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

ii. Allegations of Violations of California Law

The Government has also alleged that Registrant's prescribing practices in regards to the subject patients violated state law. OSC, at 4–7. Echoing the federal regulations, California law requires that a ''prescription for a controlled substance shall only be issued for a medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code 11153(a). Therefore, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Registrant violated this provision with respect to the controlled substance prescriptions for Patients K.K., G.K., T.L., J.P., and Y.P. I also find based on the uncontroverted evidence that Registrant issued these same controlled substance prescriptions without ''an appropriate prior examination and a medical indication,'' which is a violation of Cal. Bus. & Prof. Code 2242(a).[7]

In sum, I find that the record contains substantial evidence that Registrant issued a multitude of prescriptions for controlled substances, including high dosages of opioids, to multiple patients beneath the applicable standard of care, outside the usual course of the professional practice, and in violation of federal and state law. I, therefore, find that Factors Two and Four weigh in favor of revocation. *See Mark A. Wimbley, M.D.,* 86 FR 20713, 20726 (2021).

III. Sanction

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

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

In this matter, Registrant did not avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA or made any demonstration that he can be trusted with a registration. The evidence presented by the Government of Registrant's conduct clearly indicates that he cannot be so entrusted.

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

Order

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

Anne Milgram,

Administrator.

[FR Doc. 2022–07685 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

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

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–38]

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

I. Introduction

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

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

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

medical standards applicable to the practice of medicine in California.'' *Id.* at 3. The OSC sets out specifics of Respondent's alleged prescribing for six individuals to support its allegations. *Id.* at 4–10.

According to the OSC, in view of the information before the DEA at the time, the former Acting Administrator preliminarily found that Respondent's continued registration was ''inconsistent with the public interest,'' that Respondent's issuance of multiple controlled substance prescriptions was ''without any legitimate medical purpose,'' and that his ''continued registration during the pendency of these proceedings would constitute 'an imminent danger to the public health or safety' because of the substantial likelihood of an imminent threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of . . . suspension.'' *Id.* at 10–11. Citing 21 U.S.C. 824(d), 21 CFR 1301.36(e), and other authorities, the former Acting Administrator suspended, ''effective immediately'' and ''until a final determination is reached in these proceedings,'' BR0869719, BA7661564, and DATA-Waiver No. XR0869719, and directed the DEA Special Agents and Diversion Investigators serving the OSC to take possession of those certificates. *Id.* at 11.

The OSC notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). According to the Government's Notice of Service, a member of the DEA Riverside District Office personally served the OSC on Respondent on August 9, 2019. ALJX 2 (Government's Notice of Service of Order to Show Cause and Immediate Suspension of Registration dated August 12, 2019), at 1.

By letter dated August 20, 2019, Respondent timely requested a hearing. ALJX 3, at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ). During the pre-hearing phase of this proceeding, the parties agreed to and submitted 116 joint stipulations (hereinafter, Jt. Stip.) that, at the hearing, the parties accepted as ''binding facts in these proceedings.'' Prehearing Ruling dated September 20, 2019, at 2–10; Parties' Additional Joint Stipulations dated October 28, 2019, at 1–13; Transcript page number (hereinafter, Tr.) 9. The final, agreed-to Stipulations as set out by the ALJ are:

Controlled Substances

1. Tetrahydrocannabinol (hereinafter, THC) is an illicit Schedule I Controlled Substance pursuant to 21 CFR 1308.11(d)(31).

2. Amphetamine salts (Adderall) are Schedule II Controlled Substances pursuant to 21 CFR 1308.12(d)(1).

3. Fentanyl (Duragesic patch) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(c)(9).

4. Hydrocodone (Norco) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(vi).

5. Hydromorphone (Dilaudid) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(vii).

6. Methadone is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(c)(15).

7. Oxycodone (Oxycontin or Roxicodone) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(xiii).

8. Oxycodone-acetaminophen (Percocet) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(xiii).

9. Alprazolam (Xanax) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(2).

10. Carisoprodol (Soma) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(6).

11. Clonazepam (Klonopin) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(11).

12. Diazepam (Valium) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(16).

13. Promethazine with codeine is a Schedule V Controlled Substance pursuant to 21 CFR 1308.15(c)(1).

Registrations Associated With Respondent

14. Respondent is registered as a practitioner with the DEA to handle controlled substances in Schedules II through V under DEA COR number BR0869719 at 73–950 Alessandro Drive, Suite 4, Palm Desert, California 92260.

15. Respondent's DEA COR expires by its terms on April 30, 2021.

16. Government Exhibit 1 contains a true and correct copy of Respondent's DEA COR number BR0869719.

17. Respondent operates Aurora Surgery Center LP.

18. Aurora Surgery Center LP is organized in the State of California as a Limited Partnership.

19. Respondent is listed as the one and only General Partner on Aurora Surgery Center LP's Certificate of Limited Partnership.

20. Government Exhibit 2 contains a true and correct copy of the Certificate of Limited Partnership for Aurora Surgery Center LP.

21. Aurora Surgery Center LP is registered as a hospital/clinic with the DEA to handle controlled substances in Schedules II through V under DEA COR number BA7661564 at 73–950 Alessandro Drive, Palm Desert, California 92260.

22. Aurora Surgery Center LP's DEA COR expires by its terms on June 30, 2020.

23. Government Exhibit 1 contains a true and correct copy of Aurora Surgery Center LP's DEA COR number BA7661564.

24. Respondent is a DATA-waived (Drug Addiction Treatment Act) physician certified to treat 100 patients for substance abuse.

25. Respondent's DATA-Waiver Identification number is XR0869719.

26. Respondent is licensed in the State of California to practice medicine pursuant to state license number G59060.

27. Respondent's state medical license expires by its terms on February 29, 2020.

Investigation

28. Government Exhibit 3 contains true and correct copies of the administrative subpoenas issued to Respondent, dated January 16, 2019.

29. Government Exhibit 4 contains true and correct copies of the administrative subpoenas issued to various pharmacies, dated April 19, 2019.

30. Government Exhibit 6 is a true and correct copy of the ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons'' published by the Medical Board of California in 2013.

31. Government Exhibit 7 is a true and correct copy of the ''Guidelines for Prescribing Controlled Substances for Pain'' published by the Medical Board of California in November 2014.

32. Government Exhibit 8 is a true and correct copy of ''Calculating Total Daily Dose of Opioids for Safer Dosage'' published by the Centers for Disease Control and Prevention (CDC).

33. Government Exhibit 9 contains a true and correct copy of ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' published by the Food and Drug Administration (FDA).

34. Government Exhibit 9 contains true and correct copies of the FDA labels for Klonopin, Valium, and Xanax.

35. Government Exhibits 10A and 10B contain true and correct copies of the

CURES reports for Respondent's prescribing behavior between January 1, 2018 and August 20, 2019.

Patient A.A.

36. Government Exhibits 12A and 12B contain true and correct copies of Respondent's patient medical file for Patient A.A.

37. On the following 16 occasions, Respondent issued a prescription for 180 tablets of Percocet 10–325 mg, a prescription for 60 tablets of Xanax 2 mg, and a prescription for 180 tablets of methadone 10 mg for Patient A.A.:

a. December 26, 2017
b. February 2, 2018
c. March 7, 2018
d. April 3, 2018
e. May 1, 2018
f. June 1, 2018
g. July 2, 2018
h. August 1, 2018
i. August 31, 2018
j. September 28, 2018
k. October 31, 2018
l. November 30, 2018
m. January 3, 2019
n. January 28, 2019
o. February 27, 2019
p. March 25, 2019

38. Government Exhibit 11 contains true and correct copies of the prescriptions listed in Stipulation 37.

Patient R.B.

39. Government Exhibits 14A and 14B contain true and correct copies of Respondent's patient medical file for Patient R.B.

40. Respondent issued the following 44 prescriptions for Patient R.B.:

a. January 10, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
b. February 7, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
c. March 7, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
d. April 4, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
e. May 1, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
f. May 31, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
g. June 27, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
h. July 25, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
i. August 22, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
j. September 17, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
k. October 12, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
l. November 9, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
m. December 10, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
n. January 9, 2019: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
o. February 8, 2019: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
p. March 8, 2019: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
q. April 5, 2019: 120 tablets of oxycodone 30 mg and 60 tablets of ibuprofen 800 mg

41. Government Exhibit 13 contains true and correct copies of the prescriptions listed in Stipulation 40.

Patient S.D.

42. Government Exhibits 16A, 16B, 16C, and 16D contain true and correct copies of Respondent's patient medical file for Patient S.D.

43. Respondent issued the following 41 prescriptions for Patient S.D.:

a. January 16, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
b. February 14, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
c. March 21, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
d. April 20, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
e. May 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
f. June 14, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
g. July 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
h. August 15, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
i. September 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
j. October 19, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
k. November 19, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
l. January 2, 2019: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 120 tablets of Soma 350 mg
m. February 4, 2019: 180 tablets of Roxicodone 15 mg and 120 tablets of Soma 350 mg
n. March 1, 2019: 180 tablets of Roxicodone 15 mg and 120 tablets of Soma 350 mg
o. April 2, 2019: 180 tablets of Roxicodone 15 mg

44. Government Exhibit 15 contains true and correct copies of the prescriptions listed in Stipulation 43.

Patient L.D.

45. Government Exhibits 18A and 18B contain true and correct copies of Respondent's patient medical file for Patient L.D.

46. Respondent issued the following 28 prescriptions for Patient L.D.:

a. January 8, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
b. March 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
c. May 4, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour

d. July 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
e. September 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
f. November 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
g. January 4, 2019: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
h. March 4, 2019: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 20 Duragesic patches 100 mcg/hour

47. Government Exhibit 17 contains true and correct copies of the prescriptions listed in Stipulation 46.

Patient S.H.

48. Government Exhibit 20A and 20B contains true and correct copies of Respondent's patient medical file for Patient S.H.

49. On the following 17 occasions, Respondent issued a prescription for 90 tablets of Roxicodone 30 mg, a prescription for 90 tablets of Dilaudid 8 mg, and a prescription for 60 tablets of methadone 10 mg for Patient S.H.

a. December 26, 2017
b. January 29, 2018
c. February 20, 2018
d. March 23, 2018
e. April 23, 2018
f. May 21, 2018
g. June 18, 2018
h. July 18, 2018
i. August 15, 2018
j. September 12, 2018
k. October 10, 2018
l. November 7, 2018
m. December 5, 2018
n. January 2, 2019
o. January 30, 2019
p. February 27, 2019
q. March 27, 2019

50. Government Exhibit 19 contains true and correct copies of the prescriptions listed in Stipulation 49.

Patient J.M.

51. Government Exhibits 22A, 22B, 22C, and 22D contain true and correct copies of Respondent's patient medical file for Patient J.M.

52. Respondent issued the following 33 prescriptions for Patient J.M.

a. January 26, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
b. February 23, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
c. March 22, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
d. April 19, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
e. May 16, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
f. June 13, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
g. July 13, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
h. August 9, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
i. September 6, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
j. September 27, 2018: 90 tablets of alprazolam 2 mg
k. October 5, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
l. November 5, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
m. November 26, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
n. January 4, 2019: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
o. January 31, 2019: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
p. February 26, 2019: 180 tablets of OxyContin 80 mg and 150 tablets of Roxicodone 30 mg
q. March 28, 2019: 180 tablets of OxyContin 80 mg and 150 tablets of Roxicodone 30 mg

53. Government Exhibit 21 contains true and correct copies of the prescriptions listed in Stipulation 52.

Exhibits

54. Respondent stipulates to the admissibility of Government Exhibits 1–4 and 6–22.

55. Xanax (alprazolam) is a benzodiazepine.

56. Valium (diazepam) is a benzodiazepine.

57. Klonopin (clonazepam) is a benzodiazepine.

Patient A.A.

58. On the following 16 occasions, Respondent prescribed for Patient A.A. oxycodone for 60 mg a day and methadone for 60 mg a day:

a. December 26, 2017
b. February 2, 2018
c. March 7, 2018
d. April 3, 2018
e. May 1, 2018
f. June 1, 2018
g. July 2, 2018
h. August 1, 2018
i. August 31, 2018
j. September 28, 2018
k. October 31, 2018
l. November 30, 2018
m. January 3, 2019
n. January 28, 2019
o. February 27, 2019
p. March 25, 2019

59. On June 5, 2013, Respondent increased Patient A.A.'s dosage of Percocet (oxycodone-acetaminophen) 10–325 from 90 tablets to 120 tablets.

60. On July 23, 2013, Respondent increased Patient A.A.'s dosage of Percocet (oxycodone-acetaminophen) 10–325 from 120 tablets to 180 tablets.

61. On January 11, 2013, Respondent increased Patient A.A.'s dosage of methadone 10 mg from 90 tablets to 120 tablets.

62. On June 2, 2014, Respondent increased Patient A.A.'s dosage of methadone 10 mg from 120 tablets to 180 tablets.

Patient R.B.

63. Respondent's first documented visit with Patient R.B. occurred on January 8, 2016.

64. During Respondent's January 8, 2016 initial visit with Patient R.B., Patient R.B. reported to Respondent that he was constantly in pain and had previously taken oxycodone and was then currently taking six tablets of Norco (hydrocodone-acetaminophen) 10–325 mg a day.

65. During Respondent's January 8, 2016 initial visit with Patient R.B., Patient R.B. tested positive for THC in a urine drug screen.

66. On January 8, 2016, Respondent issued a prescription for 90 tablets of oxycodone 30 mg to Patient R.B.

67. On February 8, 2016, Respondent had a second visit with Patient R.B.

68. On Respondent's February 8, 2016 second visit with Patient R.B., Patient R.B. reported to Respondent feeling much improved, with a pain level of one or two out of 10.

69. On Respondent's February 8, 2016 second visit with Patient R.B., Patient R.B. tested positive for THC and for a benzodiazepine.

70. On Respondent's February 8, 2016 second visit with Patient R.B., Respondent issued a prescription for 90 tablets of oxycodone 30 mg.

71. On the following occasions, Patient R.B. tested positive for THC in a urine drug screen:

a. January 8, 2016
b. February 8, 2016

c. April 6, 2016
d. May 4, 2016
e. June 7, 2016
f. July 11, 2016
g. August 8, 2016
h. September 7, 2016
i. October 5, 2016
j. November 2, 2016
k. December 2, 2016
l. January 2, 2017
m. January 30, 2017
n. March 1, 2017
o. March 29, 2017
p. April 26, 2017
q. May 24, 2017
r. June 26, 2017
s. July 24, 2017
t. August 23, 2017
u. September 18, 2017
v. October 16, 2017
w. November 15, 2017
x. December 13, 2017
y. February 7, 2018

72. Respondent did not document in Patient R.B.'s patient file any urine drug screens performed for Patient R.B. on January 10, 2018 and between March 7, 2018 and February 8, 2019.

73. On the following 17 occasions, Respondent prescribed Patient R.B. oxycodone of 120 mg a day:

a. January 10, 2018
b. February 7, 2018
c. March 7, 2018
d. April 4, 2018
e. May 1, 2018
f. May 31, 2018
g. June 27, 2018
h. July 25, 2018
i. August 22, 2018
j. September 17, 2018
k. October 12, 2018
l. November 9, 2018
m. December 10, 2018
n. January 9, 2019
o. February 8, 2019
p. March 8, 2019
q. April 5, 2019

74. On an April 6, 2016 visit with Patient R.B., Respondent increased Patient R.B.'s oxycodone 30 mg prescription from 90 tablets to 120 tablets.

75. On an April 6, 2016 visit with Respondent, Respondent documented in R.B.'s medical file that Patient R.B. reported feeling improved.

Patient S.D.

76. On the following occasions, Patient S.D. tested positive for THC:

a. June 19, 2012
b. October 10, 2012
c. December 13, 2012
d. January 11, 2013
e. February 8, 2013
f. March 8, 2013
g. July 12, 2013
h. August 9, 2013
i. September 9, 2013
j. October 7, 2013
k. March 18, 2014
l. April 15, 2014
m. May 14, 2014
n. August 8, 2014
o. October 7, 2014
p. December 9, 2014
q. February 6, 2015
r. March 6, 2015
s. April 29, 2015
t. June 5, 2015
u. July 1, 2015
v. July 29, 2015
w. September 29, 2015
x. December 23, 2015
y. February 24, 2016
z. March 21, 2016
aa. May 23, 2016
bb. July 20, 2016
cc. August 17, 2016
dd. September 16, 2016
ee. October 17, 2016
ff. January 13, 2017
gg. February 13, 2017
hh. March 13, 2017
ii. April 10, 2017
jj. July 5, 2017
kk. August 28, 2017
ll. September 27, 2017
mm. November 22, 2017
nn. December 19, 2017
oo. February 14, 2018
pp. March 21, 2018
qq. April 20, 2018
rr. May 21, 2018
ss. June 14, 2018
tt. August 15, 2018
uu. November 19, 2018

77. On the following three occasions, Respondent prescribed Patient S.D. methadone at 60 mg a day and oxycodone at 90 mg a day:

a. January 16, 2018
b. February 14, 2018
c. March 21, 2018

78. On the following nine occasions, Respondent prescribed Patient S.D. methadone for 90 mg a day and oxycodone for 90 mg a day:

a. April 20, 2018
b. May 18, 2018
c. June 14, 2018
d. July 18, 2018
e. August 15, 2018
f. September 18, 2018
g. October 19, 2018
h. November 19, 2018
i. January 2, 2019

79. On the following three occasions, Respondent prescribed Patient S.D. oxycodone at 90 mg a day:

a. February 4, 2019
b. March 1, 2019
c. April 2, 2019

80. On February 24, 2016, Respondent increased Patient S.D.'s methadone 10 mg prescription from 120 tablets to 180 tablets.

81. On April 20, 2018, Respondent increased Patient S.D.'s methadone 10 mg prescription from 180 tablets to 270 tablets.

Patient L.D.

82. Respondent's first documented visit with Patient L.D. occurred on June 20, 2011.

83. On Respondent's initial June 20, 2011 visit with Patient L.D., Respondent documented in Patient L.D.'s patient file that Patient L.D. was taking amphetamine.

84. During a September 23, 2011 visit, L.D. tested positive for amphetamine on a urine drug screen.

85. As of the September 23, 2011 visit, Respondent had prescribed Patient L.D. amphetamine, hydromorphone, fentanyl, and clonazepam.

86. On the following eight occasions, Respondent prescribed Patient L.D. Duragesic patches at 100 mcg per hour every two days and Dilaudid for 48 mg a day:

a. January 8, 2018
b. March 5, 2018
c. May 4, 2018
d. July 5, 2018
e. September 5, 2018
f. November 5, 2018
g. January 4, 2019
h. March 4, 2019

87. On January 16, 2012, Respondent increased Patient L.D.'s prescription for Dilaudid 8 mg from 90 tablets to 180 tablets.

88. On July 14, 2015, Respondent increased Patient L.D.'s prescription for Duragesic patches 100 mcg/hour from 10 patches (1 patch every 72 hours) to 15 patches (1 patch every 48 hours) for a thirty day supply.

89. In May and July 2014, Respondent documented in Patient L.D.'s patient file that Patient L.D. and her husband had been criminally convicted.

Patient S.H.

90. Respondent's first documented visit with Patient S.H. occurred on August 24, 2010.

91. On Respondent's visit with Patient S.H. on August 4, 2015, Patient S.H. tested positive only for oxycodone.

92. On Respondent's visit with Patient S.H. on August 4, 2015, Patient S.H. reported to Respondent that he was taking Adderall, hydromorphone, methadone, and oxycodone.

93. An X-Ray taken for Patient S.H. on October 7, 2010 reported normal results for neck and spine.

94. An MRI taken for Patient S.H. on April 26, 2011 reported normal results for the spine.

95. An MRI taken for Patient S.H. on January 17, 2012 reported normal results for the neck.

96. On the following occasions, Patient S.H. had been prescribed methadone by Respondent:

a. August 4, 2015
b. September 1, 2015
c. April 24, 2017
d. December 4, 2017

Patient J.M.

97. Respondent's first documented visit with Patient J.M. occurred on May 17, 2011.

98. On Respondent's initial visit with Patient J.M. on May 17, 2011, Patient J.M. reported to Respondent that he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.

99. During a June 17, 2011 visit with Patient J.M., Respondent documented in Patient J.M.'s patient file that Patient J.M. came to the office with his mother.

100. During a June 17, 2011 visit with Patient J.M., Respondent documented in Patient J.M.'s patient file that Patient J.M. came to ''plead mercy'' and ask for a second chance at being treated.

101. During a June 17, 2011 visit with Patient J.M., Respondent issued Patient J.M. a prescription for 180 tablets of oxycodone 30 mg

102. During a June 17, 2011 visit with Patient J.M., Respondent noted in Patient J.M.'s patient file that he would give Patient J.M. ''[o]ne final chance.''

103. On the following occasions, Respondent checked the CURES database for Patient J.M.:

a. May 17, 2011
b. June 13, 2011
c. July 15, 2011
d. September 9, 2011
e. August 10, 2012
f. October 12, 2012
g. March 4, 2013
h. June 28, 2013
i. February 28, 2014
j. November 10, 2014
k. May 4, 2016
l. September 6, 2018

104. On March 23, 2012, Respondent increased Patient J.M.'s oxycodone 30 mg prescription from 180 tablets to 240 tablets.

105. On September 4, 2012, Respondent decreased Patient J.M.'s oxycodone 30 mg prescription from 240 tablets to 180 tablets.

106. On September 21, 2012, Respondent increased Patient J.M.'s oxycodone 30 mg prescription from 180 tablets to 240 tablets.

