observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *https://www.uscourts.gov/rules-policies/records-rules-committees/agenda-books.*

DATES: April 28, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: February 8, 2022.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2022–02960 Filed 2–10–22; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Evidence Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Evidence Rules; notice of open meeting.

SUMMARY: The Advisory Committee on Evidence Rules will hold a meeting on May 6, 2022 in Washington, DC. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *https://www.uscourts.gov/rules-policies/records-rules-committees/agenda-books.*

DATES: May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: February 8, 2022.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2022–02963 Filed 2–10–22; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–03]

John X. Qian, M.D.; Decision and Order

On November 18, 2019, a former Acting Administrator, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC/ISO) to John X. Qian, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause), at 1. The OSC proposed the revocation of Respondent's Certificates of Registration Nos. FQ7186174, FQ7906968, and BQ7364970, and denial of the pending application for a new DEA Certificate of Registration (hereinafter, COR or registration), Application No. W18124091C, pursuant to 21 U.S.C. 824(a)(4) ''because [his] continued registration is inconsistent with the public interest. . . .'' *Id.* (citing 21 U.S.C. 823(f)).

I. Procedural History

The OSC alleged that ''from at least early 2017, through at least April 29, 2019,[1] [Respondent] unlawfully issued or approved the issuance of prescriptions for controlled substances'' to three patients ''that were not for a legitimate medical purpose, were beneath the standard of care for the practice of medicine in the State of California, and were not issued in the usual course of professional medical practice.'' *Id.* at 5. The OSC alleged violations of 21 U.S.C. 841(a) and 842(a); 21 CFR 1306.04(a); Cal. Health & Safety §§ 11153(a), 11154(a); and Cal. Bus. § Prof. §§ 725(a), 22334, and 2242(a). *Id.*

Pursuant to 21 U.S.C. 824(d) and 21 CFR 1301.36(e), the former Acting Administrator immediately suspended Respondent's Certificate of Registration, found ''that [Respondent's] continued registration [was] inconsistent with the public interest'' and that ''continued registration while [the] proceedings are pending constitutes an imminent danger to the public health or safety.'' *Id.* at 13. Pursuant to 21 U.S.C. 824(f) and 21 CFR 1301.36(f), the former Acting Administrator authorized DEA Special Agents (hereinafter, SA) and Diversion Investigators (hereinafter, DI) serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances that Respondent possessed pursuant to the suspended registrations and to take the registrations themselves. *Id.*

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 13 (citing 21 CFR 1301.43).

By letter dated November 21, 2019, Respondent timely requested a hearing.[2] ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Mark M. Dowd (hereinafter, ALJ). In addition to the traditional procedural history, the parties filed robust Joint Stipulations of Facts, ALJX 10 (Joint Stipulations of Facts), and the Government filed several Motions in Limine, which I will briefly summarize here. The first, a Motion in Limine to Exclude Second Expert Witness, ALJX 11, sought to exclude the testimony of a second expert witness identified a week before the hearing in this matter was scheduled to begin. *Id.* at 1. The ALJ found good cause for the Respondent's delay and agreed to permit both of Respondent's experts to testify so long as the testimony was not cumulative or repetitive. ALJX 12 (Order Granting in Part Government's Motion in Limine and to Exclude Evidence). Respondent ended up calling only the later-added expert witness to testify. The second was a Motion in Limine to Exclude Character Witnesses, ALJX 13, which alleged that the dozen character witnesses that Respondent proposed could only offer testimony that was either irrelevant or duplicative. ALJX 13. The ALJ did not grant the Government's motion, but he did limit the number of witnesses who could discuss Respondent's character and dispensing experience to three patients and four medical professionals and limited the scope of the testimony to what was relevant to the hearing. Transcript of Proceedings in the Matter of John X. Qian, M.D. (hereinafter, Tr.), 7–10. In the end, Respondent did not call any witnesses for these purposes but instead presented documentary evidence. During the hearing, the Government filed a Motion in Limine to Strike Testimony and Evidence, ALJX 18, related to Respondent's treatment of E.N. that predated the medical records provided to the Government in response to a subpoena (which began in July 2012). ALJX 18, at 1. The ALJ

[1] In the Prehearing Statement, the Government clarified the relevant time period to be between early 2017 and ''late 2019.'' ALJX 4, at 15.

[2] I find that the Government's service of the OSC was adequate.

determined that the issue was simply a miscommunication between the parties and denied the Government's motion. ALJX 21 (Order Denying Motion to Strike).

The hearing in this matter took place both in-person in San Diego, California, and virtually, and spanned eight days in February and May of 2020. Recommended Decision (hereinafter, RD), at 1. On July 27, 2020, the ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision. The Respondent filed Exceptions to the Recommended Decision on August 14, 2020.[3] (hereinafter ''Respondent's Exceptions'') ALJX 30. The Government was granted leave to file a response to the Respondent's Exceptions, and it filed them on September 11, 2020. *See* ALJX 31–33. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

Having considered the record in its entirety, I find that Respondent issued one-hundred and fifteen prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in California in violation of federal law, and I find that Respondent committed violations of state law. I agree with the ALJ that revocation is the appropriate sanction. RD, at 242. I make the following findings of fact.

II. Findings of Fact

A. DEA Registration

The parties stipulated that Respondent is registered with DEA as an individual practitioner authorized to handle controlled substances in schedules II through V under DEA Certificate of Registrations FQ7186174, at 5360 Jackson Drive, Suite 100, La Mesa, CA 91942, scheduled to expire on April 30, 2020;[4] FQ7906968, at 7024 Seville Ave., Suite D, Huntington Park, CA 90255, scheduled to expire on April 30, 2021; and BQ7364970 (and XBQ7364970), at 5395 Ruffin Rd., Suite 204, San Diego, CA 92123, scheduled to expire on April 30, 2022. ALJX 10, at 1; GX 1a–c (Respondent's Certificates of Registration), 2a–c (Respondent's Certificate of Registration Histories); RD, at 159. The parties further stipulated that Respondent submitted an application for a DEA COR as an individual practitioner authorized to handle controlled substances in scheduled II through V under Application No. W18124091C, at 344 F St., Suite 203, Chula Vista, CA 90910. ALJX 10, at 1; RD, at 160.

B. Government's Case

The Government's documentary evidence[5] consisted of voluminous patient records for three individuals to whom Respondent issued the controlled substances prescriptions that are at issue in this case. *See e.g.,* GX 4, 5, 8, 9, 12, and 13. The Government's evidence also contained prescription records and California Controlled Substance Utilization Review and Evaluation System (hereinafter, CURES) reports for those three individuals, the Curriculum Vitae for its expert witness, some DEA records, and an Accusation filed against Respondent by the Medical Board of California (hereinafter, MBC). *See* GX 1–3, 6, 7, 10, 11, 14–16, 23. Finally, the Government produced a number of guidelines and publications that it presented as evidence in support of establishing the standard of care in California. GX 17–22. Additionally, the Government called three witnesses: DI, the Government's expert Dr. Timothy Munzing, and a systems analyst for an electronic medical record program, Mr. Parag Deshpande.

DI testified regarding her professional background and education. Tr. 66–69. She also testified about her investigation-related actions since early-2019 in this matter including, but not limited to, her involvement in obtaining and reviewing CURES reports, pharmacy records, and records from Respondent pursuant to the May 7, 2019 administrative subpoena, including records for patients D.B., B.G., and E.N. *Id.* at 71–168. DI testified that her review of the records indicated that various red flags were present and she retained Dr. Munzing as an expert to review the records at issue. *Id.* at 167, 169, 183–222. Having read and analyzed all of the record evidence, I agree with the ALJ that DI's testimony was ''credible and should be afforded considerable weight.'' RD, at 165.

