Dr. Daniels, absent his acceptance of responsibility and an acknowledgement of the responsibilities attached to a registration, would totally defeat the concept of specific deterrence.

* [Here, there is insufficient evidence in the record to demonstrate that Respondent can be entrusted with a registration. *See Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988) (describing revocation as a remedial measure ''based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.''). Due to the extent and egregiousness of Dr. Daniels' misconduct, his failure to adequately accept responsibility, Dr. Daniels has not given me reassurance that he can be entrusted with a registration.]

Therefore, I find that granting a Certificate of Registration to Dr. Daniels, at this time, would be inconsistent with the public interest.[30]

[30] I have given consideration to recommending that Dr. Daniels' application be granted, but limited to Schedule V, to accommodate his current medical practice. *See supra* FF 8. While Dr. Daniels' continued efforts to provide medical assistance to underserved communities is commendable, there is insufficient evidence in the Administrative Record to support such a recommendation. *[I agree, and I disagree with Respondent's Exception stating that ''limitation to Schedule V would protect the public interest since he will not be practicing in high risk areas.'' Resp Exceptions, at 3. Respondent has not provided me with adequate reasons to entrust him with a controlled substance registration at any schedule.]

Recommendation

Accordingly, I *Recommend* that Dr. Larry C. Daniels' application for a DEA Certificate of Registration, Control Number W18024499C, be *Denied*.

Dated: January 24, 2020.

Charles Wm. Dorman,

U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W18024499C, submitted by Larry C. Daniels, M.D., as well as any other pending application of Larry C. Daniels, M.D. for additional registration in Louisiana. This Order is effective December 6, 2021.

Anne Milgram,

Administrator.

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