107. Between August and September 2012, Respondent increased Patient J.M.'s prescription for 90 tablets of OxyContin 60 mg to 180 tablets of OxyContin 80 mg.

108. On the following occasions, Patient J.M. tested positive for the following controlled substances in a urine drug screen:

a. July 15, 2011: benzodiazepine
b. August 12, 2011: THC
c. September 9, 2011: THC
d. December 2, 2011: THC and benzodiazepine
e. January 27, 2012: benzodiazepine
f. March 23, 2012: THC and benzodiazepine
g. May 18, 2012: THC
h. July 12, 2012: THC and benzodiazepine
i. August 10, 2012: THC
j. September 21, 2012: THC and benzodiazepine
k. November 7, 2012: THC and benzodiazepine
l. December 7, 2012: THC
m. January 7, 2013: THC
n. March 4, 2013: THC
o. March 29, 2013: THC and benzodiazepine
p. May 3, 2013: THC
q. June 28, 2013: THC
r. August 27, 2013: THC
s. November 5, 2013: THC
t. December 3, 2013: THC and benzodiazepine
u. December 27, 2013: THC and benzodiazepine
v. January 30, 2014: THC and benzodiazepine
w. February 28, 2014: THC and benzodiazepine
x. April 1, 2014: THC
y. April 30, 2014: THC and benzodiazepine
z. July 23, 2014: THC and benzodiazepine
aa. August 14, 2014: THC and benzodiazepine
bb. October 13, 2014: THC and benzodiazepine
cc. December 8, 2014: THC and benzodiazepine
dd. March 31, 2015: benzodiazepine
ee. April 29, 2015: THC
ff. June 24, 2015: benzodiazepine
gg. August 21, 2015: THC
hh. November 12, 2015: THC and benzodiazepine
ii. April 4, 2016: THC and benzodiazepine
jj. May 4, 2016: benzodiazepine
kk. September 16, 2016: THC and benzodiazepine
ll. October 13, 2016: THC and benzodiazepine
mm. December 12, 2016: benzodiazepine
nn. May 5, 2017: THC and benzodiazepine
oo. August 4, 2017: THC and benzodiazepine
pp. September 29, 2017: THC and benzodiazepine
qq. October 27, 2017: THC and benzodiazepine
rr. November 27, 2017: THC and benzodiazepine
ss. December 21, 2017: THC and benzodiazepine
tt. January 26, 2018: THC and benzodiazepine
uu. September 6, 2018: THC and benzodiazepine

109. During the periods referenced in Paragraph 108, Respondent had not prescribed Patient J.M. a benzodiazepine.

110. On a May 5, 2017 visit with Respondent, Respondent documented in Patient J.M.'s patient file that Patient J.M. had taken a ''headache pill'' from his mother.

111. On a May 5, 2017 visit with Respondent, Patient J.M. tested positive for morphine.

112. As of the May 5, 2017 visit with Respondent, Respondent had not prescribed Patient J.M. any morphine.

113. Respondent's Exhibit 1 is a true and correct copy of the New England Journal of Medicine article ''No Shortcuts to Safer Opioid Prescribing.''

114. Respondent's Exhibit 2 is a true and correct copy of an April 10, 2019 letter from the Center for Disease Control and Prevention to Dr. Alford.

115. Respondent's Exhibit 3 is a true and correct copy of a media statement from the Center for Disease Control and Prevention titled ''CDC Advises Against Misapplication of the Guidelines for Prescribing Opioids for Chronic Pain.''

116. Respondent's Exhibit 4 is a true and correct copy of the American Medical Association Resolution 235 ''Inappropriate Use of CDC Guidelines for Prescribing Opioids D–120.932.''

ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law and Decision dated February 25, 2020 (hereinafter, RD), at 24–40.

The hearing in this matter was held in Los Angeles, California, and, although originally scheduled for four days, lasted five days, November 18–22, 2019. Notice of Hearing dated October 28, 2019, at 1; Transcripts Received dated November 18–22, 2019, at 1–5. The RD is dated February 25, 2020. It recommends that the three registrations at issue be suspended until August 8, 2021, ''but that . . . [the] suspensions not be lifted until . . . [Respondent] has met . . . [two] conditions.'' [2] RD, at 161. The two conditions are (1) completion of courses, other than courses used to

[2] The ALJ ''note[d] that . . . [his] Recommendation would be the same had . . . [he] sustained all of the allegations to which the Government presented expert testimony.'' RD, at 161.

meet any continuing medical education requirement, approved in advance by DEA in prescribing controlled substances and in preparing and maintaining patient medical records, and (2) submission to DEA of a signed ''consent[ ] to inspections by DEA personnel of . . . [Respondent's] medical practice without the need for DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection'' that ''shall be valid for three years from the date . . . [Respondent's registrations] are restored or renewed, whichever occurs latest in time.'' [3] *Id.* The Government filed exceptions to the RD, dated March 16, 2020 (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I conclude that the record establishes, by substantial evidence, that Respondent committed acts rendering his continued registration inconsistent with the public interest. I further conclude that Respondent did not unequivocally accept responsibility for the founded violations and that, even if he had, Respondent did not offer adequate remedial measures.

Accordingly, I conclude that the appropriate sanctions are (1) the revocation of BR0869719 and BA7661564, along with DATA–Waiver No. XR0869719; (2) the denial of any pending application(s) to renew or modify these registrations; (3) the denial of any other pending application(s) by Respondent or by Respondent on behalf of Aurora Surgery Center LP for registration in California; and (4) affirmance of the already issued Order of Immediate Suspension of Registrations. I make the following findings.

II. California Physicians' and Surgeons' Standard of Care

According to the Controlled Substances Act (hereinafter, CSA), ''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). The CSA's implementing regulations state that a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

The OSC is addressed to Respondent at his registered medical practice in California. Therefore, I also evaluate Respondent's actions according to California law and the applicable California standard of care.[4] California, similar to the CSA, requires, during the time period at issue in this adjudication through to the present, that a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a) (Effective April 4, 2011, operative Oct. 1, 2011). This statute explicitly includes two examples of prescriptions that are not legal. First, in salient part, ''an order purporting to be a prescription which is issued not in the usual course of professional treatment'' and, second, ''an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.'' *Id.* California makes the violation of this provision a criminal offense punishable by imprisonment, fine, or both. *Id.*

Other provisions of the California Code further address the characteristics of a lawful controlled substance prescription. For example, the Health and Safety Code prohibits the knowing prescribing of a controlled substance ''to or for any person'' ''[e]xcept in the regular practice of his or her profession.'' Cal. Health & Safety Code § 11154(a) (Current with urgency legislation through Ch. 145 of 2021 Reg.Sess.). Another example is a provision of the Business and Professions Code, in effect during the period of the violations alleged in the OSC, which stated that ''[p]rescribing . . . dangerous drugs . . . without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.'' [5] Cal. Bus. and Prof. Code § 2242(a) (Effective Jan. 1, 2007 to Oct. 10, 2019). By way of further example, section 725(a) of the Business and Professions Code states that ''[r]epeated acts of clearly excessive prescribing . . . of drugs or treatment . . . is unprofessional conduct for a physician.'' Cal. Bus. & Prof. Code § 725(a) (Effective Jan. 1, 2008 to the present). Section 725 makes such clearly excessive prescribing a misdemeanor punishable by fine, imprisonment, or both. The provision explicitly states that a ''practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution,'' and ''[n]o physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with section 2241.5.'' [6] *Id.*

The ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons'' published by the Medical Board of California (hereinafter, MBC) (7th ed. 2013) (hereinafter, MBC Guide to the Laws), informs my interpretation of these California statutes and the applicable California standard of care.[7] According to the MBC Guide to the Laws, ''[o]nly physicians . . . are authorized to write prescriptions under California law'' and ''may prescribe only in the regular practice of their profession, after an appropriate prior examination, and may not furnish any controlled substance to persons not under their care.'' MBC

[3] The RD ''further recommended that if the Administrator has not issued a Final Order . . . prior to the dates that . . . [Respondent's] current . . . [registrations] expire by their own terms, that if . . . [Respondent] has submitted renewal applications, that those renewal applications be approved[,] . . . subject [also] to the two conditions . . . and subject to the condition that . . . [Respondent] not commit any further violations of the . . . [Controlled Substances Act (hereinafter, CSA)] between now and the date of the Final Order.'' RD, at 161.

[4] *See Gonzales* v. *Oregon,* 546 U.S. 243, 269–71 (2006); *see also* OSC, at 2–3.

[5] The California statutory definition of ''dangerous drug'' includes any drug whose dispensing without a prescription is prohibited by federal law. Cal. Bus. & Prof. Code § 4022 (Effective Jan. 1, 2004 to the present).

[6] Section 2241.5 of the California Business & Professions Code, during the time at issue in this proceeding, concerned a physician's prescribing of controlled substances for the treatment of pain or a condition causing pain, including intractable pain. Cal. Bus. & Prof. Code § 2241.5(a) (Effective Jan. 1, 2007 to the present). According to that provision, ''[n]o physician . . . shall be subject to disciplinary action for prescribing dangerous drugs or prescription controlled substances in accordance with this section,'' among other things. Cal. Bus. & Prof. Code § 2241.5(b) (Effective Jan. 1, 2007 to the present). The provision explicitly excepts from its disciplinary action prohibition violations of section 2234 (regarding gross negligence, repeated negligent acts, or incompetence), section 2241 (regarding treatment of an addict), and 2242 (regarding performing an appropriate prior examination and the existence of a medical indication for prescribing dangerous drugs), among others. Cal. Bus. & Prof. Code § 2241.5(c) (Effective Jan. 1, 2007 to the present).

[7] GX 6. Respondent did not object to the admission into evidence of the MBC Guide to the Laws. Tr. 29–30. California law assigns the MBC the responsibilities of, among other things, enforcing the disciplinary and criminal provisions of the California Medical Practice Act, revoking or otherwise limiting certificates after the conclusions of disciplinary actions, reviewing the quality of medical practice carried out by physician and surgeon certificate holders under its jurisdiction, and issuing licenses and certificates under its jurisdiction. Cal. Bus. & Prof. Code § 2004 (Current with urgency legislation through Ch. 145 of 2021 Reg.Sess). Accordingly, the MBC Guide to the Laws informs my understanding of the standard of care applicable in this matter.

Guide to the Laws, at 53. The MBC Guide to the Laws explains that the ''[i]nappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs.'' *Id.* at 55. It reiterates the statutory permission, *supra,* that a ''physician and surgeon . . . may prescribe for . . . a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.'' *Id.* at 56.

The MBC Guide to the Laws sets out the California Medical Board's expectation that ''physicians . . . follow the standard of care in managing pain patients.'' *Id.* at 57. The MBC Guide to the Laws states that the standard of care includes the ''accomplish[ment] of a medical history and physical examination,'' meaning ''an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions and documentation of the presence of a recognized medical indication for the use of a controlled substance.'' *Id.* It explains, among other things, that the ''complexity of the history and physical examination may vary based on the practice location. . . . In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exam.'' *Id.*

The MBC Guide to the Laws discusses the treatment plan, advising that it ''should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* It explicitly points out that ''the physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient'' and that ''[m]ultiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.'' *Id.* The ''annotations'' associated with this section of the MBC Guide to the Laws state that ''[p]hysicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan'' and ''[w]hen the patient is requesting opioid medications for his or her pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.'' *Id.*

The next section of the MBC Guide to the Laws concerns ''informed consent.'' *Id.* at 58. This section states that the ''physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver, or guardian.'' *Id.* The annotation for this section states, in part, that a ''written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent.'' *Id.*

The MBC Guide to the Laws next addresses the matter of ''periodic review.'' *Id.* It makes three points. First, it states that the ''physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health.'' *Id.* Second, it explains that ''[c]ontinuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.'' *Id.* Third, it elaborates by stating that, ''[i]f the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.'' *Id.* Regarding the process of determining whether the response to treatment is satisfactory, the MBC Guide to the Laws states that satisfactory response to treatment ''may be indicated by the patient's decreased pain, increased level of function, or improved quality of life.'' *Id.* It also notes that physicians and surgeons ''should . . . consider[ ]'' ''[i]nformation from family members or other caregivers . . . in determining the patient's response to treatment.'' *Id.*

The next part of the MBC Guide to the Laws is about consultation. *Id.* It states that physicians and surgeons ''should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.* It addresses abuse and diversion by stating that ''physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.'' *Id.* It also warns that the ''management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation, and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.'' *Id.*

The last section in this part of the MBC Guide to the Laws is entitled, ''Records.'' *Id.* at 59. It states that physicians and surgeons ''should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.'' *Id.* The MBC Guide to the Laws also states that ''[t]here is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.'' *Id.*

In compiling the California standard of care applicable to this matter, I looked for, but did not find, any relevant exceptions to the applicable California standard of care I set out above, such as those suggested by Respondent's Case. *Infra* sections III.E. and III.F.

The record that the ALJ transmitted to me includes opposing interpretations of the applicable California standard of care. *See, e.g.,* RD, at 16–17. My adjudication of these differences begins with the appropriate scope of the testimony of the Government's expert witness, includes comparing the testimony of the parties' experts with the applicable California standard of care I set out above, and concludes with my determinations of which expert's testimony to credit. *Infra* sections III.D., III.E., and III.F.

III. Findings

A. Respondent's DEA Registrations

The parties stipulated that Respondent was registered as a practitioner in schedules II through V under DEA Certificate of Registration No. BR0869719 at 73–950 Alessandro Drive, Suite 4, Palm Desert, California 92260. Jt. Stip. Nos. 14, 16; *see also* Government Exhibit (hereinafter, GX) 1, at 3–4. The parties stipulated that Respondent was also registered as a DATA-waived (Drug Addiction Treatment Act) physician certified to treat 100 patients for substance abuse under DATA–Waiver No. XR0869719. Jt. Stip. Nos. 24–25; *see also* GX 1, at 3–

4. This registration expired on April 30, 2021. Jt. Stip. 15; GX 1, at 3–4.

The parties stipulated that Respondent operated Aurora Surgery Center LP and that Aurora Surgery Center LP was registered as a hospital/clinic in schedules II through V under DEA Certificate of Registration No. BA7661564 at 73–950 Alessandro Drive, Palm Desert, California 92260. Jt. Stip. Nos. 17–21; *see also* GX 1, at 1–2. This registration expired on June 30, 2020. Jt. Stip. 22; GX 1, at 1–2.

The OSC suspended all of these authorities. OSC, at 11. While Respondent disputes the immediate suspensions of these authorities and the allegations in the OSC, he did not submit arguments challenging the propriety of the OSC's inclusion of registration No. BA7661564 in its requested relief. *See, e.g.* Tr. 5; *id.* at 43–47; *id.* at Tr. 47–61; *supra* n.1.

B. The Investigation of Respondent

The Diversion Investigator (hereinafter, DI) began investigating Respondent in March 2018 after several databases flagged Respondent as a ''high-risk opioid prescriber.'' Tr. 27; *see also, e.g.,* Jt. Stip. Nos. 37, 40, 43, 46, 49, 52, 58–62, 76–81, 91–95, 98–102, 104, 106–112. The DI's investigative work regarding Respondent, among other things, showed a ''high volume of [opioid] prescriptions, in the thousands, . . . at maximum dosages with little or no change and several months at a time[,] . . . a lot of drug combinations, opioids with benzodiazepines and opioids with stimulants[, and] . . . the holy trinity of an opioid, . . . a muscle relaxer and a benzodiazepine.'' Tr. 33. The DI testified that ''those stood out immediately. . . . [T]hose are the things that we've been trained to look for in analyzing . . . possible diversion or misuse of controlled substances.'' *Id.*

C. The Allegations of Dispensing Violations [8]

Citing 21 U.S.C. 824(a)(4) and 823(f)(2) and (4), the OSC alleges that Respondent's continued registration is inconsistent with the public interest due to his having issued multiple controlled substance prescriptions outside the usual course of professional practice and without any legitimate medical purpose. OSC, at 2, 3, 10. As already discussed, the parties agreed to and submitted 116 joint stipulations. *Supra* section I. Accordingly, there is factual agreement on a significant number of matters.[9] When there is legally relevant factual disagreement, my resolution of the disagreement involves the applicable law and my credibility assessments.

D. The Government's Case

The Government stated its case as being that Respondent ''churn[ed] out dangerously high dosages of controlled substances month after month without any medical justification.'' Government's Proposed Findings of Fact and Conclusions of Law dated January 24, 2020 (hereinafter, Govt Posthearing), at 1. The Government's arguments include that Respondent prescribed dangerously high dosages of controlled substances for years without performing initial physical examinations and evaluations, without performing periodic urine drug screens (hereinafter, UDSes), without addressing aberrant UDSes, without justifying increased dosages, without justifying dangerous controlled substance combination prescribing, and without adequately resolving indicia of abuse and diversion. *Id.* The Government presented its case with two witness, the DI and its expert witness, Timothy Munzing, M.D., and with about 1,750 pages from Respondent's medical records. *See id.* at 43. According to the Government, Respondent's ''insistence that he simply did not document his reasoning or actions was not credible,'' his ''recollection was faulty,'' he ''essentially admitted that he knew and was okay with his patient's drug abuse,'' and was ''nowhere near contrite.'' *Id.* at 1.

Regarding its expert, the Government offered Dr. Munzing ''as a medical expert in the treatment of pain with controlled substances in the State of California.'' Tr. 68. According to the RD, Dr. Munzing ''is not listed as a pain specialist'' on Kaiser's roster of pain specialists, ''does not have fellowship training in pain management,'' and was accepted ''as a medical expert in the treatment of pain with controlled substances in the State of California'' over Respondent's objection. RD, at 12. According to the RD's third footnote, ''[s]ignificantly, Dr. Munzing was not proffered as an expert in the standard of care in California, or as an expert concerning the usual course of professional practice in California.'' *Id.* at 12, n.3; *see also id.* at 13 (''Although not proffered as an expert in such, Dr. Munzing provided extensive testimony in general terms about the standard of care in California.''); *id.* at 17 (''I find Dr. Munzing's testimony concerning the general standard of care to be credible. Since he was not proffered as an expert in the standard of care in California, or in the usual course of professional practice in California, I give limited weight to that testimony.''). The RD's third footnote also records the ALJ's awareness that the ''Acting Administrator previously accepted Dr. Munzing as an 'expert in standard of care for prescribing controlled substances in California,' in a previously published Agency decision.'' *Id.* at 12, n.3. The footnote elaborates by stating that ''[t]here was no hearing in that case, however, and the Acting Administrator relied on Dr. Munzing's declaration, with no expert evidence presented by the respondent.'' *Id.*

As the RD also notes, Respondent objected to the Government's proffer of Dr. Munzing and the ALJ determined that Respondent wanted to voir dire Dr. Munzing. Tr. 68. Voir dire ensued.[10] *Id.* at 69–83. Respondent's voir dire addressed Dr. Munzing's exposure to, and knowledge of, the applicable standard of care. *See, e.g., id.* at 71 (Respondent during voir dire: ''Now you mentioned that you took a couple of courses on pain management and that's how you began to get your exposure to pain . . . standards of care?''); *id.* at 72 (Dr. Munzing during voir dire: ''I am considered to be a specialist in the prescribing of opiates as far as for pain.''); *id.* at 81 (Respondent during voir dire: ''Do you believe as a physician . . . that a physician who's treating 30 patients for a particular condition over

[8] ''Dispense,'' among other things, means ''to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing . . . of a controlled substance.'' 21 U.S.C. 802(10).

[9] Although he stated that he ''would normally accept stipulations between the parties without question,'' the ALJ ''cannot accept'' Stipulation 52j because ''[a]ll parties apparently missed the fact that the actual prescription for alprazolam in September 2018, that is contained in the administrative record, was [not] written by . . . [Respondent]. RD, at 148. I agree with the ALJ, although I note that Stipulation 52j is irrelevant to my Decision/Order given the magnitude and seriousness of the unlawful controlled substance prescribing evidenced elsewhere in the record.

[10] During Dr. Munzing's direct testimony and during Respondent's cross examination of Dr. Munzing, Respondent moved to strike portions of Dr. Munzing's testimony. I do not always agree with the ALJ's decisions to sustain Respondent's objections and to strike Dr. Munzing's testimony. *See, e.g.,* Tr. 305–06 (Respondent's interruption of Dr. Munzing's response to Respondent's question with his motion to strike Dr. Munzing's in-process answer as non-responsive and the ALJ sustaining the motion); *id.* at 384–85; *id.* at 562–63; *but see id.* at 387–88. Other times, I agree with the ALJ's handling of Respondent's motions to strike Dr. Munzing's testimony. *See, e.g. id.* at 334–35 (ALJ's second and third rulings during a line of questioning denying motions to strike because the ALJ ''ha[s]n't heard the rest of the answer yet'' and because the ALJ ''think[s] it's not as responsive as . . . [Respondent] wanted''). To benefit Respondent, despite my disagreement, I accept all of the ALJ's rulings on Respondent's objections and I do not consider any of Dr. Munzing's stricken testimony in my Decision/Order.