Dr. Munzing testified regarding his professional and educational background. Tr. 249–256; GX 16 (Curriculum Vitae of Dr. Munzing); RD, at 27–30. He graduated medical school from the University of California, Los Angeles, in 1982 and has been Board-certified in family medicine since 1985. *Id.* at 250–51. He has been employed with Kaiser Permanente for thirty-five years and has experience treating pain patients. *Id.* at 250–254, 971–72, 980–83. Also, he has authored several peer-reviewed publications on pain management and prescribing for chronic pain.[6] *Id.* at 253–55, 952–53. Dr. Munzing has testified as an expert witness approximately thirty times and has been qualified as an expert witness in cases where the respondent was a pain specialist. *Id.* at 257–60. Dr. Munzing was accepted in this matter as ''an expert in the standard of care [for] prescribing controlled substances in the State of California, including for management of pain.''[7] Tr. 260, 265.

[3] This decision, as compared to the ALJ's decision with which Respondent took exception, has been simplified and narrowly focuses on the issues that are relevant to my determination as to whether or not the relevant prescriptions were issued within the usual course of professional practice and standard of care in California and in compliance with the relevant state laws, as it was established in this case. Several of Respondent's Exceptions relate to findings in the ALJ's decision that I have not determined to be relevant to my decision and, accordingly, I have not addressed those Exceptions in detail. Throughout this decision, I have addressed in detail Respondent's exceptions to findings that my decision relies upon.

[4] The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019). Accordingly, even though one of the registrations at issue in this case has expired, it is still included as part of my revocation order. *Infra* ''Order.''

[5] I have reviewed and considered all of the documentary evidence presented by both the Government and Respondent, and hereby incorporate the entire record; I have not cited to every record in this decision.

[6] Dr. Munzing describes chronic pain as ''pain that last[s] three months'' or more and that is ''less likely to suddenly get completely better.'' Tr. 276. In contrast, Dr. Munzing explains that acute pain is shorter term such as when you are injured and your body heals with or without surgery. *Id.*

[7] At the hearing, Respondent objected to Dr. Munzing's qualification as an expert based on his ''lack of specialty in the area of pain management.'' Tr. 262. Throughout the hearing stage, Respondent repeatedly argued that Dr. Munzing's experience in pain management is lacking, that his lack of experience is evident in his testimony, and that his opinions can be afforded no weight. ALJX 28 (Respondent's Posthearing), at 4–7, 11–2, 21–22, 25–28; ALJX 30 (Respondent's Exceptions), at 2–10, 14–21. Respondent also took exception to the ALJ's determination that Dr. Munzing was qualified as an expert in this matter. ALJX 30, at 2–7. I have fully considered these arguments. Many of the areas where Respondent focused on Dr. Munzing's lack of experience, such as in determining what morphine milligram equivalent (MME) is too high for a particular patient, developing a titration schedule for patients, or managing a patient's pain pump, did not end up being relevant to my decision in this case. This is because the record established through the testimony of both experts that the standard of care does not set a cap on MMEs, it does not dictate a titration schedule, and it does not have firm rules for managing pain pumps. *Infra* II.D.3.a. Moreover, Respondent's general medical decision making is not the basis for the allegations in the OSC; the OSC allegations are focused on whether or not the identified prescriptions were issued in accordance with the applicable standard of care and in the usual course of professional practice and in accordance with state law. *See generally,* OSC. The expert testimony in this case is necessary, in conjunction with California law and guidelines, to understand the applicable standard of care. Dr. Munzing clearly demonstrated his expertise in how the standard of care applied to the facts in this case and furthermore, his testimony regarding his expertise was credible. Tr. 1112–16, 1199–1201, 1206–07. Moreover, as is demonstrated below, *infra* II.D., in those places where Dr. Munzing's and Dr.

The ALJ conducted a thorough analysis of Dr. Munzing's credibility, *see* RD, at 165–169 and I agree with much of it. I agree that Dr. Munzing's prior experience as a government witness and his compensation therefore does not create an actual credibility concern. RD, at 165. I agree that Dr. Munzing's professional experience with regard to pain management, while sufficient to be qualified as an expert witness and to offer credible opinions, was not as robust as Dr. Polston's. RD, at 167. Dr. Munzing was a family practitioner, he was not Board-certified as a pain management specialist, Tr. 251, 973, 976; however, Dr. Munzing explained that in the Kaiser Permanente system (where he worked), the family practitioner managed pain conditions and prescribed the necessary medication even when consulting with a pain management specialist. Tr. 971–72, 980–83. The nature of Dr. Munzing's practice, along with his peer-reviewed publications in pain management, Tr. at 253–55, 952–53, suggest that he had more experience in prescribing controlled substances for pain management than a typical family practitioner. Dr. Polston, however, was a Board-certified pain management specialist and had more clinical experience treating complex pain in patients with chronic conditions including more experience titrating patients down from extraordinarily high levels of opioids and managing patients with pain pumps.[8] *Infra* II.C.; RD, at 167.

The ALJ found that ''Dr. Munzing's testimony critiquing [Respondent's] actual treatment of the three subject patient[s] carrie[d] limited weight,'' because it did not ''address[] the patient-specific strategies used and described by [Respondent].'' RD, at 168–69. I disagree. I find that, overall, Dr. Munzing's testimony was more detailed and reflected a much more thorough review of the Respondent's records than Dr. Polston's. Dr. Polston opined regarding the medical records in their entirety, which allowed Dr. Polston to apply subsequent prescribing rationale retroactively to justify earlier prescriptions, even though there was no documented justification at the time that the prescription was issued. Tr. 616. However, Dr. Munzing approached each prescription individually while also looking at the records as a whole. Tr. 1196–97. His testimony focused on whether the medical records justified each prescription at the time the prescription was issued consistent with 21 CFR 1306.04. Tr. 1233; *infra* III.A.2.a.

With regard to recordkeeping, the ALJ found that ''Dr. Munzing's testimony . . . was internally consistent, did not depend [on] specialized expertise relating to the evaluation of pain management specialists, was consistent with the relevant statute and Guidelines, and thus was wholly credible.'' RD, at 169. I agree that Dr. Munzing's testimony regarding recordkeeping was wholly credible.

The ALJ found, and I agree, that ''[t]he basic tenets of the standard of care for prescribing opioids, as described by Dr. Munzing, was fully credible and not controverted by the Respondent.'' RD, at 168. Ultimately, as addressed with more specificity in the Standard of Care section below, where the two experts differed regarding application of the standard of care, I find that Dr. Munzing's testimony was more detailed and more closely aligned with the law and guidelines governing the standard of care in California. *Infra.* II.D. I therefore find Dr. Munzing's testimony to be fully credible.

As a rebuttal witness, the Government called Mr. Deshpande who was a systems analyst with BizMatics, the company who developed the electronic medical record (hereinafter, EMR) program used by Respondent and his practice. Tr. 1874–75, 1878–79. Mr. Deshpande explained the operation of Respondent's EMR system, Tr. 1892–1901, and explained that physicians have the ability to ''copy over'' specific sections of information from a previously completed visit report to the current visit for the same patient. Tr. 1901. The system can also be set up so that it automatically copies information from the most recent previous visit into the current visit record. Tr. 1902–03. Finally, Mr. Deshpande explained his assessment of the number of times entries and findings from precious encounters were automatically copied into the record for a current encounter related specifically to the three individuals for whom the controlled substance prescriptions at issue in this case were written. Tr. 1910–49. The ALJ found, and I agree, that Mr. Deshpande had ''a high level of expertise in each of the areas in which he offered testimony.'' RD, at 170. The ALJ also found, and I agree, that ''[h]is testimony was internally consistent and generally consistent with the testimony of [Respondent] regarding the basic functioning of the program.'' *Id.* Therefore, the ALJ ''found his testimony fully credible and deserving considerable weight.'' *Id.* I agree.