10 years and a patient [sic] who has treated 3,000 patients, that the person who treated the 3,000 patients might have a better understanding of the medications and the impacts and the standard of care?''). After the conclusion of Respondent's voir dire, the Government again offered Dr. Munzing ''as an expert on the treatment of pain with controlled substances in California.'' *Id.* at 83. The ALJ ruled immediately, stating that he ''recognize[d] Dr. Munzing as an expert, relying upon the *Gonzalez* case, 76 FR [63118], a 2011 case from DEA'' and ordered the Government to proceed with questioning. *Id.* at 83–84. I find substantial evidence in Respondent's voir dire of Dr. Munzing that it was clear to Respondent that the Government was offering Dr. Munzing as an expert in the applicable standard of care.[11]

While the RD finds ''Dr. Munzing's testimony to be thorough, detailed, and internally consistent,'' it is also critical of it and lists ''several aspects'' of Dr. Munzing's ''testimony and qualifications'' that ''detract from his overall credibility.'' RD, at 14; *see also id.* at 15–17. For example, the RD states that Dr. Munzing ''was going out of his way to assist the Government in presenting its case,'' ''was not simply stating his professional expert opinion in an unbiased manner,'' ''refused to concede rather obvious points,'' ''frequently volunteered testimony beyond a pending question, testimony beneficial to the Government . . . [that] was distracting and unnecessarily extended the hearing,'' and ''did not seem as familiar with the facts or the law as he should have been as an expert witness.'' *Id.* at 14–16.

I do not share all of the RD's perspectives and conclusions about Dr. Munzing.[12] Regarding the ''rather obvious points'' that the RD states Dr. Munzing ''refused to concede,'' the RD cites Dr. Munzing's refusal to state that Respondent ''had more experience treating chronic pain patients than he did.'' *Id.* The RD correctly characterizes Dr. Munzing's testimony to be that Respondent ''may have more experience in the procedural end of it, but 'in the area of appropriate pain management, I, not sure I would say that.' '' *Id.* The RD criticizes Dr. Munzing by stating that ''the questions asked nothing about appropriate care.'' [13] *Id.*

By way of further example, the RD states that, ''when asked the general question of whether a doctor [Respondent] who had treated 3,000 patients for a particular condition might have a better understanding of how to treat those patients than a doctor who had only treated 30, Dr. Munzing would not agree.'' *Id.* at 14–15. ''Rather,'' the RD criticizes Dr. Munzing, stating ''he answered another question. 'Having reviewed some of those patients I have great concern . . . .' It was a general question, but even during voir dire Dr. Munzing was testifying about how bad of a doctor he believed . . . [Respondent] to be.'' [14] *Id.* at 15.

I do not share these RD criticisms. For example, when Respondent asked Dr. Munzing whether Respondent ''has significantly more experience treating chronic pain patients than you do,'' Dr. Munzing's response agreed, in part, when he said that Respondent did have more experience ''especially in the procedural end of it.'' Tr. 80. I credit Dr. Munzing because he gave an honest answer, even admitting the dearth of his experience ''in the procedural end of it.'' *Id.* In the context of this proceeding, I further note Dr. Munzing's obvious appreciation that my responsibilities under the CSA do not call for me to rubber stamp a registrant's controlled substance prescribing based on the ''significantly more experience'' he might have ''treating chronic pain patients than'' the Government's expert witness. *Id.* Instead, Dr. Munzing's responses to Respondent's voir dire show me that Dr. Munzing knows to distinguish between the number of individuals a registrant has seen in his practice and the registrant's compliance with the applicable standard of care when ''treating'' those individuals. *See id.*

As already discussed, when the ALJ recognized Dr. Munzing as an expert, he stated that he was doing so ''relying upon the *Gonzalez* case.'' [15] *Id.* at 84. He did not, however, identify the relevant portion of *Gonzalez* upon which he was relying. *Id.* My review of the Chief ALJ's (adopted) Recommended Decision in *Gonzalez,* as I endeavor to understand the ALJ's thought process, indicates that

[11] *See also United States* v. *Diaz,* 876 F.3d 1194, 1199 (9th Cir. 2017) (citing *United States* v. *Chube,* 538 F.3d 693, 698 (7th Cir. 2008) (''When all is said and done, we agree with the Government that it is impossible sensibly to discuss the question whether a physician was acting outside the usual course of professional practice and without a legitimate medical purpose without mentioning the usual standard of care.'')).

[12] Regarding ''not seem[ing] as familiar with the facts or the law as he should have been as an expert witness,'' the RD states ''[f]or example, Dr. Munzing relied on the . . . [Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain—United States (2016) (hereinafter, CDC Guidelines)] when formulating his opinions in this case'' and ''[i]t is obvious that he did not learn that those Guidelines did not apply to . . . [Respondent] until after he began to testify.'' RD, at 16. On these points, I note several occasions during voir dire when Dr. Munzing provided his view of the CDC Guidelines, Respondent objected as ''not responsive,'' and the ALJ sustained the objection. For example, on voir dire, Respondent asked Dr. Munzing: ''With respect to the CDC guidelines, is it your opinion they apply to pain specialists or not?'' Tr. 82. Dr. Munzing responded by stating that ''these are guidelines. These are not required. But the general principles, I think, are good principles for everyone who is prescribing controlled substances. Again, they're not required.'' *Id.* When Respondent moved to strike ''as not responsive,'' the ALJ sustained his motion. *Id.; see also id.* at 77 (Respondent's questioning of Dr. Munging: ''Q: Are you aware that the CDC guidelines in 2016 applied to primary care and to family medicine but are not intended to apply to pain specialists? A: Well, the CDC guidelines are guidelines strictly. They're not standard of care. And so the intent is to protect patients and patient safety.'' Respondent: ''Move to strike as not responsive, Your Honor. Judge Dorman: Granted.''). These struck responses of Dr. Munzing concerning the CDC Guidelines do state that the CDC Guidelines are not the standard of care, that there is no requirement for Respondent to have followed them, and, nevertheless, that they are ''good principles'' commended to ''everyone who is prescribing controlled substances.'' *Id.* at 77, 82. Accordingly, I disagree with the RD that Dr. Munzing is ''not . . . as familiar with the facts or the law as he should have been as an expert witness,'' impacting Dr. Munzing's ''overall credibility.'' RD, at 16; *see also, e.g.,* Tr. 532 (Dr. Munzing's testimony that his opinion does not depend on the strict application of the CDC guidelines); *id.* at 533 (Dr. Munzing's testimony that CDC is only one of many entities that issue controlled substance related guidelines, along with the American Academy of Pain Medicine, the American Pain Society, and the Agency Directors in Washington, and noting that only one aspect of his report dealt with the CDC's perspective on Morphine Milligram Equivalents).

[13] I note that ''appropriate pain management'' and ''appropriate care'' are relevant to my adjudication of the OSC.

[14] The question Respondent asked that the RD quotes Dr. Munzing as answering was: ''Do you believe as a physician that a patient—that a physician who's treating 30 patients for a particular condition over 10 years and a patient [sic] who has treated 3,000 patients, that the person who treated the 3,000 patients might have a better understanding of the medications and the impacts and the standard of care?'' Tr. 81. In other words, contrary to what the RD suggests, Respondent *did ask* Dr. Munzing about Respondent's ''understanding of . . . the standard of care,'' as well as Respondent's ''understanding of'' controlled substances and the impact of controlled substances. *Id.* According to the transcript, I also note, Dr. Munzing did *not* state that he treated ''30 patients for a particular condition over 10 years.'' Instead, after Respondent asked Dr. Munzing, ''Since 2011, approximately how many patients have you managed for chronic pain,'' Dr. Munzing responded ''[p]robably in the neighborhood of 30 to 50 *on an ongoing basis.*'' *Id.* at 71. Respondent followed up, asking, ''With respect to, *I think you said between 30 and 50 patients total that you've managed in the last 10 years with chronic pain,* what percentage of those were you prescribing medications to?'' *Id.* at 72 (emphasis added). Dr. Munzing responded that, ''I should probably rephrase that, is [sic] those are the ones who probably were being prescribed probably about 30 opiates on an ongoing basis. If you want to know total patients with chronic pain at any time, that would be hundreds.'' *Id.*

[15] In *Carlos Gonzalez, M.D.,* 76 FR 63118 (2011), the then-Administrator adopted the Recommended Decision of the Chief Administrative Law Judge, John J. Mulrooney, II, ''except as discussed below.'' 76 FR at 63118.

the Government expert ''was offered and accepted as an expert in the area of pain management.'' 76 FR at 63125. I note that the Government, in this matter, similarly offered Dr. Munzing ''as an expert in the treatment of pain with controlled substances in California.'' Tr. 68.

In *Gonzalez,* the Chief ALJ criticized the report of the Government's expert witness as being ''confusing and singularly unhelpful,'' and ''disorganized, unfocused, and written in a manner that bespeaks a free association narration of documents and other items provided to him by the Government in no particular order.'' 76 FR at 63125. The Chief ALJ was also critical that the Government's expert in *Gonzalez* was ''asked to review a mass of paper wherein patient charts that were eventually properly admitted into evidence are interspersed with DEA investigative reports and other documents that were not.'' *Id.* The RD in this matter gives no indication that the ALJ has these, or similar, criticisms.

At the same time, the Chief ALJ's (adopted) Recommended Decision in *Gonzales* attributes to the Government's expert witness, and relies on, input regarding the applicable standard of care and whether the respondent prescribed and dispensed controlled substances other than for a legitimate medical purpose or outside the usual course of professional practice. *See, e.g.,* 76 FR at 63145–46 (''The uncontroverted and persuasive testimony of the Government's expert . . . established, by a preponderance of the evidence, that the Respondent's prescribing practices fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents, as well as to the patients whose charts he reviewed. On this record, the Government has established that the Respondent employed his . . . [registration] and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice, based on the absence of acceptable physician-patient relationships and even minimal due care in documentation as those concepts are dealt with under federal and Florida state law.''). In other words, despite concerning issues, such as with the expert's report, the Chief ALJ, in *Gonzalez,* credited the testimony of the Government's expert witness in his (adopted) Recommended Decision.

In sum, the meaning of the ALJ's statement, that he admitted Dr. Munzing as an expert witness ''relying upon the *Gonzalez* case,'' is not apparent from the RD. It is clear, though, that the words the Government used at this and the *Gonzalez* hearings to proffer its expert witnesses are strikingly similar. It is also clear that the Chief ALJ relied on the testimony of the Government's expert witness in *Gonzalez* about the applicable standard of care, respondent's compliance with the applicable standard of care, and whether respondent's controlled substance prescribing and dispensing were for other than a legitimate medical purpose or outside the usual course of professional practice. *Supra.* The RD's third footnote and other statements about the scope of Dr. Munzing's proffered expertise, therefore, do not appear to be consistent with the ALJ's reliance on *Gonzalez* when accepting Dr. Munzing as an expert witness.[16] *Supra.* I conclude and find, including based on the Government's proffer of Dr. Munzing as ''an expert in the treatment of pain with controlled substances in California'' and on the ALJ's identification of *Gonzalez,* that the appropriate scope of Dr. Munzing's expert witness testimony includes the applicable standard of care for Respondent's controlled substance prescribing in California, whether Respondent's controlled substance prescribing complied with the applicable standard of care, and whether Respondent's controlled substance prescribing was outside the usual course of professional practice.

The RD further minimizes Dr. Munzing as an expert witness by concluding that the ''expert qualifications'' of Respondent's expert witness, Dr. Standiford Helm, II, are ''superior qualifications to testify concerning pain management'' and that, ''[i]n fact, . . . [Respondent's] credentials, based upon experience and training, surpass Dr. Munzing's credentials with respect to pain management.'' RD, at 16. The RD, adding the ''standard of care'' to these ''pain management'' conclusions, then states that, ''Thus, on issues of pain management, and the standard of care concerning pain patients, I will give greater weight to the testimonies of Dr. Helm and to that of . . . [Respondent]'' than to Dr. Munzing.[17] *Id.* at 16–17. Based on my analysis of the applicable standard of care, *supra,* and my review of the entire record transmitted to me, I reach a different conclusion.

My responsibilities under the CSA and the content of the OSC issued to Respondent mean that the focuses of my adjudication of this matter include the applicable standard of care for controlled substance prescribing, whether Respondent issued controlled substance prescriptions in compliance with the applicable standard of care, and whether Respondent issued controlled substance prescriptions outside the usual course of professional practice. While the experience of an expert is important in my assessment of the weight to give the expert's testimony, the reliability of that testimony is paramount. According to the Supreme Court, evidence and expert testimony must '' 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance,'' and ''any and all scientific testimony or evidence admitted . . . [must] not only [be] relevant, but reliable.'' *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 589, 591 (1993). In assessing reliability, an expert's experience, standing alone, is not a sufficient foundation for rendering reliable *any* conceivable opinion an expert may express. *See, e.g., United States* v. *Frazier,* 387 F.3d 1244, 1261 (11th Cir. 2004). Further, an expert's overwhelming qualifications may bear on the reliability of his testimony, but they are by no means a guarantor of reliability. *See, e.g., Quiet Technology DC–8, Inc.* v. *Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1341 (11th Cir. 2003). Accordingly, I use ''what is known,'' in this situation, the applicable standard of care drawn from California law and issuances of the MBC, *supra* section II, to evaluate the reliability of the record expert witness testimony, not merely each expert's experience and training. *See, e.g., United States* v. *Frazier,* 387 F.3d at 1261.

Dr. Munzing testified that the MBC Guide to the Laws ''informed . . . [his] opinion on what the standard of care is in California and what is done in the usual course of professional practice.''

[16] In addition, I note that the ALJ explicitly allowed Dr. Munzing to give his opinion about the standard of care and the usual course of professional practice, without raising the scope of Dr. Munzing's expert testimony. *See, e.g.,* Tr. 206 (ALJ overruling Respondent's ''vague and ambiguous as to time, and asked and answered'' objection to the Government's question to Dr. Munzing of whether ''[i]n . . . [his] opinion, did that combination of prescriptions [methadone, Roxicodone, and Soma] issued by . . . [Respondent] meet the standard of care or was issued in the usual course of professional practice?'').

[17] The RD continues, ''[t]hat being said, I find Dr. Munzing's testimony concerning the general standard of care to be credible. Since he was not proffered as an expert in the standard of care in California, or in the usual course of professional practice in California, I give limited weight to that testimony.'' RD, at 17.

Tr. 85. He also testified that the ''main categories'' of the MBC Guide to the Laws are ''very consistent with the general practice of medicine . . . even though the fine details may pertain to controlled substances.'' *Id.* at 87–88. Dr. Munzing testified about the main categories of the applicable standard of care as addressed in the MBC Guide to the Laws and the ''fine details.'' *Id.* at 528 (Dr. Munzing's testimony identifying history, physical examination, evaluation, minimizing risk, and the dangers of combination of medicines); *see also, e.g., id.* at 87–89 (Dr. Munzing specifically agreeing with the Annotation in the MBC Guide to the Laws that ''[i]n continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam'').[18]

Dr. Munzing's testimony in response to questions about whether the applicable standard of care or the usual course of professional practice in California for the treatment of pain with controlled substances depends on the specialty of the prescribing physician is consistent with the MBC Guide to the Laws.[19] Dr. Munzing testified that the applicable standard of care and usual course of professional practice in California apply equally to any physician prescribing controlled substances for chronic pain over a long period of time regardless of the physician's specialty. *Id.* at 123–25. He specifically testified that ''taking history, do[ing] an exam, trying to mitigate risk, informed consent, those key aspects are really whether you're in family medicine, internal medicine, pain management, whoever is doing that, whoever's prescribing those medications.'' *Id.* at 124; *see also id.* at 124–25 (''[W]hen I'm working hand in hand with our pain management specialist, . . . we basically are following the same standards.''); *id.* at 528 (Dr. Munzing's testimony that the basic elements of the applicable standard of care are the same regardless of prescriber's medical specialty).

Dr. Munzing testified that the applicable standard of care addresses taking history, doing a physical examination, developing a treatment plan and objectives, obtaining informed consent, conducting periodic reviews, consulting, and record documentation. *Id.* at 531, citing MBC Guide to the Laws, at 57–61; *see also* Tr. 575–80 (Dr. Munzing responding to the ALJ's questions about what a doctor is required to do when issuing a new controlled substance prescription and what, if anything, a doctor is required to document when increasing the strength or the quantity of a previously prescribed controlled substance).

Regarding the applicable standard of care first prong of ''History/Physical Examination,'' Dr. Munzing's testimony tracked and elaborated on the MBC Guide to the Laws. He testified that ''certainly one would do a general exam looking at are the medications affecting you in general,'' specifically mentioning an exam of the heart and lung. Tr. 361. Regarding the specifics of the musculoskeletal exam, Dr. Munzing testified that the physician looks at the patient ''at rest and seeing certain movement, flexion, extension, lateral extension, rotation, straight leg raising test.'' *Id.* Dr. Munzing testified that neurological function is also part of the requisite examination to inform the physician about how the patient is doing, specifically mentioning sensory motor and deep tendon reflexes. *Id.* Dr. Munzing specifically testified that part of the physician's physical examination is ''actually touch[ing]'' the patient to discern abnormalities and areas of tenderness, and the change in those abnormalities and tender areas over time. *Id.* at 362. I find that Dr. Munzing's testimony is consistent with, and usefully and helpfully elaborates on, the ''History/Physical Examination'' section of the MBC Guide to the Laws. MBC Guide to the Laws, at 59.

Regarding the applicable standard of care third prong of Informed Consent, Dr. Munzing explained that ''for most of us, the most dangerous thing that we do is write a prescription for a controlled substance.'' Tr. 89. He testified that ''consistent with the practice of medicine, . . . we need to inform the patient about . . . the potential risks, the potential benefits, the alternatives.'' *Id.* at 89–90. He stated that, for controlled substances, an informed consent includes why the controlled substance is being prescribed, what the potential risks are, what the side effects, from mild to addiction, overdose, and death, could include, and that there are potential complications. *Id.* at 90–91. Dr. Munzing also testified that it is insufficient only to give a patient a document that says these are the potential hazards or benefits and risks of taking this particular drug and to maintain that document in the medical record. *Id.* at 596 (Dr. Munzing's testimony that if a doctor documents that he gave the patient the informed consent and they discussed it, that ''shows that you actually did that rather than someone at the front desk just saying sign this, it's one of 10 forms you find when you come to the office'' and the doctor need not write down everything discussed).[20]

Dr. Munzing testified about the fourth prong of the applicable standard of care, Periodic Review, describing it as how to see ''whether or not . . . our [chronic pain] management [is] working . . .[,] [a]re they getting better?'' *Id.* at 91. He explained that the Periodic Review involves determining whether there are ways to decrease pain, to improve function, to mitigate the risk, and to assess compliance. *Id.* He also testified that urine drug tests and checking CURES are part of Periodic Reviews. *Id.* When the pain improves, Dr. Munzing testified, ''many times we can then, and really should, try to decrease the risk by decreasing the medication and looking for safer alternatives.'' *Id.*

Regarding the meaning of the fifth prong of the applicable standard of care,

[18] Dr. Munzing defined ''chronic pain'' as ''probably over three months in nature . . . [although] [s]ome may use a shorter time frame or longer, but . . . three months is a time frame that many people will utilize. And so acute pain is what suddenly happens. It usually gets better, but sometimes it reverts into an ongoing, . . . chronic pain, and that's for a longer period of time.'' Tr. 89.

[19] The Medical Board of California ''expects *physicians and surgeons* to follow the standard of care in managing pain patients.'' MBC Guide to the Laws, at 59 (emphases added). I see nothing in the MBC Guide to the Laws that states, allows, or suggests a different application of its contents based on the prescriber's medical specialty.

In the second annotation to the section entitled ''History/Physical Examination,'' the MBC Guide to the Laws notes a differentiation based on where the medical treatment is provided. *Id.* That differentiation concerns the complexity of the history and physical examination ''based on the practice *location,*'' not based on the specialty of the physician or surgeon. *Id.* (emphasis added). ''In the emergency department, the operating room, at night or on the week-ends,'' the MBC Guide to the Laws states, ''the physician and surgeon may not always be able to verify the patient's history and past medical treatment.'' *Id.* This annotation in the MBC Guide to the Laws elaborates, without making a distinction based on the specialty of the treating physician/surgeon, stating ''[i]n continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exam.'' *Id.; see also supra* section II.

[20] When the ALJ asked Dr. Munzing whether, if a doctor fails to document informed consent to a controlled substance prescription, that prescription is issued outside the usual course of professional practice and for no legitimate medical purpose, Dr. Munzing responded that he ''would say that if that's the only thing that's missing, . . . [he] would probably not call it outside—. . . [he] would be concerned, but . . [he] wouldn't strictly—and also it depends on the dosages. . . . [I]f we're on huge amounts, then yes. . . . [I]f we're on large amounts, combination, things like that, but if someone is on again, hydrocodone five milligrams twice a day, no, I wouldn't say that if everything else looks fine, but if you're on high dosages, which are defined whether it be 90, 120, 200, if you're on dangerous combinations, then yes, you must have, like anything else that is potentially hazardous, even taking off a mole off your arm which is pretty minimal, you must have some informed consent.'' Tr. 594–95.

Consultation, Dr. Munzing's testimony described it as ''if people are not getting better . . . or they're getting worse,'' then there is a consultation with the appropriate specialist. *Id.* at 92–93. In addition to giving examples of a need for a cardiology, pain management, and interventionalist consultation, he testified that ''it may very well be an addiction medicine specialist to see whether or not they feel there's evidence that this person may have, in addition to a pain issue, . . . an opioid use disorder or addictive . . . issue.'' *Id.* at 93. Concerning the ''special attention'' called for by the Consultation prong of the applicable standard of care ''to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion,'' Dr. Munzing testified that ''[w]hen you're looking at patients, you also have to look at their social situation and who they're living with or they're being around.'' *Id.* He elaborated by testifying that there are ''certain situations where someone may be at risk for having medications stolen . . . whether it be family members or someone in their social milieu.'' *Id.* Dr. Munzing further elaborated by stating that being around ''people who potentially have legal issues, unless you know the specifics, it may be that they may be congregating with people who are putting the medications at higher risk for being diverted from a legitimate to an illegitimate basis.'' *Id.* at 93–94.