C. Respondent's Case

The Respondent's documentary evidence was largely duplicative of the Government's documentary evidence.[9] *See* RX E–J, N–P. The Respondent presented the Curriculum Vitae of his expert, Dr. Gregory Polston, along with his expert report. RX HHH, TTT. The Respondent also presented a number of publications including the MBC's 2007 Prescribing Guidelines, RX A, a clarification memorandum from the authors of the CDC Guidelines, RX D, an AMA article criticizing the CDC Guidelines' impact on pain treatment, RX DD, an MBC Update to Prescribers, RX SS, and an Aberrant Drug Taking Behaviors Information Sheet, RX TT.[10] Respondent introduced several curricula vitae and declarations of support from other medical professionals. *See* RX T–AA, RR, HHH, PPP. The record also contained declarations that patients of Respondent offered in support of Respondent's case. RX JJ–LL. Respondent produced records regarding training programs he had attended, RX PP–QQ, his Curriculum Vitae, RX RR, his Board Certifications, RX XX–YY, and miscellaneous records related to his practice generally, *e.g.* RX LLL–MMM, QQQ. Finally, there were some records offered in support of Respondent's treatment of the specific individuals at issue in this case. RX, JJJ–KKK, RRR–SSS, UUU–VVV. Additionally, Respondent called two witnesses: His expert, Dr. Gregory Polston, and himself.

Polston's testimony differed regarding the standard of care, California law and guidelines aligned more closely with Dr. Munzing's testimony. Accordingly, I affirm the ALJ's decision to qualify Dr. Munzing as an expert in this case.

[8] Although Dr. Polston's testimony regarding the appropriateness of Respondent's titration with respect to the standard of care was at times more detailed and credible than Dr. Munzing's, as described in *infra* II.D.3.a. and RD, at 183–87, Dr. Munzing's testimony was more far more credible than Dr. Polston's regarding the requirement to document a titration treatment and plan appropriately. Ultimately, I find that, as demonstrated by Respondent's recordkeeping, Respondent failed to provide documentation that justified the titration schedule used and the gaps between downward adjustments, and that failure to document supported a finding that Respondent issued prescriptions outside the usual course of professional practice and beneath the applicable standard of care. *Infra* II.D.3.a.

[9] Duplicative documentary evidence that was offered, but not admitted, included the CDC Guidelines; the MBC Guidelines for Prescribing; pain agreements, urine drug screens, CURES reports summaries, and patient records for the individuals at issue in this case. I agree with the ALJ's decision to not admit these duplicates.

[10] Respondent also attempted to introduce what the ALJ characterized as a ''newspaper article,'' which the ALJ did not admit because it was not ''necessarily reliable'' and was not ''authenticate[d].'' Tr. 1847. I agree that absent evidence establishing the reliability therein, newspaper articles should not be admitted into evidence. *See Jones Total Health Care Pharmacy, L.L.C.,* 71 FR 79188, 79222 n. 11 (2016).

Respondent testified regarding his medical education and background—he came to the United States as a visiting scholar to conduct research related to cancer cells in 1990. Tr. 1316–19. He then decided to change his focus to Physical Medicine and Rehabilitation (hereinafter, PMR), which complimented his specialized training in anesthesiology. Tr. 1319–22. Respondent became Board-certified in PMR in 2003, and Board-certified in pain medicine in 2005 (which he allowed to lapse in 2015). Tr. 1328–30. Respondent opened his own practice at the end of 2005, and described himself as the ''go-to-guy'' in the San Diego area for pain management and stated that his multiple practice locations see approximately 100 patients a day. Tr. 1336–43.

Respondent offered some testimony regarding his office policies, his recordkeeping practices, and how his EMR system worked.[11] *See e.g.* Tr. 1564–68. Respondent testified that he was the attending or supervising physician for each of the three individuals at issue in this case, B.G., D.B., and E.N., that he was personally responsible for the treatment each individual received from Respondent and Respondent's staff, and that he was personally responsible for the controlled substance prescriptions issued to each individual by Respondent and Respondent's staff. Tr. 1564–68; ALJX 10, at 3; *see also* Tr. 399. Respondent also offered testimony regarding his understanding of the standard of care in California, which I have credited where it aligns with the testimony of the two experts in this case. Tr. 1561–86.

The ALJ found Respondent's testimony to be credible at times.[12] *See e.g.* RD, at 199, 208, 212, and 216. But at other times, the ALJ found Respondent to be so not credible that it ''suggest[ed] [Respondent] deliberately misled [the] tribunal during the hearing.'' RD, at 225.

I find that, at times, Respondent's testimony was self-serving to the point it denied belief. On cross examination, Respondent was asked if a particular individual had ''obtained [Soma] from her daughter's prescription, then she's obtained Soma in an unlawful manner, correct?'' Tr. 1688. Respondent testified, ''[l]et's put it this way. If it's a Soma, if you [are] so close to each other, it could be from a liquid contamination to make her urine positive too.'' *Id.* When pressed by the ALJ to explain how Soma could show up in your system ''[u]nless you took the Soma tablet,'' Respondent said ''you could get contaminat[ion] with the food or drop it somewhere.'' Tr. 1689. Dr. Munzing's testimony completely discredited Respondent's suggestion of ''liquid contamination.'' Tr. 2066, 2118; *Infra* II.E.2.

Another area of Respondent's testimony that lacked credibility, as the ALJ thoroughly assessed, was Respondent's testimony regarding his recordkeeping, particularly how the patient records that were verbatim for every visit were created. RD, at 216–224 (citing Tr. 1786–1804). Specifically, the ALJ ''found that Respondent lacked candor in [the] proceeding by his fallacious explanation for the verbatim repetition of examination results throughout the medical records.'' RD, at 240. Respondent testified that the records regarding the physical examination remained the same for lengthy periods because Respondent was doing the exact same examination of the patient from the prior month. Tr. 1775–79, 1799–1801. Because the selections were the same, according to Respondent, the records produced the same narrative. *Id.* However, Respondent's version of events conflicts with Mr. Deshpande's evidence showing that the examination results were copied forward and further conflicts with Dr. Munzing's and Dr. Polston's testimony that you would expect some visit to visit variability in the examination even for patients with chronic pain. I agree with the ALJ and discredit Respondent's testimony in this area.

Overall, I find credible those portions of Respondent's testimony that were supported by the medical records, the expert testimony, and the record as a whole. Where his testimony was inconsistent with the record, I do not credit Respondent's testimony.

Dr. Polston testified regarding his professional and educational background. Tr. 509–38; RX HHH (Curriculum Vitae of Dr. Polston); RD, at 91–94. He graduated medical school from the University of Wisconsin in 1989 and has been Board-certified in anesthesiology since 1999. Tr. 509–10, 519; RX HHH, at 2. He completed a fellowship in pain management in 2001 and his practice has been limited to pain management since that time. Tr. 513. His experience includes work as a private practice pain physician with the Advanced Medical Centers of Alaska, a Clinical Professor at the University of California San Diego, a Clinical Director with the Center for Pain Medicine University of California San Diego Medical Center, and a Clinical Director and a Clinical Professor with the VA San Diego Medical Center. *Id.* Also, he has authored journal articles and book chapters regarding pain management, has served on numerous committees, and has received awards for his work as is set forth in his Curriculum Vitae and in the RD. RX HHH, at 2–8; RD, 92–94. Dr. Polston has been retained as an expert witness on behalf of physicians approximately ten times, Tr. 535, and has assisted the MBC in evaluating pain physicians since approximately 2010, Tr. 528. Dr. Polston was accepted in this matter as ''an expert in the area of pain management.'' Tr. 538.

The ALJ conducted a thorough analysis of Dr. Polston's credibility, *see* RD, at 170–171, much of which I agree with. I agree that Dr. Polston ''sometimes argued the position of his

[11] I do not find a violation with regard to the Government's allegation related to a note related to alcohol use and, therefore, I will not address this allegation further. The Government alleged that Respondent's recordkeeping was deficient because the records repeatedly included an internally inconsistent note that stated, ''[p]atient states that [she or he] drinks alcohol [she or he] never drinks alcohol.'' OSC, at 4; RD, at 205–06. Respondent explained that this note appeared as a result of a computer glitch; an error within the computer program that produced the inconsistent statement in printed records despite the proper selection of one option (drinks alcohol) or the other (never drinks alcohol) in the system's drop down menu. Tr. 1412–24, 1831–32. As the computer error was corroborated by Mr. Deshpande's testimony, Tr. 2000–04, I agree with the ALJ and find that the Government did not sustain their burden as to this allegation. RD, at 206. In his decision, the ALJ found for Respondent but noted there was ''some level of negligence attributable to him for his failure to confirm the EMR was operating properly.'' RD, at 206. The Respondent took exception to this note. ALJX 30, at 14. I do not see anything in the record that suggests that Respondent's failure to catch the computer glitch meant that the relevant prescriptions were issued outside the standard of care. Accordingly, the ALJ's note is not relevant to and is not being considered as part of my decision in this matter.

[12] The ALJ evaluated Respondent's credibility, ''within the relevant factual findings.'' RD, at 171. Many of the specific factual findings where the Respondent was found credible were on issues that I have found were not material to the case. For example, the ALJ credited Respondent's testimony that Retrospective Drug Utilization Review letters were so routine in the practice of pain management that they did not represent red flags under the circumstances of this case. RD, at 212. However, I found that the government did not explain why the 2016 Drug Utilization Review letter at issue in this case was relevant to the 2017–2019 prescribing so the issue is not material to my decision. *See infra* n. 55. The ALJ credited Respondent's testimony that he was aware of and investigating E.N.'s 2015 increase in pain, RD, at 216; but again, the Government did not explain how this 2015 issue was relevant to the relevant prescribing in 2017–2019. *Infra* n. 52. The ALJ credited Respondent's testimony that an inconsistent drug screen was not aberrant because medication infused through a pain pump would not be expected to show up in urine. Tr. 208. This issue was abandoned by the Government and is not material to my decision in this case. *Infra.* n. 49.

sponsor in lieu of a direct response.'' [13] RD, at 170. I agree that Dr. Polston's professional experience with regard to pain management was robust and that he appeared to have more hands-on professional experience in the areas of downward titration and pain pump management than Dr. Munzing.[14] RD, at 167, 171. I disagree with the ALJ that Dr. Polston ''offered credible detailed testimony relating to the specifics of [Respondent's] treatment, prescribing and titration strategies.'' RD, at 170. Instead, I find that Dr. Polston's testimony lacked detail and often took the specific facts of the case, excused gaps or filled them with speculation, and then conclusively determined that the standard of care was met without adequately explaining why.[15] *See* Tr. 714–16, 756, 773. I find that Dr. Polston's testimony, while generally credible, was not as thorough or as specific as Dr. Munzing's.

The two experts were generally in agreement about the basic elements of the standard of care in California. However, Dr. Polston seemed to advocate for leniency in the standard of care when applied to pain physicians, testifying that guidelines for prescribing opioids for pain have been and are continuing to evolve, and that because of this, ''pain physicians, maybe, should be judged differently . . . [because] across the country, [there is] a wide variance of how . . . opioids are'' prescribed. Tr. 566–68.[16] Dr. Polston rarely expanded upon the text of the law and guidelines governing the standard of care in California. In one place where Dr. Polston did expand—namely regarding what constitutes a sufficient physical examination to satisfy the standard of care in California, his testimony appeared to be in conflict with the relevant guidelines. *See infra* II.D.2. and II.E.2. With regard to recordkeeping, the ALJ found that ''Dr. Polston's opinions had diminished reliability,'' because the ''testimony was inconsistent with the relevant Guideline, was sometimes illogical, and frankly, sometimes defied common sense.'' RD, at 171.

Ultimately, as addressed with more specificity in the Standard of Care section below, I find that Dr. Munzing's testimony regarding the standard of care was more detailed and more closely aligned with the law and guidelines governing the standard of care in California. Accordingly, I differ with the ALJ, and find generally overall, not just on recordkeeping, that Dr. Munzing's testimony is more credible than Dr. Polston's where the two experts offered different opinions.

[13] For example, Dr. Polston testified that in the prior seven years, he, himself, had not prescribed controlled substances to a chronic pain patient on a regular basis above 800 MME. Tr. 703. Right after this acknowledgment, the ALJ asked Dr. Polston, ''other than palliative care, cancer patients, have you ever taken a patient to 2,400 MME?'' *Id.* at 704. Dr. Polston evasively replied, ''That's where I—that's where some of the caution that—that some of those patients who have come in—they have come into my practice. And I don't think that that is—at the—at those higher doses that I would—would say that coming from before these documents came in, and at the time when they came in, suddenly there was a lot of physicians who stopped prescribing, and that they . . . taken them off, and then we were faced with a lot of these kind of patients.'' Tr. 704. I found this testimony to be evasive and it caused me to question Dr. Polston's objectivity.

Another example of evasiveness and inconsistency occurred during Dr. Polston's testimony regarding whether it is outside of the standard of care to repeatedly copy physical examination notes from a prior office visit into physical exam notes for a current office visit without performing a physical examination during the current visit. *See* Tr. 717–23. Documentation of a physical examination that did not occur seems to be patently false, yet Dr. Polston evaded acknowledging this.

[14] Ultimately, as explained herein, I did not find that Respondent's titration schedule or use of pain pumps was in itself outside the standard of care. *Supra* n. 7–8; *infra* n. 28, 49.

[15] By way of one example, when asked if there was a physical examination performed on patient B.G. regarding his MS during a specific office visit, Dr. Polston answered ''[there is] a lot of inference there. One that . . . there's no significant changes in the physical exam since the last follow-up visit. The fact that he's got good hygiene is telling me . . . that he's being cared for and getting himself dressed.'' Tr. 773. Dr. Polston seems to be stating that the note ''good hygiene'' was sufficient to satisfy the physical examination requirement of the standard of care. Not only is his opinion based on an ''inference,'' but Dr. Polston's testimony reflects an extreme departure from Dr. Munzing's credible testimony on what a physical examination requires. *See infra.* II.D.2, II.E.1.

Additionally, when Dr. Polston testified about whether the physical examination notes are simply ''cop[ied] forward'' from past office visits, he stated, ''when I see a 'just copy forward,' and I see other changes, then I would say that I would think that most physicians are doing . . . hopefully are doing the right things.'' Tr. 716. Again, Dr. Polston evaded the question and filled the gap with an assumption.