Concerning records, the sixth prong of the applicable standard of care, Dr. Munzing testified that ''[i]t's vitally important to have accurate, complete medical records.'' *Id.* at 115. ''This is not an area where you want to skimp,'' he stated. *Id.* Specifically, according to Dr. Munzing, ''at every visit one needs to make sure that they document what they do and don't document things that weren't done.'' [21] *Id.* Dr. Munzing highlighted two areas for medical record documentation. First, he testified that ''it's important to document what you do when you have that variances [sic] to explain those so people can look at it and go, okay, the doctor paid attention to it, whether it be an abnormal lab test, imaging test, urine drug test, CURES that doesn't look right, and so the doctor paid attention to it, addressed it.'' *Id.* Second, Dr. Munzing identified addressing the pain management plan and the management of the patient in the records, testifying that the records need to show that the physician is ''not just throwing [a] controlled substance at it but in the great scheme of things and making efforts to try to mitigate the risk . . . making attempts to try to bring down the medications whenever possible and reduce the potential interactions between opiates and other medications.'' *Id.* at 115–16.

Dr. Munzing testified about the medical care Respondent provided, and controlled substance prescriptions Respondent issued to, A.A., R.B., S.D., L.D., S.H., and J.M. *Id.* at 125–301). He testified about why the applicable standard of care requires physicians to reduce the daily morphine milligram equivalents (hereinafter, MME) they prescribe.[22] *Id.* at 113. He framed his testimony by stating that physicians ''take care of patients for all kinds of issues that are inherently dangerous, and constantly look[ ] at how can we minimize and reduce the risk to the patient.'' [23] *Id.* at 112. He stated that ''really . . . there is no safe, inherent safe dosage in opiate.'' *Id.* at 119. Dr. Munzing cited studies showing that opiates, ''even at the level of 50 . . . [MME/day, increase] the risk for overdose and death.'' *Id.* at 113. He continued his testimony by stating that ''[o]nce you get to 100 [MME/day], it goes up even farther. It's approximately 8.9 times more risky for overdose than someone who is on a very low dosage.'' *Id.; see also id.* at 120 (Dr. Munzing's testimony that ''[s]tudies have shown that when you go over 120, the risk of developing opiate abuse or opiate use disorder goes up . . .[,] [t]he numbers are as high as 20 to 30 percent over that amount''). Dr. Munzing testified that the applicable standard of care ''requires that we try to mitigate the risk any way possible.'' *Id.* He testified that there are patients for whom opiates cannot be reduced and that there are patients who are ''optimized'' at a low dosage that is ''not a very dangerous level, and so it may be that you continue.'' *Id.* ''But,'' Dr. Munzing testified, ''when someone's on the higher end, probably, you know, somewhere over 100, 120, 150 . . . [MME/day], if there are ways we can bring them down, you're greatly benefitting them because they are in the higher risk kind of category.'' [24] *Id.* at 114; *see also id.* at 807–10 (Dr. Helm's testimony that he thinks it is ''obvious'' that higher doses of controlled substances carry higher risk and that, if a physician is going to prescribe high doses, the physician has ''got to document why these doses are appropriate'').

Similarly, Dr. Munzing also testified about how, consistent with the applicable standard of care and the usual course of professional practice, a physician increases the dosage of a controlled substance. *Id.* at 91–92. According to Dr. Munzing, a physician would increase the dosage of a controlled substance due to ''continued symptoms and . . . potentially worsening symptoms.'' *Id.* at 92. Before increasing the dosage of a controlled substance, the applicable standard of care calls for an updated history to determine, for example, whether there was a sudden injury or accident, and an evaluation of the severity of the associated symptoms, for example, determining whether there are neurological and other symptoms. *Id.* Following the applicable standard of

[21] Dr. Munzing testified that, with electronic medical records, ''it's sometimes easy to get things in the records that didn't really happen.'' Tr. 115.

[22] Dr. Munzing also testified that there is no ''maximum MME . . . that a physician can no longer prescribe,'' that ''there are medically necessary reasons for why a physician might prescribe more than 90 MME to treat pain,'' but that ''[n]inety is certainly recognizing that the risks kind of continue going up, and so one constantly needs to look at the potential risks and potential benefits.'' Tr. 118–19.

[23] A non-controlled substance example that Dr. Munzing offered is the use of chemotherapy. Tr. 113. While chemotherapy has risks, he stated, it is given to cancer patients. *Id.* As soon as possible, he added, the patient is taken off chemotherapy to discontinue those risks. *Id.* ''[S]o that really pertains to medicine in general, not only to controlled substances,'' Dr. Munzing testified. *Id.*

[24] The Government asked Dr. Munzing whether ''Calculating Total Daily Dose of Opioids for Safer Dosage,'' GX 8, a two-page CDC document, ''inform[ed] . . . [his] opinion on what the standard of care is for what physicians should do in the usual course of professional practice in California.'' Tr. 116. Dr. Munzing answered that ''I don't know that this document does, but the general concepts do because they're consistent with a lot of other—the CDC guidelines and others. And so I don't know that this sheet of paper did, but the concepts certainly do.'' *Id.* This and other testimony show that Dr. Munzing familiarizes himself with relevant published literature and uses material in that literature that is consistent with the applicable standard of care to assist his implementation of the applicable standard of care. *See, e.g., id.* at 110 (Dr. Munzing's testimony referring to published literature, in this instance, about the frequency of conducting UDSes based on the dosage of the prescribed controlled substance); *id.* at 112–13 (Dr. Munzing's reference to studies showing that opiates increase the risk for overdose and death and that twice the MME per day of those opiates increases that risk about 8.9 times); *id.* at 113–14 (Dr. Munzing's reference to two entities' definitions of ''high'' opiate ranges, analysis of those ranges, and use of that authoritative input to implement the applicable standard of care to reduce the risk to, and benefit, patients); *id.* at 119–20 (Dr. Munzing's reference to organizations and agencies that are now recommending more frequent urine drug tests when high dosages of opiates are being prescribed); *id.* at 335. Dr. Munzing's practice of familiarizing himself with relevant published literature and using material in that literature that is consistent with the applicable standard of care to assist his implementation of that standard of care contributes to the value of his testimony to my adjudication of the OSC. Accordingly, as already discussed, I disagree with the RD's conclusion that Dr. Munzing ''did not seem as familiar with the facts or the law as he should have been as an expert witness,'' citing, as an example, Dr. Munzing's statements about the CDC Guidelines. RD, at 16.

care, the physician would do a thorough exam of the pained area, which may or may not call for imaging and laboratory testing. *Id.* According to Dr. Munzing, under the applicable standard of care, the physician is ''to determine that what . . . [the physician is] doing needs to be increased[, to] weigh that with the increased risk or potential risk . . . [to] the patient, . . . typically looking at kind of a multidisciplinary, multimodal way of managing[, and to determine] are there safer alternatives that we can bring in, whether it be physical therapy or others, that might be of benefit that may be safer.'' *Id.* Dr. Munzing also stated that ''certainly, when you go over 90 [MME], one needs to make it clear to the patient that . . . the risk . . . is higher and so, again, the informed consent.'' *Id.* at 119.

Regarding monitoring, given the increased risk that increased MME may lead to opiate abuse or opioid use disorder, Dr. Munzing testified about the physician's continuing need to look for whether there is ''any evidence that there's any opioid abuse going on, addiction going on.'' *Id.* at 120. ''[S]o,'' he stated, ''it's more intense monitoring once you're over'' 120 MME. *Id.* Referencing ''a number of organizations and agencies . . . [that] are recommending more frequent urine drug tests,'' Dr. Munzing's testimony stated that ''monitoring . . . [patients] more closely . . . , seeing them more frequently, urine drug tests more frequently, checking CURES or the PDMPs more frequently to ensure that they're actually complying with what you're doing.'' [25] *Id.* at 119–20. Dr. Munzing stated that there are patients who ''desperately need'' high dosages of opioids, ''but one would want to ensure that they're in full compliance with what you're prescribing and that you're benefitting [them]—and, again, once you're over . . . [120 MME] constantly trying to see when can we start to step down if at all possible.'' [26] *Id.* at 120.

Dr. Munzing also testified about the need for physicians to be looking out for red flags of abuse or diversion.[27] *Id.* at 95–96; *see also id.* at 581–82 (Dr. Munzing responding to the ALJ's question about what, if anything, a doctor should do if a patient requests a particular medication). Stating that ''there's probably a list of at least 20 or more'' red flags, Dr. Munzing specifically identified refilling medications early; escalating dosages of opiates; seeing multiple physicians to get controlled substances; using multiple pharmacies; driving long distances to see the physician or provider; and having opiates in combination with benzodiazepines, with benzodiazepines and muscle relaxants, and with stimulants.[28] *Id.* at 95.

The Government asked Dr. Munzing to address urine drug testing. *Id.* at 102. Dr. Munzing explained that controlled substances are ''scheduled because they're dangerous drugs in many ways.'' *Id.* at 100. According to his testimony, ''[i]t's vitally important when you're prescribing controlled substances . . . to do the best that we can as prescribers to ensure that the patient is complying with what we're prescribing'' to determine, for example, ''if there's any conflicts between medications'' and to try to ''mitigate the risk of the treatments'' and to ''optimize treatment.'' *Id.* at 100, 102. Dr. Munzing testified that drug testing indicates ''whether or not . . . medications that you're prescribing [are] showing up as they should . . . [and whether] other things [are] showing up that shouldn't be there.'' [29] *Id.* at 102.

Dr. Munzing described aberrant drug test results. *Id.* at 103–09. He testified that a positive test for a substance that the physician did not prescribe is an aberrant result, that ''it's your responsibility to try to find out why that is there,'' that the result of the inquiry ''should be very well documented in the record,'' and that, ''if it's not legitimate, then what are your actions based on the non-legitimate result?'' *Id.* at 103–04; *see also id.* at 584–85 (Dr. Munzing's testimony responding to the ALJ's question about whether the applicable standard of care requires a doctor to document an aberrant UDS result); *id.* at 775 (Dr. Helm's testimony ''agree[ing] that there should be, and this holds throughout whenever there's a UDS which is not consistent for whatever reason, including this one, that yes, there should be a discussion of your findings on the UDS''). Dr. Munzing also testified that a negative test for a drug that the physician prescribed, when the testing took place less than 30 days after a 30-day prescription was filled, is aberrant. *Id.* at 104. He testified that it's ''incumbent'' on the physician ''to try to investigate'' the negative result. *Id.; see also id.* at 111 (Dr. Munzing's testimony equating his use of the word ''incumbent'' with the ''standard of care in the usual course of professional practice''). For example, he testified, it could be negative due to the ''sensitivity of the test, if they're on a fairly low dosage.'' *Id.* at 105; *see also id.* at 110–11 (citing GX 7, at 19). In such a situation, Dr. Munzing stated that he has ''called the toxicology lab, talked to the person, and they said, oh, well, the number was this[, . . .] [i]t's just under that and so they're really taking it, but it comes across negative.'' *Id.* at 105; *see also id.* at 110–11. Dr. Munzing again testified that the physician's inquiry would be ''well documented in the record so someone looking at it . . . [knows] that they are taking it, but it just doesn't test positive because we're looking at a negative positive, not at a

[25] ''PDMP'' means a Prescription Drug Monitoring Program, such as CURES.

[26] I note that there are instances when Dr. Munzing's testimony sets out the applicable standard of care even though he does not explicitly state that he is doing so. *See, e.g.,* Tr. 119–20.

[27] Regarding the section in the MBC Guidelines for Prescribing Controlled Substances for Pain (2014) (hereinafter, MBC Guidelines for Prescribing) addressing ''Ongoing Patient Assessment'' and Dr. Munzing's testimony about it, they also are consistent with the MBC Guide to the Laws. *See, e.g.,* MBC Guide to the Laws, at 58 (material addressing periodic reviews).

The Government also asked Dr. Munzing to testify about the section called ''Compliance Monitoring'' in the MBC Guidelines for Prescribing. Tr. 100–01. Dr. Munzing testified that ''compliance monitoring'' is ''trying to do the best that we can as prescribers to ensure that the patient is complying with what we're prescribing.'' *Id.* at 100. When asked for examples of what physicians can do to ensure compliance, Dr. Munzing's testimony addressed ''monitoring and checking'' CURES which, he stated, is ''[n]ow . . . mandatory in the State of California . . . whether it be in primary care, specialty care, pain medication—pain management, we have to check all patients on chronic controlled substance medications on at least an every four-month basis.'' *Id.* at 101. ''And,'' he testified, ''if you start a new medication, you've got to check it again.'' *Id.* In response to the ALJ's questioning, Dr. Munzing testified that checking CURES became mandatory on October 2, 2018. *Id.* Some of the controlled substance prescribing about which the parties stipulated occurred after October 2, 2018. *See, e.g.,* Stipulations 37 (A.A.), 40 (R.B.), 43 (S.D.), 49 (S.H.), and 52 (J.M.).

[28] Dr. Munzing's testimony is consistent with the section called ''Important Information for Patients'' in the Food & Drug Administration's (hereinafter, FDA) publication entitled ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' August 31, 2016, GX 9, at 1–2. That section states, in part, that ''FDA is warning patients and their caregivers about the serious risks of taking opioids along with benzodiazepines or other central nervous system (CNS) depressant medicines, including alcohol. Serious risks include unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, coma, and death. These risks result because both opioids and benzodiazepines impact the CNS, which controls most of the functions of the brain and body. . . . If you are taking both opioids and benzodiazepines together, consult your health care provider to see if continued combined use is needed.'' *Id.*

[29] Dr. Munzing testified that the frequency of conducting urine drug testing ''depends on a lot of issues.'' Tr. 109. Dr. Munzing stated that ''a lot depends on the dosage that they're on. Are they on a low dosage, a medium dosage, a high dosage? And are they on multiple controlled substances? Is it just one opiate, or is it an opiate and other medications? And so a lot goes into the determination, but at least once a year, and on high dosage, probably once a month.'' *Id.* at 110.

numerical number.'' *Id.* at 105; *see also id.* at 111–12.

Dr. Munzing testified that a negative UDS result for a prescription drug, filled more than thirty days before the UDS, is aberrant. *Id.* at 106. He stated that the way such an aberrant result is handled depends on the circumstances. *Id.* When the drug that tested negative is a very high dose of a prescription drug, the individual for whom the drug was prescribed is ''probably going through withdrawal'' if the individual is ''really . . . out'' of the drug. *Id.* at 106–07. Consequently, ''you need to inquire of them, are you having withdrawal symptoms?'' and employ one of the standardized objective withdrawal scales to assess the presence of withdrawal. *Id.* at 107. Dr. Munzing also testified that ''if people desperately need these medications, they usually will do everything possible not to run out.'' *Id.* With that starting point, Dr. Munzing testified that he would ''use that as an opportunity . . . to start bringing you down, not necessarily to zero, but start cranking it down a little bit over time and using that as an opportunity.'' *Id.* Dr. Munzing immediately added, ''[b]ut that again would be well documented in the records.'' *Id.*

Dr. Munzing also testified that, for non-cancer pain patients, it is not safe to use marijuana while also taking prescribed opioids due to the ''inherent risks of THC'' and ''it's . . . [his] responsibility as a treating physician to try to keep you as safe as possible in . . . managing . . . patients . . . [a]nd if there's something else coming into that that . . . [he] can't determine what dosage of THC, . . . it just puts the patient at much higher risk.'' *Id.* at 108–09; *see also id.* at 701–02 (Dr. Helm's testimony about THC). He also testified that he has ''seen a few people where they encourage the use of THC as they are tapering down significantly, and so you can see that this is part of their management plan.'' *Id.* at 109. In this instance, ''[a]gain, that would be very well documented in the medical records exactly what the plan is, how we're going to reduce that.'' *Id.*

When the aberrant result is due to non-compliance with the treatment, the applicable standard of care informs the physician's response based on the cause of the aberrancy, Dr. Munzing testified. *Id.* at 106. For example, Dr. Munzing testified, the physician may treat for addiction, do more frequent compliance monitoring, or change treatment. *Id.* ''So,'' Dr. Munzing testified, ''it all depends on what you determined was the cause of the aberrancy . . . [b]ut whatever you choose to do, it needs to be well documented so it's obvious for anyone else looking at it.'' *Id.*

E. Respondent's Case

Respondent testified and called one witness, Dr. Standiford Helm, II, his expert. *Id.* at 628. According to Respondent's case, he, as a fellowship-trained pain specialist, received extensive training in both medication and procedural pain treatments, has an unblemished medical record, has never been sued for medical malpractice, and has never had any disciplinary action brought against his license, presumably meaning his medical license. Respondent's Post-Hearing Brief dated January 24, 2020 (hereinafter, Resp Posthearing), at 2, 21–22. His position is that, due to the ''totally inaccurate and baseless opinion'' of the Government expert, eight ''DEA agents raid[ed] his office and then had his DEA certificate suspended.'' *Id.* at 2. According to Respondent, ''[t]here was never any malpractice lawsuit; no patient overdose; no patient harm; no adverse Medical Board action; nor any criminal activity or even suspicion of malfeasance.'' *Id.* Respondent's position is that ''this process has been ruinous to . . . [his] career and dangerous to his patients'' and the ''destruction of a fellowship-trained professional all occurred because a family doctor offered inaccurate opinions without bothering to read the complete medical records and who lacked basic knowledge on many topics related to opiates.'' *Id.* Respondent testified that ''[u]nfortunately, everything has become so difficult these days. And again, . . . [he has] been doing this for 30 years, and . . . [his] training is very, very different.'' Tr. 920.

Respondent testified about each of his medical files at issue in the OSC and, in the process, gave his perspective on many matters relevant to this adjudication. Regarding UDSes, Respondent testified about his use of UDSes in his practice, stating that ''we do our very best to check'' UDSes and ''have done it for years and years and years,'' and that they are ''just one component of patient compliance.'' *Id.* at 1099–100; *see also id.* (Respondent's testimony that CURES is another way to check compliance although he ''clearly understand[s]'' that CURES only shows prescriptions that are filled, not prescribed drugs that are being ingested); *id.* at 1120–22 (Respondent's testimony confirming that S.D. received carisoprodol prescription from him and from another physician within two weeks of each other, and admitting that he has no recollection of addressing that with S.D.).

According to Respondent's testimony, ''under the best circumstances'' it ''would be preferable'' to have UDS results before seeing the patient ''but [that] didn't always happen.'' *Id.* at 1098. He testified that he did not recall whether he conducted a UDS and did not document it, or whether he did not conduct a UDS. *Id.* at 933 (Respondent's testimony that it does not appear that he ordered a UDS for A.A. in 2011); *id.* at 935–41 (Respondent's testimony that he was ordering UDSes in 2011 but that he did not recall whether he had A.A. take a UDS on her first two visits with him and did not document having done so, or whether he did not have A.A. take a UDS on those first two visits).

Respondent testified that he did not consider a UDS to be aberrant if it is negative for a substance he prescribed, admitting that his ''attorney then, you know, corrected me on that statement.'' *Id.; see also, e.g., id.* at 1077–78, 1085; *but see id.* at 1144–51 (Respondent's testimony that UDSes are ''appropriate'' when a drug he prescribed is missing because, even though it was not documented, he ''discussed with the patient every single time'' and because Respondent had a ''clear understanding'' with at least one of his patients that the patient ''only took medication that was needed'' and that he ''could afford'' financially). Instead, Respondent testified, he used UDS to look for the presence of substances that he had not prescribed. *Id.* at 1098; *id.* at 910–15 (Respondent's testimony that he ''wanted to make sure that there was no illicit substances being used'').

Regarding an A.A. visit when her UDS was aberrant because it was negative for the Percocet he had prescribed, Respondent testified that ''she only had three Percocet a day . . . [a]nd if she had excessive knee pain, for the last two weeks, she obviously finished her Percocet early.'' *Id.* at 938. When asked if taking medication early was a deviation from his prescribing instructions, Respondent testified that it ''[m]ight be a deviation from instructions, but she had an acute exacerbation of pain that she was trying to treat.'' *Id.* at 938–39; *see also id.* at 950 (Respondent's testimony about another aberrant A.A. UDS). Regarding A.A.'s methadone-negative UDS in February of 2013, Respondent testified that ''in this particular case, she took more [m]ethadone. And she saved the Oxy for the end. So she's playing around—again assuming no operator error. Assuming no manufacturer's error. Assuming they didn't read the fake lines. I mean I have to assume all these things.'' *Id.* at 957. Respondent testified that he had no problem with

A.A.'s ''playing around'' with the controlled substances he had prescribed for her, testifying that ''she had an allowance of four [m]ethadone a day. And she took them earlier because she was having these issues with pain, and she was saving the Oxycodone for later. But she was using her allowance.'' *Id.* at 958. He compared A.A.'s ''us[ing] her allowance'' of controlled substances with a child who receives a $5.00 allowance, uses it all on Monday, and does not have ''any money the rest of the week,'' testifying that A.A. is a ''grown-up . . . [who] can make . . . those [controlled substance dosing] decisions.'' *Id.* at 946.