[16] The standard of care guidelines that are being relied upon in this case explicitly state that they are the ''standard of care in managing pain patients,'' and that physicians and surgeons are expected to follow them. GX 17, at 59. I cannot see any justification for carving out pain specialists who are managing pain patients from its requirements. Notably, the MBC Guide to the Laws states ''[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.'' GX 17, at 59. This suggests that Dr. Polston's position of leniency is inconsistent with the standard of care. The standard of care applied here is that standard of care that was in place in the State of California at the time of Respondent's actions as determined by the exert testimony and supporting literature. Any differences in the standard of care that existed prior to or after Respondent's actions are not relevant to this matter, nor is the standard of care in other geographic locations.

D. The Standard of Care in the State of California

The parties seem to be largely in agreement as to the general components of the standard of care in this case, that the standard of care is primarily informed by California law and guidance, and that it is primarily captured by a 2014 publication from the MBC entitled, ''The Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,'' (hereinafter, MBC Guide to the Laws). Tr. 266–67, 554–55, 567, 698; RD, at 168, 172–73; GX 17 (MBC Guide to the Laws). Based on this publication and the entire record, I find that the standard of care for managing pain patients in California requires: (1) History and physical examination; (2) treatment plan objectives; (3) informed consent; (4) periodic review; (5) consultation; and (6) complete and accurate records. Tr. 270–87, 694–95; RD, at 31–32, 172–73. Additionally, according to Dr. Munzing, there is a 2014 publication from the MBC titled, ''Guidelines for Prescribing Controlled Substances for Pain'' (hereinafter, MBC Guidelines for Prescribing). GX 18. According to Dr. Munzing, this publication is ''not intended to mandate the standard of care,'' but it provides examples of how the standard of care captured in the MBC Guide to the Laws applies to the prescribing of controlled substances for pain. Tr. 291–92, 567. Dr. Munzing testified that the MBC Guidelines for Prescribing is ''a little bit more expansive, but . . . in alignment with the [MBC Guide to the Laws].'' Tr. 292. Additionally, in 2016, the Center for Disease Control (hereinafter, CDC) issued ''Guidelines for Prescribing Opioids for Chronic Pain'' (hereinafter, CDC Guidelines) which, according to Dr. Polston, provide ''recommendations'' specifically for primary care physicians, but that pain management ''[s]pecialists will take into consideration all aspects in . . . the literature . . . and review those documents.'' Tr. 550, 552; *see also* Tr. 1586.

1. Requirement To Keep Records

Dr. Munzing clearly testified that each element of the standard of care ''must be documented in the medical records because [the physician] may not be the only person managing that patient.'' Tr. 299. Dr. Munzing testified ''[t]his patient may be seen by the emergency room, may be seen by the primary care physician may be seen by other sub-specialists, orthopedists, psychiatric

doctors.'' [17] *Id.* at 299–300. Dr. Munzing further testified that if a physician is not maintaining adequate and accurate medical records then the physician is acting outside the standard of care. *Id.* at 301. Dr. Polston agreed that ''[m]edical records are incredibly important for physicians.'' Tr. 705.

Dr. Munzing's testimony is supported by the MBC Guide to the Laws, which requires that the physician ''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.'' [18] GX 17, at 61; *see also id.* at 67. Additionally, the MBC Guide states that ''[d]ocumentation of the periodic reviews should be done at least annually[;]'' and ''[p]ain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver and objective findings by the physician.'' *Id.*

Similarly, the MBC Guidelines for Prescribing explain that

> for a physician treating a patient with opioids for chronic, non-cancer pain, an adequate medical record includes, but is not limited to, the documentation of: the patient's medical history; results of the physical examination . . . ; patient consent; pain management agreement; . . . description of treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity); instructions to the patient, including discussions of risks and benefits with the patient . . . ; results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement; notes on evaluations by, and consultations with, specialists; any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors . . . ; . . . and results of CURES/PDMP data searches.

GX 18, at 22.

Dr. Polston's opinion regarding the standard of care with regard to recordkeeping was more focused on obstacles created by electronic recordkeeping. *See* Tr. 619–21. Dr. Polston testified that through ''repopulation'' or copying and pasting, electronic records can ''make clinic and visits more efficient.'' Tr. 527. However, he also emphasized limitations in medical software because sometimes a physician may not ''even attempt to copy it or however it was done, and I see errors being repopulated.'' Tr. 615–16. He also explained that some recordkeeping issues occur ''because the electronic record only allows you to enter data in certain spots, and some of the electronic record [do not] have the same amount of power or freedom to document and change things.'' Tr. 616. Dr. Polston seemed to look at records in totality, and seemed to find that here, where the conditions were chronic, justification for a prescription on one date could justify that same prescription on previous dates.[19] Tr. 616, 618–19, 631, 716–17. Regarding recordkeeping, I find that Dr. Munzing's testimony is more in line with California's law and guidance.

Based on the experts' testimony and California law and guidance, I find that the applicable standard of care requires that a physician collect a patient's history and perform a physical examination, create treatment plan objectives, obtain informed consent, conduct a periodic review, and consult with others when needed. The standard of care further requires that the actions taken by the physician and information obtained by the physician in completing each of the standard of care requirements be accurately and completely recorded. Tr. 287. The requirement that information be accurately and completely recorded appears to apply equally to handwritten or electronic records. Based on both Dr. Munzing and Dr. Polston's testimony and California law and guidance, I find that accurate and complete records are an important aspect of prescribing within the standard of care in California.

2. History and Physical Examination

Dr. Munzing testified that obtaining a history and performing a physical exam ''are critically important'' to get specific information about the individual patient's pain, including the duration, location and severity of the pain.[20] Tr. 270. According to Dr. Munzing, the history and exam are also necessary to determine the existence of chronic illnesses, mental health disorders, or alcohol and drug use and abuse. *Id.* Importantly, according to Dr. Munzing, ''[t]he physical exam is important to find out specifically about if you can come up with the most reasonable differential diagnosis or sometimes an exact diagnosis.'' Tr. 270–71.

Consistent with Dr. Munzing's testimony, the MBC Guide to the Laws states that a ''medical history and physical examination must be accomplished.'' GX 17, at 59; *see also* Tr. 271–72. ''This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; as 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.'' GX 17, at 59. Notably, the MBC Guidelines for Prescribing state that ''[t]he 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. See also,* GX 18, at 54. Further, the requirement for a physical examination is codified in California law. Cal. Bus & Prof. Code § 2242(a) states that it is unprofessional conduct to prescribe controlled substances ''without an appropriate prior examination and a medical indication.'' *See also,* Tr. 286.

The MBC Guide to the Laws also states the physician ''should keep accurate and complete records . . . including the medical history and physical examination.'' GX 17, at 61. It goes on to state that ''[p]ain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.'' *Id.* According to Dr. Munzing, the referenced documentation requirement mandates that a physician keep progress notes or other ''documentation verif[ying] what the history showed, what the exam showed . . . so one can look at the documentation . . . and see how did the physician decided that this is . . .

[17] According to Dr. Munzing, when prescribing high doses of opioids, *see infra* II.D.3.a., the documentation should make ''very clear that [the physician] understand[s] the added risks [of prescribing over 80 MME] and . . . how [the physician] came to that determination . . . knowing that [he or she is] putting the patient at higher risk.'' *Id.* at 300.

[18] Dr. Polston agreed that the MBC Guide to the Laws stated this. Tr. 692.

[19] Dr. Munzing explicitly rejected the notion that something documented later in time can justify what occurred prior in time and testified; ''You have to treat a patient in real time. . . . You have to document it [in] real time.'' Tr. 1233.

[20] Dr. Polston cautioned that a patient's assessment of pain ''is a subjective response that . . . is very difficult . . . to quantitate'' because patients are afraid that their medication will be taken away ''[i]f they answer that they have too much pain . . . [or] if they [do not] reflect pain.'' Tr. 817. Dr. Polston's testimony demonstrates why a physical examination with objective findings is important to complement subjective complaints of pain. *See* GX 17, at 61.

the right diagnoses or diagnosis.'' Tr. 272.

Dr. Polston agreed that there needs to be a physical exam to prescribe within the standard of care. Tr. 694. However, he opined that a physician can either perform a ''focused exam'' or can conduct an examination ''just by looking at the patient and—and interacting. . . .'' Tr. 618. According to Dr. Polston, ''physicians are conducting exams just by interviewing and talking to a patient. We're always looking at how [they are] walking, how [they are] . . . sitting, . . . the degree of pain, . . . is it congruent with what [they are] reporting?'' [21] Tr. 718–19. Dr. Polston's latter definition of a physical examination is inconsistent with Dr. Munzing's and I find Dr. Munzing to be more credible. Dr. Munzing testified that the type of information Dr. Polston described as an acceptable physical examination is actually collecting information for the ''history of present illness.'' *See e.g.* Tr. 1139–40. While collecting information regarding the history of present illness is part of the standard of care, it is separate and distinct from the physical examination requirement.[22] Tr. 1143. According to Dr. Munzing, ''[t]he history of present illness is not an exam . . . [it is] not actually examining the patient, physically touching the patient, maneuvering the patient.'' Tr. 1143.

I find that the applicable standard of care in California requires a practitioner treating pain in chronically ill patients, to perform and document an appropriate physical exam, including an assessment of pain and physical and psychological function.

3. Treatment Plan Objectives

Dr. Munzing explained that the history and physical exam requirements help a practitioner arrive at a diagnosis and that the treatment plan is the ''assessment . . . based on what [a practitioner has] determined is the diagnosis.'' Tr. 273. In addition, Dr. Munzing explained that documentation is required ''[s]o one can look at the documentation to . . . see how the physician decide[d] that this is . . . the correct management plan, both initially [and on] an ongoing basis.'' Tr. 272.

The MBC Guide to the Laws requires that the treatment plan ''state[[23]] objectives by which the treatment plan can be evaluated'' such as ''control of pain, increase in function, and improved quality of life.'' GX 17, at 59. ''Multiple 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 MBC Guidelines for Prescribing state that ''[p]ain relief is important, but it is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. Effective pain relief improves function, whereas addiction decreases functionality.'' GX 18, at 13.

a. Treatment Plans With >80 MME Prescribed

According to Dr. Munzing, morphine milligram equivalent (hereinafter MME) is a term reflecting the ''common platform [used] when looking at . . . the strength of opioid treatment.'' [24] Tr. 294–94. In California, according to Dr. Munzing, there is a ''yellow flag warning'' meaning that physicians ''should be concerned if the total dosage for a day is 80 milligrams or higher . . . [and] proceed cautiously. Referral to an appropriate specialist should be considered with higher doses.'' Tr. 296. Dr. Munzing explained that ''as one goes higher on the MED or MME[[25]], the . . . risk of the medication increases.'' Tr. 296. The risk increases at higher MME levels ''regardless of how long'' a patient has been prescribed opioids, although for patients on long-term opioids ''the risk probably is somewhat less.'' [26] Tr. 296–97. Dr. Munzing explained that the ''yellow flag warning'' applies equally to pain specialists, because ''the medication is [what is] putting the patient at risk . . . it [does not] change based on the letters at the end of the name of the person prescribing.'' Tr. 298. According to the CDC Guidelines, ''prescriptions opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually.'' GX 19 (CDC Guidelines), at 15; *see also* Tr. 306.

Dr. Munzing clarified that despite the ''yellow flag warning . . . there are times when the indications are there and you weigh the potential benefits with the potential risks and one decides that . . . the potential benefits far outweigh the risks and you can proceed at higher amounts.'' Tr. 298. Dr. Munzing testified that there is no cap on the level of MME/day that can be prescribed, but as the dose and ''risk significantly goes up . . . one needs to justify'' the prescribing. Tr. 308–09. Dr. Polston likewise explained that the intent of the CDC Guidelines was not to set 50 or 90 MME as ''hard limits'' and agreed that ''when patients come to a physician already on high doses of opioids, it is permissible to continue on those doses if the doctor believes it is appropriate.'' Tr. 558, 564.[27]

However, the fact that a patient was already on high doses of controlled substances, alone, is not sufficient justification to continue prescribing at that level. Tr. 1217–18. According to Dr. Munzing, physicians who inherit patients on high levels of MME have an obligation to attempt to try alternatives, whether alternative forms of treatment or prescribing lower doses, to ''decrease the risk of the patient while still certainly making every attempt to decrease pain, improve activity.'' Tr. 1277, 1275, 2040–43.

Dr. Munzing explained that when prescribing opioids, it is important to ''titrate up, so slowly adjust up or titrate down, slowly adjusting'' the doses. Tr.

[21] Elsewhere, Dr. Polston seemed to testify that how the patient looks and talks is not a complete physical examination, but only a part of the examination. *See* Tr. 730.

[22] This distinction is also supported by the MBC Guide to the Laws, which separates the history and presentation from the physical examination, stating, ''[i]f a patient's request for opioid medication for pain is inconsistent with the patient's history, presentation, or physical findings, the physician may withhold the medication but must document the reason for the decisions.'' GX 17, at 59 (emphasis added).

[23] I find that the reference to what the treatment plan should ''state'' is a clear indication that the treatment plan must be documented as is also indicated by Dr. Munzing's testimony.

[24] For additional information on how the MME is calculated, *see* Tr. 311–16; GX 21 (Publication by Centers for Medicare & Medicaid Services); GX 22 (Publication by Centers for Disease Control & Prevention).

[25] Dr. Munzing testified that morphine milligram equivalent or MME and morphine equivalent dose or MED have ''identical'' meanings and the two phrases are used interchangeably throughout the record. Tr. 295.

[26] Dr. Munzing explained that there are no studies that look at the effects of a patient who is on, for example, ''300 [MME] for 3 months as opposed to a year,'' and they are ''not going to do that study because of the inherent risks to patients.'' Tr. 297.

[27] I conclude based on the testimony of both of the experts in this case that the Government has not presented substantial evidence of a MME ceiling above which a prescriber would be per se in violation of the standard of care for prescribing controlled substances. Accordingly, if the intent of the Government's allegations regarding prescribing over 90 MME was that any such prescribing per se violated the standard of care, such an inference is unsupported by the record and is not sustained. *See* RD, at 178–83. However, the Government has presented substantial evidence that controlled substance prescriptions must be justified. Tr. 281 (Dr. Munzing testified ''California . . . says that the prescribing must be justified. It has to be in the usual course of professional practice.''). Accordingly, where the evidence in the case established that controlled substance prescribing was not justified by appropriate documentation in the medical records, I have found that the Government established a violation of the standard of care. Dr. Munzing testified that, particularly for B.G. and E.N., the documentation in the medical record did not come anywhere close to justifying the ''extraordinarily high'' levels of opioids Respondent prescribed. Tr. 389, 433–34, 912–13; *infra* II.E.1, II.E.3.