When asked if such a deviation from his prescribed controlled substance dosing was grounds for terminating the doctor-patient relationship, Respondent interrupted the question, responding ''[u]nder no . . . circumstances.'' *Id.* at 939. He testified that A.A. ''had three Percocet a day . . . [,] 30 milligrams. I know in today's world three Percocet is devastating. I get it. But three Percocet is not devast[at]ing to an opioid-tolerant patient who's had three back surgeries, has significant pain, and has been on pain medication for a long time.'' *Id.* According to Respondent's testimony, A.A.'s negative UDSes ''tell[ ] me that she's not taking any medications that she wasn't prescribed. And that's what's important.'' *Id.* at 953; *see also id.* at 944–45 (Respondent's testimony that ''if she was taking more Percocet, that's fine. . . . It's a sign not of abuse, and not of diversion. It's a sign that she's not having adequate pain relief''); *id.* at 964 (Respondent's testimony describing A.A. as someone who ''is following the rules'' and, therefore, her increasing the Percocet dosage he prescribed for her ''was no issue'').

When asked why he did not document his thoughts about A.A.'s aberrant UDS, Respondent testified that ''[b]ecause I'm sure this visit went on forever and ever. And I'm injecting her knee, and I'm doing everything. And it was just, it was not of significance to me. . . . I'm just saying, it was not of concern to me.'' *Id.* at 940. Also during his testimony, Respondent dismissed his inaccurately documented medical records by stating that he was ''so busy talking to the patient'' and ''again, from this chart, that's not a big problem, because it's historically her left knee,'' not her right knee as he had inaccurately documented. *Id.* at 962–63. In his testimony, Respondent admitted that he is ''the keeper of . . . [his medical] records'' and stated that he was ''not restoring backwards.'' *Id.* at 972. According to Respondent's testimony, ''a lot of the [medical] records have been read wrong and interpreted wrong because I'm doing a million things at once, and people are trying to read the exact word.'' *Id.*

Additionally, Respondent's case highlighted that his medical records show he explored surgical options, physical therapy, and the like, reduced the controlled substances he prescribed, complied with documentation requirements, and reduced pain.[30] *See, e.g., id.* at 377 (surgery option explored); *id.* at 738 (surgery option explored); *id.* at 437 (injection); *id.* at 451–52 (injection); *id.* at 453 (physical therapy); *id.* at 742–43 (intrathecal pump); *id.* at 461–62 (increase non-opioid therapy); *id.* at 446 (decrease controlled substances prescribed); *id.* at 478–80 in conjunction with GX 14B, at 31–42 (Respondent's medical records for R.B. showing that Respondent increased oxycodone 30 mg prescription to 150 tablets on June 26, 2017, due to new ''hand pain'' (finger fracture) injury, reissued the increased number of oxycodone 30 mg tablets on July 24, 2017, reduced the number of oxycodone 30 mg tablets prescribed to 140 tablets on August 23, 2017, and returned the number of oxycodone 30 mg prescribed to the prescription's May 24, 2017 amount of 120 tablets on October 16, 2017);[31] Tr. 692 (Dr. Helm's testimony that Respondent, for S.D., substituted Zanaflex for Soma and tried to wean S.D. off Norco); *id.* at 434–35, 663 (spinal cord stimulator trial); *id.* at 488–89 in conjunction with GX 18B, at 141 (Respondent's medical records for L.D. stating ''[w]ould like to attempt to decrease narcotics'' and showing that Respondent decreased the Fentanyl patch he prescribed for her from 100 micrograms every other day to 75 micrograms every other day); *see also* Tr. 490 (discontinuation of Fentanyl patch); *but see id.* at 504–05 in conjunction with GX 18B, at 76–81 (showing that Respondent resumed prescribing Fentanyl patches (every three days) after L.D. slipped and sprained her left knee, and then increased the prescription to every other day);[32] Tr. 414–15 (documentation of A.A.'s daughter stealing controlled substances Respondent prescribed for A.A.); *id.* at 476 (medical records showing that the controlled substances Respondent prescribed ''appeared to be reducing'' R.B.'s pain); *id.* at 485 (Dr. Munzing's testimony that Respondent managed R.B.'s pain); *id.* at 515 (Dr. Munzing's testimony that, based on Respondent's notes, L.D.'s pain appeared to decrease); *id.* at 519–20 (Dr. Munzing's testimony that S.H.'s function improved over time); *id.* at 526 (Dr. Munzing's testimony that ''pain medication is helping . . . [S.H.] be more productive'').

Based on substantial record evidence, however, Respondent was not successful at rebutting the OSC's allegations that he prescribed controlled substances beneath the applicable standard of care and outside the usual course of professional practice, including that Respondent failed to conduct the requisite physical examinations, failed to obtain the requisite history, failed to develop an appropriate treatment plan, failed to conduct appropriate monitoring of those for whom Respondent prescribed controlled substances, and failed to comply with recordkeeping requirements. *Supra* section II.; *infra* section III.F.

[30] I note, however, that Dr. Helm, Respondent's expert, testified that the difference between when a physician first writes a prescription for an opioid patient versus when a pain specialist assumes care of the patient is that the ''option we have of looking at non-opioid alternatives has been taken away from us.'' Tr. 631–32.

[31] *See also* Tr. 558–60 (Dr. Munzing's testimony) and *id.* at 684 (Dr. Helm's testimony).

I note that Respondent's medical records for R.B. on this point are not accurate and, therefore, that they do not comply with the applicable standard of care. MBC Guide to the Laws, at 61 (accurate and complete medical records). For four visits, from July 24, 2017 through October 16, 2017, Respondent inaccurately stated under ''Current Medications'' the number of oxycodone 30 mg tablets he last prescribed for R.B. GX 14B, at 32–38; *see also* GX 18B, at 70–78 (inaccuracies in medical records concerning Respondent's prescribing of Fentanyl patches to L.D.). I further note that I did not consider these matters in my Decision/Order because they were not noticed or litigated by consent.

[32] *See also* Tr. 554–58 (Dr. Munzing's testimony that, although the x-ray of L.D.'s knee was ''normal'' (GX 18A, at 39), an x-ray may not show all injuries, and that a Fentanyl patch is a controlled substance for chronic pain, not for treating an acute injury, such as a knee injured due to a slip, for a brief period of time); *id.* at 570–71 (re-cross); *id.* at 573, 614 (re-direct).

I credit Dr. Munzing's testimony that Fentanyl patches are normally written for every three days, not every other day as Respondent prescribed them for L.D. Tr. 489.

Further, there is substantial record evidence that Respondent did not identify as problematic requests for specific controlled substances by name and self-dosing contrary to his prescribed dosing orders. *See, e.g.,* Tr. 966 (Respondent's testimony that A.A. ''all of a sudden'' said she would like to try Oxycodone instead of Methadone and that is ''perfectly fine'' with him); *id.* at 1030–32 (Respondent's testimony about L.D.'s non-appointment appearance at Respondent's office ''with a crippling illness'' for which she asked Respondent, and received, a Fentanyl patch (12.5 microgram) prescription, her ensuing complaint that the dosage he issued for her was too low, L.D.'s subsequent ''classic'' self-dosing ''up to 75 micrograms,'' and his description of L.D. as ''an actress, to be honest''); *see also id.* at 1124–28 in conjunction with GX 18B, at 79–81 (Respondent's testimony that L.D. ''historically treated her pain with either 75 microgram or 100 microgram [Fentanyl] patches,'' that he re-started L.D. on 12.5 microgram per hour Fentanyl patches ''because she had not been on it for quite some time,'' that L.D. ''found the dosage strength of 75 micrograms per hour helpful in this—what turned out to be a very devastating injury and cascade of events, this all made absolute perfect sense,'' and that he was thus justified to prescribe 75 micrograms per hour Fentanyl patches on a visit when L.D.'s UDS was positive only for benzodiazepine); Tr. 1101–04 (Respondent's testimony that it is not unusual for his patients, ''within . . . [the] allotted allowance of the month'' to choose to ''vary,'' despite his prescribing instructions, the amount of controlled substances ingested each day ''based on . . . activity level and based on what . . . needed to [be] accomplish[ed] that day'' and that he would tell them ''there would be a maximum amount that . . . [he] would be comfortable with'' their ingesting each day); *id.* at 1039–42, 1108 (Respondent's testimony that he complied with R.B.'s request for a specific controlled substance prescription—stating that he ''felt for this man'' given his experiences with his 86 year-old father whom he ''can't really take anywhere because he has this cough that embarrasses the entire family in a restaurant and everything else like that,'' minimizing the controlled substance prescribing as ''22 doses of cough syrup a month,'' and pointing out that he stopped prescribing controlled substances on behalf of other doctors because he ''didn't want to be further involved in it'').

I decline to adopt Respondent's excuses and arguments to overlook his failures to follow the applicable standard of care and to act within the usual course of professional practice. *See, e.g., id.* at 452 (the prolonged use of anti-inflammatories can cause serious organ damage); *id.* at 456 (a loose screw was subsequently discovered in S.D.'s spine justifying Respondent's ''dramatically increased'' controlled substance prescribing); *id.* at 481–83 in conjunction with GX 14B, at 11 (a pulmonologist may have subsequently prescribed Promethazine); Tr. 419–20 (there is no record evidence that Respondent's controlled substance prescribing led to respiratory depression, overdose, or side effects); *see also id.* at 535 (Dr. Munzing's testimony that ''just because someone doesn't have a terrible outcome doesn't mean that what you did was correct and right''); *id.* at 1153–54 (Respondent's testimony stating his belief that another pain doctor picking up his medical records ''would gain a much greater knowledge from . . . [his] records than they would many other physician's records,'' instead of answering the ALJ's direct questions of whether ''they would be able to pick up from where you left off based on the content of your records'' and whether ''they [would] understand what you had'').

Having read and analyzed all of the record evidence, I find that Respondent is the witness with the most at stake in this adjudication. I find that, while Respondent's testimony does include reliable statements, it also includes statement that lack credibility, are implausible, and/or are not persuasive. I find that Respondent's testimony must be considered with much caution, and where his testimony conflicts with credible record evidence and the applicable standard of care, I do not credit it. *Supra* section II and section III.D.; *infra.*

According to Respondent's case, the Government's expert witness is trained in family medicine, not in pain medicine, and did not do, let alone complete, a fellowship in pain management. Resp Posthearing, at 23. The testimony of the Government's expert witness, Respondent charges, ''was rife with error,'' including its reference to the CDC Guidelines during his evaluation of the controlled substance prescribing of Respondent, a pain management specialist. *Id.*

According to Respondent's case, his expert witness, Dr. Standiford Helm, II, is a ''pre-eminent expert in the area of pain management,'' ''holds diplomate status with a number of organizations specializing in the treatment of pain,'' and has affiliations with various pain organizations and ''top journals in the area of pain management.'' *Id.* at 25–26. Dr. Helm, according to Respondent, ''is one of the authors of pain guidelines for . . . [the American Society of Interventional Pain Physicians (hereinafter, ASIPP)], and those guidelines were used as evidence in this hearing'' and ''has served as an expert reviewer for the Medical Board of California for pain specialists, because he is a pain specialist.'' [33] *Id.* at 26. Respondent offered, and the ALJ accepted, Dr. Helm ''as an expert in support of . . . [Respondent] and the care rendered by . . . [Respondent] to the patients in the areas of pain management and for these specific treatments for the patients at issue.'' Tr. 628.

According to Dr. Helm's testimony, he was trained in internal medicine and anesthesiology, became involved in pain management ''[p]robably about '82,'' and ''evolved'' with the field as the field evolved.[34] *Id.* at 620–21. He was ''able to be grandfathered'' when ''the first boarding became available in 1993'' and ''then just continued from there to the point where since then . . . [he has] been very active nationally and internationally, lectured and written and continued to do those things.'' *Id.* at 621. Dr. Helm testified that he received research support from the manufacturer of opioids in this case, Purdue Pharma, one of whose founders was a ''marketing genius'' who ''probably helped develop the [opioid] problem.'' *Id.* at 626–27.

Dr. Helm testified that a doctor is required to do several things when issuing a new controlled substance prescription: ''review whatever records are available,'' including ''whatever past medical records you have and have

[33] Dr. Helm testified that, as an author of the ASIPP Guidelines, he agrees with their content, specifically addressing the ASIPP Guidelines' statements about pain contracts and obtaining informed consent. Tr. 758. Yet, Dr. Helm testified that Respondent's pain contract, while not in compliance with the ASIPP Guidelines, ''can be accepted as an informed consent agreement although it . . . could be more fully documented and, you know, if you wanted to, the language could be changed from any form of . . . opioids or narcotics to any controlled substances, you know, there is that variation.'' *Id.* at 758–59; *see also id.* at 748–50 (Dr. Helm's testimony about Respondent's pain contract and its non-compliance with the MBC Guidelines for Prescribing concerning obtaining a patient's informed consent about the ''risk'' of using controlled substances). Dr. Helm's testimony also stated that ''not complying with this [sic] specific guidelines and deviating from standard of care are two different—two different entities, two different thesis [sic].'' *Id.* at 759.

[34] Respondent's Exhibit (hereinafter, RX) 5 is Dr. Helm's *curriculum vitae.*

access to;'' ''meet with the patient;'' ''obtain a thorough history;'' ''perform an exam, really focused on, attempting to find out what the cause of the pain is, if you can;'' ''integrate that data, come up with a treatment plan;'' ''get[ ] a urine drug screen;'' ''risk stratification;'' and ''obtain[ ] informed consent and pain agreement.'' [35] *Id.* at 864–65. I find that Dr. Helm's response lists half of the elements of the applicable standard of care.[36] *Supra* section II.

Dr. Helm's testimonial elaboration on, and application of, these elements and on other matters pertaining to the applicable standard of care, however, fall far short and I do not credit them.[37] For example, Dr. Helm's testimony was inconsistent. While initially testifying that a UDS is one of the things a doctor is required to do when issuing a new controlled substance prescription, he subsequently testified that ''as long as the physician is seeing the patient and carrying out an exam and coming to a determination absent either one of those data points—either the CURES or the UDS, it is still within the course of professional practice.'' Tr. 870–71. Further, Dr. Helm testified that a doctor is required to have a ''legitimate encounter'' with the individual before he writes a controlled substance prescription and, during that ''legitimate encounter,'' is to get a ''current history,'' ''perform[ ] [an] appropriate exam,'' and ''com[e] to a determination.'' *Id.* at 871. According to Dr. Helm, then, if one of the elements he initially testified to being required before the issuance of a new controlled substance prescription is not performed, ''even if those errors are made, you're still within the professional practice.'' *Id.*

By way of further example, Dr. Helm was asked whether Respondent's patient contracts satisfy informed consent. *Id.* at 876. Dr. Helm testified that those contracts ''referred to side effects'' but ''they didn't specifically discuss some of the specific risks, tolerance, death.'' *Id.* Dr. Helm testimony concluded, though, that, although they are not ''optimal,'' the contracts are ''close enough to at least be acceptable.'' *Id.*

Regarding his testimony that a doctor must ''perform an exam, really focused on, attempting to find out what the cause of the pain is, if you can'' and ''integrate that data, come up with a treatment plan,'' Dr. Helm testified that Respondent's initial prescribing of amphetamine salts for L.D. preceded Respondent's noting the chronic fatigue syndrome diagnosis in the medical records for L.D.'s third visit. *Id.* at 879–82; *accord id.* at 1122–24 (Respondent's testimony). Nevertheless, Dr. Helm excused Respondent's failure, testifying that Respondent was ''maintaining a medication'' that a different medical professional had previously prescribed. *Id.* at 880; *but see id.* at 1135–36 (Respondent's failure to answer fully the ALJ's question about the purported ''list of . . . [L.D.'s] meds'' and physicians at GX 18A, 82–83) and *infra* n.38. Dr . Helm testified that he viewed Respondent's failure as ''an error in documentation,'' but not an ''error in documentation [that] takes it outside the usual course of professional practice.'' [38] Tr. 880.

Regarding UDSes, Dr. Helm testified that the controlled substance prescriptions Respondent issued on the visit at which L.D.'s UDS was positive for cocaine were issued within the usual course of professional practice, even though Respondent did not ''resolv[e]'' the cocaine aberrancy. *Id.* at 882. Dr. Helm's testimony was that Respondent's actions were a ''documentation problem, rather than taking [sic] outside the practice of medicine.'' *Id.* at 885; *but see id.* at 1136–37 (Respondent's testimony that the cocaine-positive UDS of L.D. ''must have been a click of the box error'' because ''one thing my boys did if there was ever an elicit [sic] drug, they immediately brought the dipstick to me and we evaluated it together''); *id.* at 1025–26 (Respondent's testimony that L.D. ''did not use cocaine,'' that he phoned L.D. after reviewing the medical records the week before the hearing and received L.D.'s ''confirmation'' that she did not use cocaine, that he trusts his patients because they are ''honest'' with him, and that he has to ''assume'' the cocaine-positive result was the error of one of his employees who ''clicked the wrong box''). Instead of explaining his ''documentation problem'' assessment, however, Dr. Helm warned against stopping opioid prescriptions ''abruptly unless you had documentation that the[y] weren't taking the opioids just because of the withdrawal issue.'' *Id.* at 883. Dr. Helm's testimony did not elaborate on what ''documentation that the[y] weren't taking the opioids'' he believes is needed, how a physician would obtain that documentation, and the bases for his conclusion that Respondent's failure to address the cocaine UDS aberrancy was a ''documentation problem.'' *Id.* at 882–83, 885. He did testify, however, that he is ''not aware of anywhere where it is codified that one needs to—and forget UDS—any inappropriate result or after, whether again, malignancy, tests, whatever it's going to be—anything that would require—high blood pressure—it would require a response despite the absence of codification.'' *Id.* at 884–85.

Dr. Helm testified that there is no upper limit for the MME dosages a physician can prescribe, stated that guidelines exist but do not determine the standard of care, and defined the standard of care as ''what a reasonably trained physician in the community would do in similar circumstances at a similar time.'' *Id.* at 625–26; *see also id.* at 630; *id.* at 807–11. According to his testimony, guidelines do not apply equally to all specialties in the area of opioid prescribing, stating that the CDC guidelines, explicitly, and MBC guidelines, implicitly, apply to primary care physicians.[39] *Id.* at 630. Dr. Helm's testimony was that the MBC guidelines implicitly apply to primary care physicians ''because they refer repeatedly to consultations not only to pain management but to other

[35] Dr. Helm also stated that a pain management doctor is to ''review a CURES Report.'' Tr. 864–65.

[36] Dr. Helm was also asked ''[w]hat, if anything, [is] a doctor acting with [sic] the usual course of professional practice required to do . . . to document an increase in strength or quantity of a previously prescribed prescription?'' Tr. 873–74. Since the question is not specifically about controlled substance prescriptions, Dr. Helm's response is not relevant to my adjudication of this matter.

[37] I credit none of Dr. Helm's responses to questions calling for a legal analysis as it is not in his expertise to provide a legal opinion. *See, e.g.,* Tr. 864–892. To his credit, Dr. Helm testified that he ''attempted'' to read *Gonzales* v. *Oregon,* found it ''very hard to read,'' called it ''interesting'' that ''DEA deferred to the state'' about the ''usual course of professional practice within California,'' and ''defer[red] to the Court'' on such matters. *Id.* at 870, 884, 873. Dr. Helm's ''deferral'' testimony and other testimony about the meaning and scope of the ''usual course of professional practice'' and the applicable standard of care support my decision to give limited weight to Dr. Helm's testimony. *See, e.g., id.* at 867–68, 870–73.

[38] Respondent subsequently testified that the only refill L.D. said she needed during her first visit with Respondent was amphetamine salts. Tr. 1019. Respondent testified that ''[m]aybe this [medical record] note is not as long as it should be. But obviously this was a very complex patient . . . [a]nd so . . . a lot of time was taken in the history and establishing a relationship.'' *Id.* 1020; *see also id.* at 1020–21 (Respondent's testimony, when asked if it was an oversight for him not to document that chronic fatigue syndrome was the diagnosis on which his amphetamine salts prescription for L.D. was based, that he ''was so busy writing down, you know, symptoms, and so busy doing other things, that . . . [he] just really didn't get to the problem list at the time''). Respondent testified that he ''was comfortable with'' issuing L.D. a prescription for amphetamine salts because he ''had a list of all of her physicians'' and ''[t]here's the CURES Report in the chart that confirms all of that information.'' *Id.* at 1020. Respondent's testimony does not include details about the source of the list of L.D.'s physicians, does not explain how the CURES Report confirms ''all of that information,'' and does not include information showing that the first visit amphetamine salt prescription complies with the applicable standard of care.