307; *see also* Tr. 700. Dr. Munzing agreed that titration is ''an individual process that differs for each patient,'' and there are no ''evidence-based guidelines . . . that say, 'This is the best way now.' '' [28] Tr. 2091, 2071. Even so, according to Dr. Munzing, it is important to ''come up with a game plan . . . In one month, [we are] going to go down X amount. The next month, [we are] going down X amount. And then you may need to alter that over the way.'' Tr. 2044. Dr. Polston further testified that the literature ''does not support abrupt tapering or sudden discontinuation of opioids,'' which can ''cause health risk for patients.'' Tr. 558, 563; GX 19.

b. Prescribing Opioids and Benzodiazepines

Dr. Munzing testified that before opiates and benzodiazepines are prescribed together, there should be an attempt to ''mitigate'' the risks to the patient and ''try alternative methods that [are] safer.'' Tr. 388. According to Dr. Munzing, healthcare practitioners, including specialists, are bound by the guidance, which states that practitioners ''should limit prescribing opioid pain medicines with benzodiazepines or other CNS [(central nervous system)] depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, [practitioners should] limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect.'' [29] GX 20, at 1; *see also* Tr. 318–19. This is because, according to Dr. Munzing and the FDA Drug Safety Communication located at GX 20, ''the co-prescribing of opioids and benzodiazepine medications'' presents a ''serious risk of death.'' Tr. 317. Similarly, Dr. Polston testified that there is ''increased risk when you use benzodiazepines . . . with opioids.'' Tr. 662.

4. Informed Consent

With regard to informed consent, Dr. Munzing testified that the standard of care requires a practitioner ''to go through the risks, the benefits, and the alternatives.'' Tr. 273. Dr. Munzing's testimony is supported by the MBC Guide to the Laws which states that ''[t]he 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.'' GX 17, at 60. ''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.*

Dr. Polston testified that the patient medication agreements and consent forms found throughout the record, standing alone, are sufficient ''documentation of discussions [regarding what] the risks and benefits of the medication were'' to satisfy the standard of care regarding informed consent. Tr. 609–10. There was limited, if any, evidence presented by the Government regarding whether the patient agreements alone were sufficient to satisfy the informed consent aspect of the standard of care. Here, Respondent's records contained patient agreements for each individual at issue in this case. Accordingly, I cannot find that Respondent violated the informed consent requirements in the standard of care for these individuals.

5. Periodic Review

According to Dr. Munzing, periodic review for patients with chronic pain conditions requires ''checking periodically to see how [they are] doing: Are they getting better with your management? Are they getting worse? Are they having side effects from your . . . management? Are there alternatives that may be safer, may be better? And so looking over time, re-examine them. Is there something new in . . . the medical community that might benefit this person?'' Tr. 274. Periodic reviews are necessary, according to Dr. Munzing, because ''pain, especially chronic pain, usually does not stay exactly the same. It waxes and wanes . . . it may be better one day, worse one day . . . [it is] infrequent that every single day is exactly the same.'' Tr. 274.

Dr. Munzing's opinion is supported by the MBC Guide to the Laws, which states ''[t]he 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. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If 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.'' GX 17, at 60. ''Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually, as required by the standard of care.'' *Id.*

It is clear throughout the record that the ''periodic review'' portion of the standard of care also includes monitoring the patient. Both experts referenced the ''four As'' as part of monitoring. The 4As are: ''analgesia, activities of daily living, adverse side effects, aberrant drug taking behaviors.'' Tr. 357, 608–09. While it is clear that there is no set formula for monitoring an individual patient, some of the tools physicians can use include, looking for compliance with the pain agreement, running CURES reports, requiring urine drug screens, checking respiration rate and O2 levels, and using an opioid risk tool. *See* Tr. 604, 684. ''Monitoring can take many forms, including regular visits, . . . updated histories, updated examinations[,] . . . urine drug tests, CURES reviews[,] . . . pill counts to ensure that [they are] taking what [they are] prescribed and not taking potentially things that [you are] not prescribing.'' Tr. 299.

Dr. Munzing described a red flag as anything that comes up while monitoring ''that catches your attention that says that this could be a problem.'' Tr. 321. It could be laboratory results, certain symptoms, something in the CURES database, or a wide variety of things. *Id.* According to Dr. Munzing, red flags require a practitioner to ''investigate further,'' take appropriate action ''determined by what . . . you found,'' and then ''all of that needs to be well-documented in the chart so if someone else . . . can look at [the] records and go, okay. He did this. He resolved that. It doesn't appear to be a problem.'' Tr. 323–24.

Dr. Polston, used the term ''red flag'' in a different way that Dr. Munzing. Dr. Polston differentiated, albeit imprecisely, between ''yellow flags'' and ''red flags'' and referred generally to ''aberrant behavior.'' Tr. 799–800. Dr. Polston described a ''red flag'' as a ''severe deviation from the opioid agreement'' that requires immediate action or even termination of care. Tr.

[28] Both experts testified that there is not a firm titration schedule that could be used to evaluate whether the applicable standard of care is met. Accordingly, to the extent that the Government intended to charge that the percentage of titration up or down for any given prescription or that the titration schedule for any particular individual was outside the standard of care, those charges are not supported by the record here. *See* RD, at 183–87. However, the Government has established that the standard of care requires documentation of a treatment plan, which includes a creation of and documentation of the titration strategy the physician is using—those allegations are addressed below. *See e.g. infra* II.E.1.

[29] The FDA Communication also requires additional warnings be given for informed consent. It states that practitioners should ''[w]arn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms.'' GX 20, at 1.

799–800, 802. Dr. Polston testified that regardless of ''whether [it is] a yellow flag, a red flag, or any kind of aberrant behavior, we would hope that [it is] recorded and [there is] some type of medical reasoning applied as to how [you are] interpreting that particular event.'' Tr. 800. He went on to testify ''that when you see something that is considered aberrant in the sense that [it is] not [what is] intended or shows signs of misuse or abuse, the . . . statute said that that needs to be addressed. . . . Simply recording . . . that you [do not] think that [the aberrancy] is significant or . . . [filing] that as the first offence . . . in some ways resolv[es] that. . . . ''[I]f other minor infractions keep occurring, that . . . [would] need[ ] to be recorded and . . . show justification of why [you are] continuing therapy for the patient.'' Tr. 801.

It appears that what Dr. Munzing refers to as a red flag encompasses all of the various aberrancies identified by Dr. Polston. Accordingly, the terms red flag and aberrancy appear interchangeably throughout the record. Regardless of the terminology, both experts seem to agree, and I find, that the applicable standard of care requires that red flags or aberrancies be investigated and that the results of that investigation be documented in the record.

a. Periodic Review With >80 MME Prescribed

Dr. Munzing particularly stressed the importance of monitoring for patients that are on opioids, and stated that a practitioner needs to ''intensely monitor'' the patient when prescribing more than 80–90 MME a day. Tr. 209. Dr. Polston likewise testified that ''[there are] more things [to be] concerned about at higher doses'' of opioids and agreed that there are ''more things [you are] tracking to ensure that the patient's health and safety [is not] at risk.'' Tr. 768.