[39] Dr. Helm did not further identify the ''CDC guidelines'' he was referencing.

specialties, too.'' *Id.* Dr. Helm was asked, but did not answer, whether the MBC Guidelines for Prescribing are relevant to pain care specialists.[40] *Id.* at 762. He testified that ''pain physicians can take it wherever we want to, but you've got to justify why you're so doing.'' *Id.* at 763. Respondent asked Dr. Helm if he ''would say that a pain care specialist has an even higher standard of care that they should follow rather than just the primary care physician,'' and Dr. Helm stated in agreement, ''Basically.'' *Id.*

Dr. Helm testified about the medical care Respondent provided, and controlled substance prescriptions Respondent issued to, A.A., R.B., S.D., L.D., S.H., and J.M. Tr. 632–897; *infra* section III.F. I find that Dr. Helm's testimony focused largely on describing, explaining, and even justifying or excusing Respondent's medical records and actions those medical records state that Respondent took, as opposed to addressing Respondent's compliance or non-compliance with the applicable standard of care and the usual course of professional practice and whether the OSC's allegations are founded and whether I should entrust Respondent with a controlled substance registration. For example, when Respondent's counsel specifically asked Dr. Helm whether Respondent's treatment plan for A.A. was appropriate, Dr. Helm responded that ''he gave early refills,'' ''[p]ost-dated triplicate for the Methadone, and then it was just continued following up for the psychological evaluation and plan to proceed to the epidural'' before being cut off by Respondent's counsel's next question. Tr. 646–47; *see also id.* at 680–81 (Dr. Helm's not responding to a question about Respondent's compliance with the standard of care, Respondent's counsel's rephrasing the question to ask about whether Respondent's controlled substance prescribing was ''acceptable,'' and Dr. Helm's response to the re-phrased question); *id.* at 731–32 (Dr. Helm's testimony, when asked, ''[i]n view of the totality of the care and the notes and the history and the information provided, how would you describe . . . [Respondent's] treatment, of this patient,'' that ''[y]ou know, I think he's allowing this gentleman to function, to support a multi-generational essentially family, although the girlfriend's not married. But he's supporting the kids, her and his grandmother, and he surely is, you know, providing a benefit to them, and there's no threat here or risk to public safety''); *id.* at 683 (Dr. Helm, answering Respondent's counsel's question about if there is any reason to doubt R.B. was in increased pain and would benefit from more medication, by stating that it is ''[r]easonable to have increased pain after a car accident''); *id.* at 715 (Dr. Helm's testimony that Respondent's medical records ''clearly showed'' that L.D.'s criminal involvement was ''business,'' but no direct response to Respondent's counsel's question of whether Respondent ''adequately document[ed]'' L.D.'s criminal status); *id.* at 687 (Dr. Helm's summary testimony, without explanation, after Respondent's counsel asked if the controlled substance prescriptions that Respondent issued to R.B. were ''medically justified,'' that ''[t]here was a legitimate medical purpose and they were done in the course of professional practice''); *id.* at 741 (Dr. Helm's conclusory testimony that continuing controlled substance prescriptions ''to allow . . . [J.M.] to perform [activities of daily living] and have quality of life despite his physical limitations'' is ''an appropriate goal for the opioid therapy'').

Another example, regarding the requisite physical examination, is Dr. Helm's testimony about Respondent's medical records for A.A. He testified about the ''type of exams done by pain specialists in the treatment of chronic pain,'' stating that Respondent conducted an ''appropriate lumbar exam'' of A.A. that was a ''focused musculoskeletal exam.'' *Id.* at 635–36; *see also id.* at 644. Dr. Helm approvingly testified about Respondent's focus on A.A.'s back, gait, response to palpation of ''various areas of the back,'' range of motion, lower extremity exam, muscle strength, reflexes, and sensation, concluding ''that's really the gist of it.'' *Id.* at 636; *see also id.* at 740 (Dr. Helm's agreement with Respondent's counsel that Respondent's examination of J.M. on all visits was ''appropriate'' without testimony about the applicable standard of care and the usual course of professional practice). Dr. Helm mentioned the heart and lungs ''because the surgery centers want[ ]'' that information ''but it's not, you know, that doesn't influence the diagnosis.'' *Id.* Dr. Helm did not address the applicable standard of care and the usual course of professional practice regarding a pain management physician's conduct of a heart or lung examination, let alone testify about the connection between the condition of a patience's heart or lung and a pain management physician's assessment of the appropriateness of prescribing a controlled substance.

A further example is Dr. Helm's testimony about the reasonableness and consistency with the standard of care of Respondent's controlled substance prescribing. Regarding A.A., for example, Dr. Helm testified that, ''[s]ure,'' the controlled substances Respondent prescribed during A.A.'s first two visits were ''reasonable and consistent with the standard of care as a pain physician,'' elaborating only that ''as long as she was getting pain relief and increased function with the medications with no side effects and there are no signs of aberrancy.'' *Id.* at 639.

Also regarding A.A., as another example, Dr. Helm testified that it was appropriate for Respondent to increase the methadone he prescribed for her on January 11, 2013, stating that ''the pain meds are worse'' and Respondent is ''carrying out a further evaluation to solve—to see if there's anything that could be identified and in the interim increasing the medications.'' *Id.* at 658. Dr. Helm testified that one methadone-negative UDS ''really it isn't a basis for . . . [a] run to action on because of one negative in the face of multiple positives.'' *Id.* at 892. He did not explain his testimony that increased methadone prescribing was ''appropriate'' in the context of Respondent's continuation of it through June 5, 2013, despite one UDS that was negative for methadone, and of Respondent's discontinuation of it, on June 28, 2013, based on a note that ''Pt would like to try Oxycontin'' and prescribing ''Oxycontin 10 mg[ ] #120 1 QID'' and ''Percocet 10/325 #120 1 QID prn.'' GX 12B, at 114; Tr. 658–60 (Dr. Helm's testimony about June 5, 2013, including A.A.'s subsequent hospitalization ''for concern of suicide''); *see also id.* 740–41 (Dr. Helm's testimony, without elaboration, that it was ''appropriate and reasonable'' for Respondent to prescribe ''anxiety-provoking . . . large quantities of narcotics'' to J.M.). Dr. Helm also did not explain his repeated testimony that Respondent's methadone prescribing for A.A. was appropriate in the face of his testimony that methadone is ''disproportionately a cause of death because the half[-]life in the body is longer than the period of pain relief'' and his agreement that there is no evidence in A.A.'s medical records that

[40] *See also* Tr. 530 (Dr. Munzing's testimony, stating that ''the guidelines aren't the standard of care and if one is in substantial compliance with the guidelines, and with any other laws that dictate the prescribing, one would be compliant with the standard of care. But could one be within the standard of care and not do one little thing within the guidelines? In my mind, yes it could be, but a substantial compliance with the guidelines, which is what . . . we all do when we're practicing is we are in substantial compliance with whatever the guidelines are for taking care of the patients for whichever problems'').

Respondent had A.A. undergo an electrocardiogram, as the ASIPP guidelines that Dr. Helm co-authored recommend, to prevent such ''big problem[s]'' as cardiac arrythmia and heart pump failure. *Id.* at 842–45; *see also id.* at 842 (Dr Helm's testimony that ''[m]ethadone's great advantage is that it's cheap'').

Regarding Respondent's monitoring of those for whom he prescribed controlled substances and his use of UDSes, Dr. Helm agreed with Respondent's counsel that there were ''several'' aberrant UDSes in Respondent's medical files. *Id.* at 650. He testified that an aberrant UDS is the ''absence of what's prescribed or the presence of what is not prescribed.'' *Id.* at 846. Regarding how to handle aberrant UDSes, Dr. Helm testified that, ''as a pain physician,'' he would ''want to discuss with the patient . . . two things.'' *Id.* at 648. First, he testified, a pain physician would want to ''find out what's going on,'' document awareness of the aberrancy, and provide counseling about how to ingest the controlled substance. *Id.* Second, Dr. Helm testified that a pain physician would want to send the urine sample out for confirmatory testing.'' *Id.* at 648–49. Dr. Helm clearly testified an aberrant UDS is ''obviously something that should be—I, you know, I have in other scenarios and continue here to say that these results need to be documented, these findings need to be documented . . . [and] [t]hey're not.'' [41] *Id.* at 651; *see also id.* at 833 (Dr. Helm's testimony that ''every aberrancy on the UDS should be documented''); *id.* at 831 (Dr. Helm's testimony that his position is ''if it's not documented it didn't happen'').

After specifically criticizing Respondent's handling of aberrant UDSes, however, Dr. Helm minimized Respondent's failures, testifying that the instances of aberrant UDSes in Respondent's medical records are ''unlikely to represent any abuse or diversion or present any risk to the public'' due to the ''analysis of the patient, and these patients, there seems to be all the confirmatory evidence from the social environment and the CURES.'' *Id.* at 649–51; *see also id.* at 896 (Dr. Helm's testimony that ''we're looking at documentation errors rather than a causative concern for public safety''). When asked about Respondent's failure to conduct UDSes for a year, Dr. Helm testified that Respondent's previous ''custom and practice was to do them, so not doing them is not related to a failure, indifference to urine drug screens.'' *Id.* at 765. Dr. Helm declined to conclude that Respondent's re-prescribing of methadone after repeated non-negative methadone UDSes was more than a ''consistent lack of documentation on that issue, and throughout all the charts.'' *Id.* at 851. Instead, Dr. Helm testified that an aberrant UDS is ''not one that in isolation should be the determinate as to what you do'' and that he ''look[s] at the totality of the data,'' including ''the patient's response to the medications, ability to function, reported decreased pain, reported increased function'' and would ''continue it.'' [42] *Id.* at 846–51; *see also id.* at 897.

At the end of his direct testimony, Dr. Helm stated his views of Respondent as a pain physician. *Id.* at 746–47. He testified that Respondent prescribed high doses of controlled substances, justifying that prescribing by stating ''but . . . his patients on high doses are having functional improvement.'' *Id.* at 746. Dr. Helm testified that Respondent monitored his patients, adding the excuse that the UDSes Respondent conducted were ''hampered by the inability to get confirmatory tests.'' [43] *Id.* He testified that Respondent ''strongly documented'' psycho-social status, which was ''confirmed by the presence of family members.'' [44] *Id.* Dr. Helm added that Respondent's medical record ''documentation is far better than that which . . . [he has] seen in many, many records that . . . [he has] reviewed.'' *Id.* at 747.

Dr. Helm disagreed with Dr. Munzing's ''criticisms overall'' of Respondent. *Id.* He testified that Respondent's pain medicine adjustments ''were not arbitrary'' and that ''the notes document rationales for the adjustments.'' *Id.* Dr. Helm testified that Respondent's ''high doses are high,'' that ''we know [high doses] do have increased risks,'' but that Respondent ''is providing the monitoring, which the author of the CDC guidelines requests be done.'' [45] *Id.* He concluded his direct testimony by referencing Respondent's UDSes and stating that he does not ''see'' that Respondent ''represents a risk.'' *Id.*

Although Dr. Helm's testimony specifically addressed Respondent's high dose prescribing, ''pain medicine adjustments,'' UDS practices, monitoring, use of CURES, and medical record documentation, it did not address them squarely in the context of the applicable standard of care and the usual course of professional practice. As already discussed, Dr. Helm's testimony contained limited and unconvincing evaluations of Respondent's controlled substance prescribing against the applicable standard of care and the usual course of professional practice. Accordingly, I give Dr. Helm's testimony limited weight in this Decision/Order.

Based on my analysis of the applicable standard of care and the existence of substantial record evidence, I credit the standard of care-related testimony of Dr. Munzing when there is a conflict between his testimony and the standard of care-related testimony of Dr. Helm or of Respondent. *Supra* sections II, III.D., and III.E.

Respondent also submitted documentary evidence, including about seventy-five pages of letters from supporters who describe themselves as physicians, patients, or family members of patients whom Respondent has treated. RX 8, at 1–76. It appears, from my having read the legible portions of the letters, that Respondent reached out regarding his ''alleged misuse of prescribing drugs.'' [46] RX 8, at 74. Although the content of RX 8 indicates the strong and positive feelings and opinions of many individuals about Respondent, I can only afford that content limited weight in this adjudication because of my limited ability to assess the credibility of the letters given their written form. *See Michael S. Moore, M.D.,* 76 FR 45867, 45873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). Further, the content of RX 8 provides limited evidence about whether Respondent

[41] Dr. Helm did not agree with Respondent's counsel that Respondent ''was ahead of the curve in terms of what he was doing to monitor patients.'' Tr. 652. Instead, Dr. Helm's responded: ''I would say that he and I are some of the few doctors in the state who still remember that back in the day you had to fax in requests for the CURES back before then Attorney General Brown went electronic with it in 2009.'' *Id.*

[42] *See also* Tr. 746–47 (Dr. Helm's testimony about J.M.'s July 13, 2018 visit with Respondent and CURES reports, stating that they ''are all consistent and compliant suggest[ing] that the UDS results, while they should be more clearly documented, . . . do not . . . provide any evidence of risk to the public, so he's really doing well''); *see also id.* at 768–69.

[43] Dr. Helm testified that it is expensive to send UDS results for confirmation. Tr. 642.

[44] Dr. Helm agreed, however, that family and friends ''may not necessarily be a good source of checking for compliance'' as ''they, too, might be abusing or diverting,'' and that family and friends attending a visit with Respondent is ''not really a substitute'' for not doing UDSes. Tr. 766–67.

[45] Again, Dr. Helm did not further identify the ''CDC guidelines'' he was referencing. I note, though, that Respondent's position in this matter is that the ''CDC Guidelines'' do not apply to Respondent.

[46] The content of RX 8 alludes to the communication but does not include it.

prescribed controlled substance in conformity with the applicable standard of care, an issue central to my legal responsibilities in this adjudication. Heart-felt statements of individuals who have suffered, or who continue to suffer, tremendously from pain, if not specific or presented in a context that allows me to apply the controlling legal standards, are of limited value in an adjudication such as this one. Accordingly, I find that the substantial record evidence of Respondent's multiple controlled substance-related violations outweighs the evidence in RX 8.

F. Allegation That Respondent Issued Controlled Substance Prescriptions Beneath the Applicable Standard of Care and Outside the Usual Course of Professional Practice

Having read and analyzed all of the record evidence, I find substantial record evidence that Respondent issued many controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Accordingly, I find that the Government has presented a *prima facie* case, as outlined below.[47]

Regarding the Xanax 2 mg controlled substance prescription that Respondent issued to A.A. on October 8, 2013, I credit Dr. Munzing's testimony. Tr. 132–36; *supra* sections II, III.D., and III.E; *see* GX 12B, at 104–06. I find substantial record evidence that Respondent's first prescribing of Xanax to A.A. was at its ''highest dosage'' for anxiety, was at A.A.'s request (''Cannot afford to see PCP; only sees him for Prilosec and Xanax. Would like me to prescribe her these meds.''), was not associated with a ''real detailed history regarding anxiety as should be included if one is going to take over the management of prescribing a benzodiazepine such as Xanax for anxiety,'' was not issued after documented consideration of a ''safer, noncontrolled medication[ ] that can be used for anxiety,'' was issued ''in conjunction with an opiate'' and, therefore, posed a ''significantly increased risk'' to A.A. and was a ''significant red flag for abuse or diversion.'' Tr. 133–36; GX 12B, at 104–06; *see also* Tr. 431–33; *id.* at 228–29 (L.D.).

Respondent testified about his decision to do A.A. that ''favor,'' to ''accommodate'' her. Tr. 1106–08. He testified that even though prescribing benzodiazepines was ''something . . . [he'd] really never done in . . . [his] practice,'' he had a ''relationship'' with A.A., seeing A.A. ''monthly for at least two years.'' *Id.* at 1106. Respondent testified that he ''did not see where . . . [Xanax] was interfering with her function.'' *Id.* at 1106–07. ''In fact,'' he testified, Xanax ''improved her anxiety and it improved her level of functioning and the like.'' *Id.* at 1107. Accordingly, when A.A. said that she ''could save some money as her funds were limited,'' Respondent decided to ''accommodate'' her. *Id.* Respondent admitted that he continued to prescribe Xanax for A.A. ''in the face of UDSes that did not detect levels of . . . [Xanax] in her body.'' *Id.* When asked whether it ''was ever a concern to him'' that A.A.'s UDSes ''did not detect levels'' of Xanax in her body, Respondent testified that A.A. ''never obtained that medication from anyone else,'' and ''if the time came at the visit where it had already been out of her system, which implied that she took a little bit more earlier in the month[,] she had her monthly allowance and she did with it what she pleased.'' *Id.; see also supra* section III.E.

Accordingly, I find substantial record evidence that Respondent's first issuance of Xanax 2 mg to A.A. was beneath the applicable standard of care and outside the usual course of professional practice.

Regarding the parties' stipulations that, on June 5, 2013, Respondent increased the monthly amount of Percocet 10/325 he prescribed for A.A. from 90 to 120 tablets, and that the next month, on July 23, 2013, Respondent again increased the monthly amount of Percocet 10/325 he prescribed for A.A. from 120 to 180 tablets, I credit Dr. Munzing's testimony responding to whether the prescriptions ''met the standard of care in California and were issued in the usual course of professional practice.'' [48] *Supra* sections II, III.D., and III.E. Dr. Munzing testified that Respondent's Percocet prescriptions for A.A. did not meet the standard of care in California and were not issued in the usual course of professional practice. Jt. Stips. 59 and 60; Tr. 137–41 (Dr. Munzing's testimony that A.A. is ''already on an extremely high dosage of opioids and no real justification [in the medical records] to increase that,'' ''it appeared to have been increased . . . without medical justification and essentially increased it and then just kept on going rather than looking for an opportunity to over time gradually reduce it by some other management of the need other than just . . . prescribing opioids,'' and ''they're not medically justified, not used in professional practice, but it's not just because of that one visit. It's because other visits that I reviewed, my opinion was the same, is that, both where it went up but also ongoing, there wasn't an ongoing plan and the patient was being put at risk over long periods of time . . . . I could easily conclude that they were not medically justified.''); *but cf.* Tr. 661–63 (Dr. Helm's testimony that Respondent's increasing the Percocet prescription was ''medically justified based upon . . . [A.A.'s] complaints and examination and history'' and the side effects she experienced from Gabapentin). I credit Dr. Munzing's testimony over Dr. Helm's testimony when the two conflict. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent's prescription of 120 tablets of Percocet 10/325 for A.A. on June 5, 2013, an increase from 90 tablets, and his prescriptions of 180 tablets of Percocet 10/325 for A.A. the next month on July 23, 2013, through March 25, 2019, were issued beneath the applicable standard of care and outside the usual course of professional practice. GX 11, at 1–31.

The parties also stipulated that, on January 11, 2013, Respondent increased the monthly amount of methadone 10 mg he prescribed for A.A. from 90 to 120 tablets, and that on June 2, 2014, Respondent again increased the monthly amount of methadone 10 mg he prescribed for A.A. from 120 tablets to 180 tablets. Jt. Stips. 61 and 62. According to Respondent's testimony, ''one source of pain in the back could

[47] The OSC's allegations include that Respondent prescribed controlled substances at daily MME levels above 90 mg per day although the CDC ''recommends avoiding or carefully justifying'' doing so. *See, e.g.,* OSC, at 4–7, 9–10. The Government's questioning of Dr. Munzing included asking him whether Respondent's medical records documented reasons or justifications for prescribing the specific MME value associated with specific controlled substance prescriptions. *See, e.g.,* Tr. 128–31, 167, 185. This questioning by the Government, though, followed Dr. Munzing's testimony that, for example, there is no maximum MME above which a physician may prescribe and ''[t]here are occasions when one needs to go beyond the 90.'' *Id.* at 118. Dr. Munzing's testimony, when he offered to explain his response with an analogy, was cut off by a ''nonresponsive'' objection by Respondent. *Id.* at 119–22 (colloquy including ALJ's ruling sustaining the objection and his subsequent recap and explanation of his ruling). Given the entirety of the record transmitted to me, including the many examples of Respondent's controlled substance prescribing beneath the applicable standard of care and outside the usual course of professional practice, there is no need for me to consider the OSC's MME-levels-above-90-mg/day allegations, I am not doing so, and those allegations play no role in this Decision/Order. *Cf. id.* at 188 in conjunction with Jt. Stip. 79 (Dr. Munzing's testimony that Respondent's prescribing 90 mg/day of oxycodone for S.D. on February 4, 2019, March 1, 2019, and April 2, 2019, was beneath the applicable standard of care and outside the usual course of professional practice ''because we just don't have any information'').

[48] The medical records for the June 5, 2013 visit state that A.A. experienced left knee pain for three weeks and that Respondent gave A.A. an intra-articular steroid knee injection under ''strict aseptic technique'' during that visit. GX 12B, at 115–17.

be adhesions in the epidural space'' from ''inserting these percutaneous leads into the epidural space'' that ''do break up adhesions and stuff like that'' and ''there is a tiny bit of a therapeutic kind of thing there when you break up some adhesions.'' Tr. 1141. He testified that A.A. ''varied her dose from three to six tablets [of methadone] a day'' meaning that she ''had increased her activity level because she was doing things at—that she didn't necessarily do'' because ''she was able to figure out, 'If I took more medication on a particular day, I was able to accomplish greater tasks.' '' *Id.* at 1142. Respondent's testimony about this matter included an example: ''I can go to Costco if I take an extra [methadone] tablet.'' [49] *Id.; see also id.* at 141–44; *id.* at 665–74 (Dr. Helm's testimony stating Respondent ''documented increased pain reports and that would provide the basis for an increase'' and concluding that ''someone could argue should you increase or not, but that's a medical judgment''). Respondent's testimony about these matters did not address safety concerns or risks to A.A. of her self-dosing methadone. *Supra* section III.E. (Dr. Helm's testimony that methadone is disproportionately a cause of death because its half-life in the body is longer than the period of pain relief).

I credit Dr. Munzing's testimony regarding the medical records Respondent created about these methadone increases. *Supra* sections II, III.D., and III.E. Dr. Munzing addressed the first part of the paragraph called ''Pain HPI'' for the January 11, 2013 visit, which states A.A. ''appeared to be improved after the stimulator was tried.'' GX 12B, at 80. He testified that ''one would not certainly want to increase . . . [methadone] when there's improvement.'' Tr. 142; *see also id.* at 551–52; *id.* at 566–67. Regarding the last part of the same ''Pain HPI'' paragraph which states ''[h]igher dose of MTD necessary lately due to the intensity of her complaints,'' Dr. Munzing testified that A.A. was already at high risk due to very high dosages and the combination of medicines. *Id.* at 143; GX 12B, at 80; *see also* Tr. 551 (Dr. Munzing's testimony that increasing methadone from four a day to six a day is a ''large jump''); *id.* at 666 (Dr. Helm's testimony that ''some consider'' Respondent's doses high). Dr. Munzing testified that ''there are other alternatives, safer alternatives than just continuing to increase the dosage of medicine and putting a patient at much higher risk than they already are.'' Tr. 143; *see also id.* at 673 (Dr. Helm's testimony that, although A.A. reported benefits at the higher dose, ''it's something you don't want to encourage going forward'' because ''patient safety is the number one concern''); *id.* at 773 (Dr. Helm's testimony that ''there's no question you don't want patients taking meds *ad lib,* and I would share that, you know, while I get somebody who tells me that they have to do something it really raises an eyebrow because I don't want them to be just doing whatever it is they feel to do because—what they feel like they should do because that does create great risk''); *id.* at 773, 778 (Dr. Helm's testimony that Respondent did not document a conversation with A.A. about her not having taken the methadone as prescribed, that Dr. Helm agrees ''that is a documentation issue,'' and, consequently, that ''[w]e don't know what's going on'') in conjunction with *id.* at 782 (Dr. Helm's testimony, positing without a factual basis, that Respondent's failure to document is not a public health issue, but that Dr. Helm's ''practice would be . . . if she'[s] taking less to provide less'') and *id.* at 674 (Dr. Helm's testimony that ''what's remarkable about these patients is that by and large they did present improved benefit, which is unusual for the high-dose opioid patients,'' citing the Opioid Pain Consortium FDA-mandated study about opioid-induced hyperalgesia); *id.* at 885–889. I credit Dr. Munzing's testimony over Dr. Helm's testimony when the two conflict, and I afford Respondent's testimony limited credibility as the respondent in this adjudication. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued the methadone prescriptions for A.A. in GX 11 beneath the applicable standard of care and outside the usual course of professional practice.[50] Tr. 144; GX 11, at 1–31.

The parties stipulated that Respondent's first medical record-documented visit with R.B. took place on January 8, 2016. Jt. Stip. 63. During that initial visit, the parties stipulated, R.B. told Respondent that he ''was constantly in pain and had previously taken oxycodone and was then currently taking six tablets of Norco (hydrocodone-acetaminophen) 10/325 mg[ ] a day.'' Jt. Stip. 64. R.B.'s urine drug screen from that first visit, according to the parties' stipulation, was positive for THC. Jt. Stip. 65. The urine drug screen results did not corroborate R.B.'s statement to Respondent that he ''was then currently taking six tablets of Norco . . . a day.'' Jt. Stip. 64. The parties further stipulated that Respondent issued R.B. a controlled substance prescription for 90 tablets of oxycodone 30 mg at this initial visit. Jt. Stip. 66.

Based on my review of the record evidence regarding R.B.'s first visit with Respondent, I find substantial record evidence that Respondent issued a controlled substance prescription to R.B., for 90 tablets of oxycodone 30 mg, without documenting his knowledge of R.B.'s medical history based on input directly from R.B.'s previous physician or physician assistant, without documenting that he addressed R.B.'s in-house, positive THC urine drug screen, and without documenting that he assessed R.B. for the risk of opioid abuse. Tr. 155–56 (Dr. Munzing's testimony, including that he ''do[es]n't see any further history and specifics in detail regarding other drug use,'' that ''there's no kind of detailed evaluation of both current and also past drug use and is there any history,'' that he ''do[es]n't see any kind of opioid risk tool or other screening for—there's SOAPP . . . and also the ORG, Opioid Risk Tool, that gives you an idea about risk for abuse,'' and that he ''do[es]n't see any specifics in past medical records that would verify a lot of this . . . [s]o you're going essentially from zero . . . immediately to 135, so . . . [he has] great concerns about that visit''); MBC Guide to the Laws, at 59–61; *see also* GX 14B, at 72–74; *compare* Tr. 675–78 (Dr. Helm's testimony that it was ''medically appropriate'' to ''initiate care'' and ''appropriate treatment'' for Respondent to prescribe oxycodone because it was of benefit in the past and the R.B. reported he was not benefitting from Norco) with *id.* at 784–85 (Dr. Helm's testimony agreeing that a physician ''can't just rely on what another physician did in . . . [his] own decisions to prescribe a particular controlled substance''). I credit Dr. Munzing's testimony.

Accordingly, I find substantial record evidence that Respondent issued the first 90 tablet oxycodone 30 mg

[49] The ALJ stated, after hearing this portion of Respondent's testimony, that ''I don't understand your answer.'' Tr. 1142.

[50] The Government alleged that Respondent's Xanax prescriptions were not legitimate because he continued them in the face of A.A.'s aberrant urine drug screens. Tr. 144–53. The Government's case did not note, analyze, or address the ''prn'' notation on the Xanax prescriptions. Accordingly, I find that the Government did not present a *prima facie* case on this allegation. *See, e.g.,* GX 11, 1–31.

The record evidence, though, that Respondent conducted urine drug screens, yet did not analyze and note, let alone act on, the results is puzzling at best. At worst, it raises serious questions about Respondent's knowledge about, and implementation of, controlled substance-related best practices. *Supra* section III.E. The Government did not pursue these matters and, accordingly, they play no role in my Decision/Order.

prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

Regarding the record evidence concerning R.B.'s second visit with Respondent, I find substantial record evidence that R.B. reported feeling ''much improved'' with ''[s]ome of . . . [his] pain . . . even down to a 1–2/10.'' GX 14B, at 70; *see also* Tr. 156, 159–60. I credit Dr. Munzing's testimony that ''you have to take in the whole context . . . [a]nd . . . [Respondent] should not have issued that prescription. You have . . . aberrant urine drug tests that aren't being explained . . . [and R.B.] starts out [saying he] is much improved. Well, if you're much improved, then maybe we've overshot and we can . . . give you much less.'' Tr. 159–60. I find no record evidence that Respondent documented use of his professional judgment to evaluate R.B.'s changed pain report and to consider adjusting the 90 tablet oxycodone 30 mg therapy he initiated on R.B.'s prior visit. GX 14B, at 70–71.

Accordingly, I find substantial record evidence that Respondent issued the second 90 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

Also concerning R.B.'s second visit with Respondent, there is substantial record evidence that the in-house UDS was again positive for THC and was also positive for oxycodone, opioid, and benzodiazepine. GX 14B, at 71; *see also* Tr. 157–58. However, there is no record evidence that Respondent ever issued R.B. a prescription for THC or for a benzodiazepine. *See, e.g.,* Tr. 1114–15. I credit Dr. Munzing's testimony, and I find substantial record evidence that this second-visit, in-house UDS was aberrant and that Respondent's medical record for this visit with R.B. does not document that he addressed this aberrancy in any way. *Id.* at 157–58; *supra* sections II, III.D., and III.E.

Accordingly, I find further substantial record evidence that Respondent issued the second 90 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. GX 14B, at 71; MBC Guide to the Laws, at 60–61.

Further, the parties stipulated that Respondent increased the oxycodone 30 mg prescription for R.B. from 90 tablets to 120 tablets on April 6, 2016. Jt. Stip. 74; GX 14B, at 69. During the same visit, however, the substantial record evidence shows that Respondent documented in R.B.'s medical record that R.B. reported ''[f]eeling much improved,'' that ''all complaints of pain are less,'' and that R.B. exercised daily, predominantly by walking four to six miles. GX 14B, at 68; *see also* Jt. Stip. 75. I find no evidence in Respondent's medical record for the April 6, 2016 visit with R.B. that Respondent documented the professional judgment and analysis that led him to increase the oxycodone 30 mg prescription he issued for R.B. from 90 to 120 tablets. Tr. 170–71; *see also* GX 14B, at 68–69; Tr. 678–79 (Dr. Helm's testimony that the rationale for Respondent's prescribing ''would have to be . . . decrease pain and increase function'').

Accordingly, I find substantial record evidence that Respondent issued the April 6, 2016 120 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. GX 14B, at 68–69; MBC Guide to the Laws, at 59–61.

I find substantial record evidence that Respondent prescribed R.B. the controlled cough medicine promethazine with codeine. *See, e.g.,* GX 14B, at 13–24. According to Dr. Munzing's testimony, which I credit, promethazine with codeine is a highly abused controlled substance. Tr. 172; *supra* sections II, III.D., and III.E. I find substantial record evidence that Respondent's medical record for R.B.'s February 7, 2018 visit states that R.B.'s primary care physician ''will no longer prescribe . . . [R.B.] the cough syrup'' and that Respondent issued R.B. a prescription for that controlled substance, including a refill, on that day. GX 14B, at 24; *see also* Tr. 1108. Dr. Munzing's analysis of Respondent's medical records for R.B., which I credit, includes that Respondent did not document conducting a lung examination or evaluation of R.B. prior to issuing this controlled substance prescription. Tr. 173; *supra* sections II, III.D., and III.E.; *see also* Tr. 480–81 and *id.* at 1109 (Respondent's testimony that he ''never delved into'' why R.B. had the cough and the ''bottom line is, he had a cough''). Dr. Munzing's testimony about Respondent's medical records states, and I credit his testimony, that the ''primary physician has cut . . . [R.B.] off[, w]e don't know why[, i]t's not explored[,] and it's not documented why the primary physician cut him off.'' *Id.* at 174; *supra* sections II, III.D., and III.E. I also find that Dr. Munzing credibly testified that Respondent is a pain management doctor, not a pulmonologist, and credibly questioned whether Respondent is the ''right person'' to diagnose a pulmonary matter and to evaluate whether this controlled substance is the appropriate way to treat this pulmonary matter. Tr. 174; *see also id.* at 481. Specifically, Dr. Munzing testified, and I credit his testimony, that ''prescribing promethazine with codeine on a chronic, ongoing basis is not the treatment for anything and is high risk for abuse.'' *Id.* at 176; *supra* sections II, III.D., and III.E.; *but cf.* Tr. 684–85 (Dr. Helm's testimony answering ''[s]ure'' when asked whether it was ''within the standard of care'' for Respondent to ''agree to take over prescribing'' the promethazine with codeine because ''the primary care physician bluntly had been low-hanging fruit for the Medical Board in terms of their prescribing, so . . . many of them just don't want to prescribe controlled substances, and it is very consistent with the environment'') and *id.* at 1108 (Respondent's similar testimony).

Accordingly, I find substantial record evidence that Respondent issued the February 7, 2018 promethazine with codeine prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

In sum, based on all of the record evidence, I find substantial record evidence that Respondent issued controlled substance prescriptions for R.B. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61; *see also, e.g.,* Tr. 164; *id.* at 166; *id.* at 175–77.

There is substantial record evidence that Respondent's controlled substance prescribing for S.D. was below the applicable standard of care and outside the usual course of professional practice. For example, there is substantial record evidence that Respondent concurrently issued on twelve occasions between January 2018 and January 2019, and S.D. filled, controlled substance prescriptions for methadone 10 mg, Roxicodone 15 mg, and carisoprodol 350 mg. GX 15, at 1–24. There is also substantial record evidence that the number of tablets Respondent prescribed for S.D. during this period increased from 180 to 270 tablets of methadone and from 60 to 120 tablets of carisoprodol. *Id.* According to Dr. Munzing's testimony, which I credit, Respondent issued these prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Tr. 206–207 (Dr. Munzing's testimony that ''based on not just the prescription but . . . what we've reviewed, the medical records, is that that's not medically justified, not

usual professional practice); *supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued these controlled substance prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

The parties stipulated that Respondent prescribed 90 mg of oxycodone/day for S.D. on February 4, 2019, March 1, 2019, and April 2, 2019. Jt. Stip. 79. According to Dr. Munzing's testimony, which I credit, Respondent's issuance of these three stipulated prescriptions did not comply with the applicable standard of care and was outside the usual course of professional practice because Respondent did not document their issuance in S.D.'s medical records. Tr. 188 (Dr. Munzing's testimony that these prescriptions were issued beneath the applicable standard of care and outside the usual course of professional practice); *supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued these controlled substance prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

The parties stipulated that, on February 24, 2016, Respondent increased the methadone prescription for S.D. from 120 tablets to 180 tablets. Jt. Stip. 80; GX 16D, at 76–77. According to Dr. Munzing's testimony, which I credit, the medical record Respondent created for S.D.'s February 24, 2016 visit, documents a ''very minimal exam'' on which the increased dosage ''couldn't be based.'' GX 16D, at 76–77; Tr. 188–89 (Dr. Munzing's testimony, including that, ''without an exam, without a lot of details . . . I don't see anything that would justify that increase''); *supra* sections II, III.D., and III.E.

Similarly, the parties stipulated that, on April 20, 2018, Respondent increased the methadone prescription for S.D. from 180 tablets to 270 tablets. Jt. Stip. 81; GX 16D, at 23–25 (''current meds are inadequate in controlling her pain even if she takes them exactly on schedule'' and ''[d]ue to inadequate pain relief, increase MTD 10 mg to #270 3 tabs TID prn. Continue other meds; appropriate refills given''). According to Dr. Munzing's testimony, which I credit, Respondent's April 20, 2018 prescription for S.D., increasing the methadone prescribed from 180 tablets to 270 tablets, was issued beneath the applicable standard of care and outside the usual course of professional practice. Tr. 190–91; *supra* sections II, III.D., and III.E. Dr. Munzing testified, regarding these methadone tablet increases, that they put S.D. ''at incredibly high risk,'' particularly because of S.D,'s age, and that there is no medical record documentation that S.D. was made aware of and consented to that ''incredibly high risk.'' Tr. 191–92.

Accordingly, I find substantial record evidence that Respondent issued his February 24, 2015 and April 20, 2018 methadone prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice.[51] MBC Guide to the Laws, at 59–61.

The parties stipulated that the first visit of Respondent with L.D. was on June 20, 2011. Jt. Stip. 82; *see also* GX 18B, at 145–46. The parties also stipulated, about this first visit, that Respondent documented that L.D. was ''taking amphetamine.'' Jt. Stip. 83; *see also* GX 18B, at 145. According to his medical records for L.D.'s first visit on June 20, 2011, Respondent documented ''[r]efill of Amphetamine salts given.'' GX 18B, at 146. Dr. Munzing testified, and I credit his testimony, that Respondent's medical record for L.D.'s first visit is ''completely unclear '' about why L.D. was taking amphetamine. Tr. 208; *see also id.* at 491–92 (Dr. Munzing's testimony that Respondent's medical records document that L.D. complained of pain, do not document that L.D. complained of fatigue, do not document an exhaustive review of symptoms, and do not document an evaluation or diagnosis of chronic fatigue syndrome); *id.* at 568–69; *id.* at 709–10 (Dr. Helm's testimony that the medical records for L.D.'s first visit with Respondent show no diagnosis for which Respondent prescribed amphetamine salt); *id.* at 797–99 (Dr. Helm's testimony that a diagnosis (chronic fatigue syndrome) that might call for treatment with amphetamine salt first appears in the medical records for L.D.'s third visit). Dr. Munzing further testified that Respondent's medical records for L.D.'s June 20, 2011 visit include ''no diagnosis of ADHD, attention deficit hyperactivity disorder, or similar'' diagnosis. *Id.* at 208. Dr. Munzing also testified that, ''typically, for most conditions, including the one that it's typically prescribed for, ADHD, when someone is on high doses of opioids, there are alternatives which generally are not controlled and are much safer, not addicting. And so one would typically not use . . . an amphetamine salt.'' *Id.* at 212–13. Dr. Munzing additionally testified that amphetamine salt ''would not typically be a medication prescribed by a pain medication pain management doctor.''[52] *Id.* at 209; *see also id.* at 491 (amphetamine salt is not a regularly labeled treatment for chronic fatigue syndrome); *id.* at 573–75. I credit Dr. Munzing's testimony. *Supra* sections II, III.D., and III.E. In addition, I note that there is agreement between Dr. Munzing and Dr. Helm on some of these matters. *Supra.*

Accordingly, I find, based on substantial record evidence, that Respondent's issuance to L.D. of a prescription for amphetamine salt on L.D.'s first visit with him was beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59.

Although Respondent's medical records for L.D. reference the criminal incarceration, up-coming trial, conviction, and sentencing of L.D.'s former spouse and L.D.'s up-coming sentencing hearing, I find no credible record evidence that they address whether the underlying criminal bases for these events were related to drugs.[53] GX 18B, at 82, 88. Dr. Munzing testified that such criminal-related litigation is a ''huge red flag'' that Respondent ''left wide open'' and ''all one needs to do is document and resolve the red flag.'' Tr. 232, 496–99; *see also id.* at 504. He testified that a ''medical record doesn't need the specifics, but it certainly does need to know does it have anything to do with the issues that we're dealing with here, and it was silent to that effect.'' *Id.* at 231; *cf. id.* at 715 (Dr. Helm's testimony that Respondent's medical records ''clearly showed'' that L.D.'s criminal involvement was ''business,'' but no direct response to Respondent's counsel's question of

[51] *See also* Tr. 190 (Dr. Munzing's testimony that S.D. ''has chronic significant medical problem[s]'' and ''[n]o one's arguing that'').

[52] According to a document in GX 18A entitled ''[L.D.'s] Doctors & Medication List,'' a pulmonologist prescribed L.D. amphetamine. GX 18A, at 82. The document is not dated and does not indicate its origin. Although Respondent testified about the document, his testimony did not address the document's origin. *Supra* section III.E.

[53] I note, in contrast, that Respondent's medical records for A.A. state that A.A.'s ''[d]aughter has been stealing her medications regularly, police report filed. Patient will now file a restraining order against her daughter,'' and that Dr. Munzing's testimony agrees with Respondent's counsel that ''[t]hat's all a very reasonable explanation to deal with stolen medication.'' GX 12B, at 154; Tr. 415. For A.A.'s next visit, Respondent wrote in the medical record that ''[d]aughter no longer living with her and therefore no further issues with meds being stolen,'' and that Dr. Munzing's testimony agrees with Respondent's counsel that that ''was good follow[-]up with respect to the daughter having stolen medications.'' GX 12B, at 151; Tr. 416; *see also id.* at 639–40 (Dr. Helm's testimony).

whether Respondent ''adequately document[ed]'' L.D.'s criminal status). ''[I]t's something that would be fairly simple to close that red flag, but was not addressed, was not done,'' Dr. Munzing further testified. *Id.* at 232. I credit Dr. Munzing's testimony that these criminal litigation-related medical records of Respondent are beneath the applicable standard of care and outside the usual course of professional practice. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent's medical records pertaining to these criminal litigation-related matters are beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 61.

As already discussed, the record evidence addresses the UDSes that Respondent conducted. *Supra* sections III.D. and III.E; *see also, e.g.,* GX 12, 14, 16, 18, 20, 22. Regarding Respondent's January 9, 2017 visit with L.D., for example, I find substantial record evidence that Respondent conducted a UDS and that Respondent's medical records show the UDS results to have been positive for benzodiazepine and opioid. GX 18B, at 35. I further find substantial record evidence that Respondent's medical records for that visit with L.D. also show that L.D.'s ''[m]eds include . . . [a]mphetamine salt 30 mg qd,'' that L.D.'s ''Current Medications'' section includes ''Amphetamine Salt Combo 30 mg Tab—Dispense: 30: 1 TABLET ORAL Q Day; Started: 06/20/2011,'' and that the ''Working Treatment Plan'' section states ''2 months scripts given for Amp Salt, DP, and Dilaudid 8 mg[ ]'' [54] *Id.* at 34–36. According to Dr. Munzing's testimony, which I credit, L.D.'s January 9, 2017 UDS result is ''[a]bsolutely'' aberrant—because it did not show a positive result for amphetamine salt—and Respondent did not address the aberrancy in the medical record. Tr. 234–35; *supra* sections II, III.D., and III.E.; *see also* Tr. 234–35 (Dr. Munzing's testimony that Respondent's compliance monitoring, including 2017 aberrant UDSes, ''certainly falls far short of the standard of care''), *id.* at 502–03 and GX 18B, at 101 (Respondent's May 14, 2013 medical records for L.D. noting ''[i]ntolerable'' pain, spasm, ''exacerbating RUE pain,'' and tension headache, yet recording UDS results as negative for prescribed controlled substances and being ''silent'' about, and recording no explanation for, the aberrancy, particularly when viewed in conjunction with the noted ''[i]ntolerable'' pain), and Tr. 236–37 (S.H.).[55]

Accordingly, I find substantial record evidence that Respondent acted beneath the applicable standard of care and outside the usual course of professional practice by failing to address an aberrant UDS and, despite the aberrancy, issued for L.D. a prescription for a two-month supply of amphetamine salt.[56] *See, e.g.,* MBC Guide to the Laws, at 60.

According to the parties' stipulation, J.M.'s first documented visit with Respondent was on May 17, 2011. Jt. Stip. 97. At that time, the parties further stipulated, J.M. ''reported to Respondent that he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.'' Jt. Stip. 98. The parties also stipulated that Respondent checked CURES for J.M. on May 17, 2011. Jt. Stip. 103.a. I find, based on substantial record evidence, that Respondent issued a controlled substance prescription for J.M. on May 17, 2011. GX 22B, at 133 (Roxicodone 30 mg 180 tablets 1 q4–6 prn to a max of 6/day).

I find, based on substantial record evidence including Respondent's medical records for J.M., that the medical office that treated J.M. before Respondent's treatment transmitted a seven-page fax to Respondent on June 14, 2011. GX 22A, at 71–77. I find substantial record evidence that the fax cover sheet states ''[p]lease see attached medical records for . . . [J.M.] per your request.'' *Id.* at 71. I find substantial record evidence that the transmittal includes a letter from the medical practice to J.M. dated June 1, 2011. *Id.* at 72. I find substantial record evidence that the letter states that ''[i]t has been brought to . . . [the] attention'' of the medical office that J.M. ''violated our Controlled Substance Policy by receiving medications from multiple physicians per the DOJ report from 05/31/2011.'' *Id.* I find substantial record evidence that, after stating that the practice has ''nothing further to offer'' J.M. due to the ensuing ''eliminat[ion] of trust,'' the letter states that J.M. ''will receive a 30-day supply of . . . Oxycontin, and Roxicodone today,'' which will be J.M.'s ''final prescriptions filled by . . . [that] office.'' *Id.*

The parties stipulated that Respondent's medical records for J.M.'s June 17, 2011 visit document that J.M.'s mother ''came to the office'' with J.M. Jt. Stip. 99; *see also* Jt. Stip. 100 and GX 22B, at 128 (''Here with mother to plead mercy. Needs a doctor close to home. Wants a second chance.''). I find substantial record evidence that, in the ''Working Treatment Plan'' section of Respondent's medical records for J.M. for the June 17, 2011 visit, Respondent wrote ''One final chance; script for #180 Roxi given.'' GX 22B, at 129; *see also* Jt. Stip. 101–02.

Respondent testified about these initial visits with J.M. Among other things, Respondent admitted in his testimony that J.M. was on a high dose of oxycodone. Tr. 1097. Regarding J.M.'s visit with Respondent on May 17, 2011, Respondent testified that he ''was trying to put the pieces of the puzzle together'' and that he was with J.M. ''for excess of an hour, observing the way . . . [J.M.] walked into the room, observing the way he left the room, [and] observing the way that he remained seated for an excess of an hour.'' *Id.* at 1138. Respondent testified that he ''felt that that was adequate exam for these particular diagnoses'' and that he ''would not expect anything acute on exam'' related to J.M.'s ''long history of compression fractures.'' *Id.*

Regarding J.M.'s June 17, 2011 visit, Respondent testified, defending his issuance of a controlled substance prescription for J.M. without having conducted a physical exam, that ''nothing had changed in these few weeks and there were no acute findings'' and that he ''again, . . . would expect absolutely nothing acute

[54] According to the testimony of Dr. Munzing, ''DP'' means Duragesic Patch, or fentanyl patch. *See, e.g.,* Tr. 208.

[55] According to the record evidence, Respondent failed to document and address, explicitly, negative UDS results for controlled substances that he prescribed ''prn.'' *See, e.g.,* GX 20B, at 67–69 (S.H./methadone). While the analysis of UDS results for controlled substances issued ''prn'' differs from the analysis of UDS results for controlled substances not issued ''prn,'' an analysis would still ensue including, if appropriate, an assessment of whether to issue another prescription for the ''prn'' controlled substance if the controlled substance was not being ingested with the frequency the prescription allowed. The record evidence does not document that Respondent conducted any such analysis; however, I do not consider these matters in this Decision/Order.

[56] I note that Respondent's medical records state that, on June 18, 2012, he issued L.D. refills of Dilaudid, Klonopin, and amphetamine salt and that L.D. would see him again in two months. GX 18B, at 118. Respondent's medical records for L.D. on that date also document that L.D.'s UDS was positive for cocaine. *Id.; see also* Tr. 594 (Dr. Munzing's testimony that a cocaine-positive UDS is ''[s]uper aberrant''). I see nothing in the medical records documenting Respondent's review, consideration, evaluation, assessment, or addressing of L.D.'s cocaine-positive UDS. I find that these medical records are substantial record evidence of Respondent's failure to comply with the applicable standard of care and the usual course of professional practice. *See, e.g.,* MBC Guide to the Laws, at 60–61; *see also* Tr. 584–85, 610–12 (Dr. Munzing's testimony); *but see id.* at 713–14 (Dr. Helm's testimony that the cocaine-positive UDS was ''probably a false positive'' because ''[t]his is not a patient who—one would think would be getting cocaine,'' that he ''would have preferred to see a note in the chart just acknowledging that the finding is there,'' and that he ''think[s] there should have been more steps to confirm'' that the cocaine-positive UDS was a ''false positive'').

on the exam'' because he was ''only treating chronic pain.'' *Id.* at 1139.

Respondent also testified about J.M.'s July 15, 2011 visit with him. According to Respondent, he conducted a comprehensive physical examination of J.M. at that visit ''[b]ecause now the dust had settled,'' ''everything's organized,'' ''we're all in agreement,'' ''[w]e understand everything that's going on,'' ''[t]here was time, and it was time to carry on with this . . . situation,'' and ''[w]e had time to develop a baseline exam and everything like that.'' *Id.* at 1139–40. Respondent also testified that, during the July 15, 2011 visit, J.M. reported experiencing ''an exacerbation of pain,'' ''changes in his range of motion,'' and ''changes in his body movement,'' and ''so then we carry on with the full exam.'' *Id.* at 1140.

Dr. Helm also testified about Respondent's initial visits with J.M.[57] According to Dr. Helm, it is ''acceptable'' to ''defer'' a physical examination for a patient who is already on medications issued by another provider. *Id.* at 733. He testified that the physician is ''deferring the bulk of the exam'' due to being ''so busy . . . collecting the history and determining on the basis of histories or [sic] legitimate medical purpose for the medications'' and ''document[s] why'' the exam is being deferred. *Id.* at 733–34. Dr. Helm testified that he ''understands'' what Respondent's documentation of ''one final chance'' means, ''that . . . [Respondent] is willing to go forward with . . . [J.M.] on a, you know, if you will, a tight leash where he's really got to continue with the meds or continue with compliance and he can't be doing what he just did.'' *Id.* at 806.

Dr. Munzing also testified about Respondent's initial visits with J.M. Regarding J.M.'s May 17, 2011 visit with Respondent, Dr. Munzing testified that Respondent prescribed controlled substances for J.M. even though ''[w]e just don't know . . . [if J.M. was] actually taking all that medication'' based on J.M.'s own documented statement to Respondent that ''he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.'' *Id.* at 548; Jt. Stip. 98; *see also* Tr. 548 (Dr. Munzing's testimony that ''[t]here's no documentation in here regarding urine drug test [sic], regarding prior records at this point, regarding any of that, and so that medication was prescribed strictly based on whether a patient told you without any other investigation, without a detailed review of the patient from what we can see, from what's documented, and without doing any examination of the patient''), *id.* at 547 (Dr. Munzing's testimony that ''[t]here's nothing—it does not appear based on what's documented that actually the Respondent even actually touched the patient, had him do any specific maneuvers . . . none of [what is done during a back exam] existed. None of that was documented.''), *id.* at 563–64 (same).

Regarding J.M.'s June 17, 2011 visit with Respondent, Dr. Munzing testified that ''it's a significant red flag that here [sic] pleading for mercy, one more chance . . . [and] no other significant information is documented. That's a great concern.'' Tr. 267. Dr. Munzing also addressed Respondent's issuance of Roxicodone 30 mg (180 tablets) and oxycodone 30 mg (180 tablets) to J.M. during their initial visits. Dr. Munzing testified that ''here we're three visits into it at least, and we have no exam at all but you're prescribing extremely high dosages of medication,'' that ''here we are just over two weeks later [from when J.M. received controlled substance prescriptions from his prior physician] and you're giving some more . . . [even though h]e should still have . . . at least another couple of weeks left, and so there's no indication to get more,'' and that ''there's a cascade of things that ought to be here,'' specifically listing information about mental health issues and about drug and alcohol current or past history, or use. *Id.* at 267–68.

I credit Dr. Munzing's testimony. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent acted beneath the applicable standard of care and outside the usual course of professional practice by, for example, issuing J.M. controlled substance prescriptions at J.M.'s first two documented visits. *E.g.,* MBC Guide to the Laws, at 59.

As already discussed, based on these founded violations alone, I find that the Government presented a *prima facie* case. Accordingly, I see no need, and I decline, to discuss and assess the other OSC allegations and the other elements of the Government's case.

IV. Discussion

A. The Controlled Substances Act

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing . . . controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

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

[57] While not explicitly addressed in the record evidence, Dr. Helm's testimony appears plausible that J.M. returned to his prior physician's medical practice after seeing Respondent on May 17, 2011, the prior physician's medical practice discovered from CURES that J.M. filled Respondent-issued controlled substance prescriptions, and the prior physician's medical practice dismissed J.M. for violating the policy of receiving medications from only one physician. Tr. 734–35. Dr. Helm's suppositions on these matters are irrelevant to, and therefore do not impact, my Decision/Order.

of a registration. *MacKay,* 664 F.3d at 821.

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its prima facie case is confined to Factors Two and Four.[58] Govt Posthearing, at 31. As already discussed, I find that a segment of the Government's case includes sufficient evidence with respect to Factors Two and Four to satisfy its prima facie burden of showing that Respondent's continued registration would be ''inconsistent with the public interest'' without my needing to consider its entire case, some of which is insufficiently developed. 21 U.S.C. 823(f). I further find that Respondent failed to produce sufficient evidence to rebut the Government's prima facie case.

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

Allegation That Respondent's Registrations Are Inconsistent With the Public Interest

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

Respondent engaged a skillful team and defended himself against all of the OSC's allegations. I read and analyzed every aspect of Respondent's defense including his record evidence. As already discussed, Respondent's evidence and argument are not persuasive on the founded violations. *Supra* section III.F.

Respondent's case admits that some of Respondent's medical recordkeeping is substandard. *See, e.g. supra* section III.F; Tr. 773, 778 (Dr. Helm's testimony about the lack of Respondent's documentation and, in the absence of his documentation, ''[w]e don't know what's going on''). Respondent's case and hearing testimony about the existence, content, and accuracy of his medical records, however, largely excuse his documentation failures. *See, e.g., supra* section III.E.; Tr. 940 (Respondent's testimony that A.A.'s aberrant UDS ''was not of significance to me'' and ''was not of concern to me'' because ''she is my patient,'' ''I'm her doctor,'' and ''I have a relationship with her . . . an understanding with her . . . [a]nd this was not a cause for alarm''); *id.* at 962–63 (Respondent's testimony that his ''record is wrong because I'm so busy talking to the patient . . . [b]ut again, from this chart, that's not a big problem, because it's historically her left knee''); *id.* at 972 (Respondent's testimony that ''a lot of [his medical] records have been read wrong and interpreted wrong [at the hearing] because I'm doing a million things at once, and people are trying to read the exact word''). Respondent's case does not include citation to the applicable standard of care's allowance for such excuses, and I found none. *See supra* section II.

By way of further example, Respondent's case admits that some of Respondent's controlled substance prescription monitoring is substandard. *See, e.g., supra* section III.E; Tr. 1098 (Respondent's testimony that he did not consider a UDS to be aberrant if it is negative for a substance he prescribed, admitting that his ''attorney then, you know, corrected me on that statement''). Respondent testified that he used UDSes to look for the presence of substances that he had not prescribed. Tr. 1098. Yet, despite this testimony, by his own admission he did not follow up on L.D.'s cocaine-positive UDS documented in the medical records until during preparations for this hearing. *Supra* section III.E.

As already discussed, there is substantial record evidence that Respondent issued controlled substance prescriptions before conducting the requisite physical examination and before documenting a diagnosis. *Supra* section III.F. There is substantial record evidence that he prescribed controlled substances as favors or accommodations. *Id.* There is substantial record evidence that Respondent increased the dosages of controlled substances he was prescribing, even controlled substances that are highly abused and diverted and that are a disproportionate cause of death, without the requisite documentation. *Id.* There is even substantial record evidence that Respondent increased the dosage of a controlled substance on the recipient's demand, against his previous medical analysis and medical judgment, and increased the dosage of other controlled substances based on ''ad lib'' self-dosing. *Id.* There is substantial record evidence that Respondent issued controlled substance prescriptions without accurate and complete documentation and based on the representations of others, as opposed to basing it on his independent medical analysis and judgment. *Id.* There is substantial record evidence that Respondent failed correctly to identify aberrant UDSes, to document them, and to resolve them before further prescribing the controlled substance at issue in the aberrancy. *Id.* There is substantial record evidence that Respondent failed to identify and resolve other red flags of abuse and diversion before further prescribing the controlled substance. *Id.*

As already discussed, I find that these unrebutted actions and inactions by Respondent in his controlled-substance related prescribing are violations of the applicable standard of care and are outside the usual course of professional practice and, therefore, are CSA violations. 21 CFR 1306.04(a). Accordingly, I find that it is appropriate to sanction Respondent for these violations.

[58] As to Factor One, the Government does not dispute, and there is no record evidence disputing, Respondent's claims that he has an unblemished medical record and has never had any disciplinary action brought against his license, presumably meaning his medical license. Resp Posthearing, at 2, 21–22; 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as prior Agency decisions have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808 (10th Cir. 2011). Those Agency decisions have therefore concluded that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

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

Summary of Factors Two and Four and Imminent Danger

As already discussed, Respondent's case does not successfully rebut the Government's *prima facie* case, established by substantial record evidence, that Respondent issued controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Accordingly, I find that Respondent engaged in egregious misconduct which supports the revocation of his registrations. *See Wesley Pope,* 82 FR 14944, 14985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial record evidence that Respondent issued controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice establishes that there was ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registrations. *Id.; see, e.g.,* Tr. 1030–32 (Respondent's testimony about his prescribing Duragesic patch when ''you haven't been on it for a while, and you might not even need that much'' and then increasing the dosage based on self-dosing reports); *id.* at 842 (the testimony of Dr. Helm that methadone is a disproportionate cause of death). Thus, I find that, at the time the OSC was issued, there was clear evidence of imminent danger.

V. Sanction

Where, as here, the Government has met its prima facie burden of showing that Respondent's continued registration is inconsistent with the public interest due to his numerous violations pertaining to controlled substance prescribing, the burden shifts to the Respondent to show why he can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *Id.* A registrant's acceptance of responsibility must be unequivocal. *Id.* In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* (collecting cases). In addition, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Id.*

Regarding these matters, I find that Respondent did not take responsibility, let alone unequivocal responsibility, for the founded violations. Tr. 1116 (Respondent's ''I don't'' response during his testimony when asked ''Do you accept responsibility for the prescriptions at issue not being issued in the usual course of professional practice?''). Concerning his medical recordkeeping, while Respondent ''acknowledged'' that it ''could be improved,'' this acknowledgement is not an acceptance of responsibility, let alone an unequivocal acceptance of responsibility. *Id.* at 1133. Further, Respondent's testimony after ''acknowledging'' that his medical recordkeeping could be improved was that ''in retrospect, thinking last night, I could have actually—even with what I have, I could have improved my recordkeeping because it's part of my electronic medical record under treatment plan where you click boxes. . . . [T]here is a section where you can click that the urine drug screens were checked.'' *Id.* at 1133–34. The ALJ followed up with the Respondent on this portion of his testimony, stating that ''these medical records that you have . . . the capability of checking a box that shows that you checked the CURES report or checking a box to show that you had conducted a UDS . . . really is not the problem with this case.'' *Id.* at 1134. ''The problem with this case,'' the ALJ continued, ''is that—it doesn't show that you did anything with it.'' *Id.* When Respondent reacted to the ALJ by stating ''[t]hat I discussed it,'' the ALJ stated ''Yes. So that's not checking a box.'' *Id.* at 1135. I agree with the ALJ. Accordingly, even if it were appropriate to consider Respondent's electronic medical record testimony to be Respondent's proposed remedial measures, I would find Respondent's proposal to be insufficient.

I also note that Respondent testified further about his substandard recordkeeping and the ways he will improve. *Id.* at 1086. Respondent testified that he ''need[s] to learn to type and speak at the same time'' instead of ''spending so much time discussing with the patient's issues.'' *Id.* He also testified that he ''guess[es]'' he could hire a scribe, ''somebody who is sitting there typing while you talk,'' but that he's ''not interested in having someone interfere with . . . [his] relationship with . . . [his] patient.'' *Id.* Respondent further testified that ''the world has changed'' and that he ''now need[s] to think of . . . [his medical records] as not about . . . [him but as a] document [that] is going to be scrutinized by everyone.'' *Id.* at 1087. I reject the suggestion that the applicable standard of care forces a physician to choose between compliance with that standard of care and providing patients medical care that complies with the applicable standard of care within the usual course of professional practice. I find that Respondent's suggestion of this false choice reflects an insufficient appreciation and understanding of medical recordkeeping standards of care and the responsibilities of a registrant.

In sum, I find that the record supports the imposition of a sanction because Respondent did not unequivocally accept responsibility and because Respondent has not convinced me that he can be entrusted with a registration.

The interests of specific and general deterrence weigh in favor of revocation. Respondent explicitly refused to accept responsibility for his substandard controlled substance prescribing. *Id.* at 1116. Respondent has not convinced me that he understands that his controlled substance prescribing fell short of the applicable standard of care and that this substandard controlled substance prescribing has serious negative ramifications for the health, safety, and medical care of individuals who come to him for medical care. As such, it is not reasonable for me to believe that Respondent's future controlled substance prescribing and recordkeeping will comply with legal requirements. Further, given the nature and number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

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

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby revoke DEA Certificates of Registration BR0869719 and BA7661564 along with DATA-

Waiver No. XR0869719 issued to Craig S. Rosenblum, M.D. I further hereby deny any pending application(s) of Craig S. Rosenblum, M.D., to renew or modify these registrations, as well as any other pending application(s) of Craig S. Rosenblum, M.D., or Aurora Surgery Center LP for registration in California. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07727 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Christopher King, C.N.P.; Decision and Order

On December 18, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Christopher C. King, N.P. (hereinafter, Applicant) of Manchester, Maine. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed to deny Applicant's DEA Certificate of Registration application, Number W19022896M, as well as to deny any pending applications for renewal or modification of such registration and any applications for any other registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because ''[Applicant's] registration is inconsistent with the public interest.'' *Id.*

The OSC alleged that Applicant had ''exhibited negative experience in handling controlled substances . . . and [had] failed to comply with applicable federal and state laws relating to controlled substances.'' *Id.* at 2. Specifically, the OSC alleged that, while employed at Mercy Hospital from April 10, 2013, to June 13, 2013, Applicant diverted controlled substances on at least two different occasions in violation of federal and state law. *Id.* at 4–6. The OSC also alleged that, while employed at St. Mary's Regional Medical Center (hereinafter, St. Mary's Hospital) from August 25, 2014, until November 1, 2016, Applicant diverted controlled substances on at least five different occasions in violation of federal and state law. *Id.* at 2–3.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 6–7 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated August 23, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Manchester District Office stated that on December 18, 2019, she sent a copy of the OSC to ''both [Applicant's] registered and mailing address via First Class Mail'' and ''sent the [OSC] via certified mail on the following day.'' DI's Declaration, at 2. The DI stated that on December 19, 2019, she ''contacted [Applicant] by phone at the mobile number listed on his application.'' *Id.* According to the DI, she ''explained what an [OSC] was, and requested that [Applicant] contact [her] when he received a copy of the [OSC].'' *Id.* The DI stated that on December 26, 2019, she received an email from Applicant that read, '' 'I have received the hard copy of the [OSC] in the mail. I do not want to pursue this matter and do not feel it is necessary to meet and discuss.' '' *Id.; see also* RFAAX 3 (email from Applicant).

The Government forwarded its RFAA, along with the evidentiary record, to this office on August 26, 2021. In its RFAA, the Government represents that Applicant did not request a hearing. RFAA, at 1. The Government requests that ''the Administrator issue a final order denying the DEA Certificate of Registration application for [Applicant]'' because ''Applicant's [r]egistration is not in the public interest.'' *Id.*

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on or before December 26, 2019. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Applicant, nor anyone purporting to represent Applicant, requested a hearing, submitted a written statement while waiving Applicant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

I. Findings of Fact

A. Application for DEA Registration

On March 12, 2019, Applicant applied for a DEA Certificate of Registration as a practitioner in Schedules II through V with a proposed registered address of 29 Bowdoin St, Manchester, ME 04351. RFAAX 1, at 1. Applicant's application was assigned Control No. W19022896M. *Id.*

B. Government's Case

The Government's RFAA includes the DI's Declaration and 10 attached Exhibits, including a copy of Applicant's application for DEA registration, various documents pertaining to the drug diversion allegations against Applicant at both St. Mary's Hospital and Mercy Hospital, and a copy of a Consent Agreement between Applicant and the Maine Board of Nursing in which Applicant's license to practice nursing was suspended. *See* RFAAX 1–10.

The DI's Declaration described the investigation into Applicant, including the collection of the Government's Exhibits. DI's Declaration, at 1–3. On June 13, 2013, Mercy Hospital issued a letter to Applicant following an investigation regarding Applicant's ''suspicious behavior'' during his shift on June 4, 2013. RFAAX 9. According to the letter, on June 4, 2013, ''medical waste (wet bloody paper towel, open syringe wrapper, syringe cap, open band aid wrapper, and an open alcohol wipe wrapper) was found in the bathroom in the staff break room.'' *Id.* Applicant's nurse manager ''had noted that [Applicant] had recently come into the area and had been in the bathroom.'' *Id.* According to the letter, video footage of the Emergency Department area prior to the medical waste being found was reviewed, and Applicant was observed pulling Dilaudid from the Pyxis machine and then entering the patient area for several minutes. *Id.* The video footage showed Applicant going to a supply cart and putting supplies in his pants pocket, then exiting the Emergency Department and entering the staff break room around the same time that Applicant's nurse manager had seen Applicant enter the bathroom. *Id.* The video footage showed Applicant returning to the Emergency Department several minutes later and going immediately to a sharps disposal container, where he pulled something from his pants pocket to dispose of in that container. *Id.* Finally, the video footage showed Applicant requesting an