6. Consultation [30]

According to Dr. Munzing, consultation is the requirement that physicians work ''much more in collaboration with each other, especially with chronic conditions.'' Tr. 276–77. Dr. Munzing stated that when ''managing a patient who is not getting better over time or getting worse, [a physician should] seek consultation with'' a specialist or a colleague for a ''second opinion.'' *Id.* The MBC Guide to the Laws similarly explains that the standard of care requires physicians to ''consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' GX 17, at 60. Additionally, the Guide notes 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.* Notably, the MBC Guide to the Laws states that ''[c]oordination of care in prescribing chronic analgesics is of paramount importance.'' *Id.*

E. Patients

1. Patient B.G.

By way of background, B.G. was first seen by Respondent on August 12, 2013, for ''pain management consultation.'' GX 8 (Medical Records for B.G.), at 1064. During that office visit, B.G. reported that he had ''been under care of Dr. [M] for pain management for 10 years. He is on high dose of Methadone 240 mg per day. He gets 720 pills per month in the last 7 years.'' *Id.* There are no records in the patient file reflecting Dr. M's care of B.G., but Respondent testified that he unsuccessfully attempted to get those records.[31] *See generally* GX 8; Tr. 341–42, 1449–50. At that time, B.G. complained of low back and leg pain. GX 8, at 1064. The records reflect a note from Respondent stating, ''I [Respondent] told him that he needs a primary care physician [for] his regular medical conditions. And a neurologist for MS in his care. Otherwise, I would not take over his care.'' *Id.* at 1067.

Dr. Munzing testified that between February 14, 2017, and October 3, 2019, Respondent issued forty-three controlled substance prescriptions to B.G. outside the usual course of professional practice and beneath the standard of care in California. Tr. 421–22, 945; GX 24 (Chart of Prescriptions Reviewed by Dr. Munzing), at 1. The prescriptions included prescriptions for Dilaudid 4 mg. ranging from 60 tablets in February 2017 to 30 tablets in August 2017 when the prescription discontinued; Valium 10 mg. ranging from 90 tablets in February 2017 to 45 tablets in October 2019; and Methadone 10 mg. ranging from 600 tablets in February 2017 to 215 tablets in October 2019. GX 24, at 1. During the relevant period Respondent, as the expert witnesses testified, reduced the prescribed controlled substances' overall quantity of opioids from an ''astronomically high'' 2432 MME per day, Tr. 387–88, to 1720 MME per day, Tr. 441 and GX 24, at 1, and his function improved, Tr. 1099, 1191.[32] Dr. Munzing opined that Respondent failed to satisfy the standard of care with regard to performance of physical examinations, treatment plans, periodic review and monitoring, and recordkeeping.

Dr. Munzing testified in great detail regarding why the February 14, 2017 prescriptions were issued outside the standard of care. According to Dr. Munzing, none of the medical records between October 24, 2013, and February 14, 2017 ''confirm that there was [a physical] exam performed.'' [33] Tr. 379. Dr. Munzing testified that a standard physical examination of a back that a pain specialist should perform consists of ''observation, . . . touching the back, range of motion, reflexes.'' Tr. 373. The physical examination notes on February 14, 2017, state:

Review: No significant changes noted in the patient's physical examination in this follow-up visit.

General: The patient is well developed and well-nourished. Patient is alert and oriented. He is in no acute distress. Patient has good hygiene.

Cardiovascular: Cardiovascular examination revealed regular rate and rhythm. No murmurs auscultated. There is no evidence of pedal edema.

Abdomen: Not an obese person. The abdomen is soft, with no masses palpated, no rebound, rigidity or tenderness.

Neurology-Coordination: Diadochokinesia is found to be normal. Finger-to-nose testing is normal. Antalgic. The patient is unable to do heel walk. The patient was unable to do toe walk.

Gait: He is on W/C.

GX 8, at 629 (emphasis removed from original). According to Dr. Munzing, this medical record has ''very little there'' and ''no documentation of any musculoskeletal exam, arm, leg, back, which were the areas that were

[30] Although consultation is not a primary issue in this case, I am including this discussion as helpful in fully understanding the applicable standard of care for prescribing in California. *See also, infra* II.E.

[31] In his fourth exception, Respondent alleges that the ALJ erred by including Respondent's failure to document a discussion with Dr. M as an example of a deficient medical record because Dr. M's died before Respondent took over care of B.G. ALJX 28, at 13. I agree with Respondent on this issue and do not consider Respondent's inability to discuss prior care of B.G. with Dr. M or his inability to obtain records from Dr. M as rendering the relevant prescriptions outside the standard of care.

[32] Dr. Munzing explained that this sort of MME reduction decreases the risk to the patient, Tr. 874, but the MME is still high (in fact, ''anything over 120 MME is high dosage'' Tr. 304), ''and the prescriptions are not medically justified.'' Tr. 389; *see also id.* at 309, 1216–17.

[33] Dr. Polston did not definitively testify regarding whether during B.G.'s October 24, 2013 office visit, the records documented a physical examination related to B.G.'s MS, but instead testified ''[there is] a lot of inference there'' such as ''good hygiene.'' Tr. 773.

complained at.'' [34] Tr. 379–80. The records confirm Dr. Munzing's testimony. Dr. Polston did not testify specifically regarding the sufficiency of the physical examinations of B.G., but did testify generally that ''[a]ll records show appropriate medical histories and examination treatment plans.'' Tr. 684. I credit Dr. Munzing's more specific opinion that this record did not document an adequate physical examination of B.G.

In addition to not covering the areas where B.G. complained of pain, the exam notes were ''always the same.'' Tr. 379. I credit Dr. Munzing's testimony that in complying with the applicable standard of care pain management physicians should see ''some visit-to-visit variability.[[35]] So you might have two visits that might be identical. But over three-and-a-half years, [it is] not going to be identical.'' Tr. 380. According to Dr. Munzing, ''when you look at the medical records . . . there really is no evidence that there is an examination that verifies that this patient is in agony and extreme pain, certainly from an exam standpoint.'' Tr. 388.

Dr. Munzing went on to testify that the remaining relevant prescriptions issued between March 14, 2017, and October 3, 2019, were issued outside of the standard of care for the same reasons as the February 14, 2017 prescriptions. Tr. 405, 407, 409, 411, 415, 433, 438, 444. With regard to the mostly identical physical examination results, Dr. Munzing's testimony is supported by Mr. Deshpande, who testified that from February 14, 2017, to May 8, 2018, twenty-one physical tests [36] of B.G. were copied forward verbatim from prior medical visits without any new information being added. Tr. 1920–22; GX 29b (Bizmatics Subpoena Response), at 4–5. Eight physical tests were added on May 8, 2018, and then all twenty-nine of those physical tests were copied forward verbatim until October 3, 2019. *Id.* Additionally, Dr. Munzing clearly testified that even on the occasions where more information was added, the records did not contain sufficient documentation to justify the high dosages of controlled substances prescribed; therefore, the prescriptions remain outside the standard of care. Tr. 438–39. He stated, ''we have just a long cascade of exams that by and large have been copy with slight variation at times . . . we're still over 2,000 methadone equivalent . . . combination with an opiate which still puts the patient at very significant risk and again, if you look at the medical records, the medical records certainly don't verify and support a prescription at that extreme.'' Tr. at 433–434.

Dr. Munzing opined that the prescriptions were also beneath the standard of care with regard to the documentation of treatment plan objectives. He testified that for the February 14, 2017 prescriptions, the ''total opiate dosage [was] extremely high [at 2,432 MMEs], astronomically high'' given the lack of ''an examination that verified that this patient is in agony and extreme pain.'' Tr. 387–88. Dr. Munzing opined that he ''[did] not see anything in the records that would justify medications anywhere in this range.'' Tr. 389. Moreover, there is a ''combination of an opiate and benzodiazepine,'' but ''[t]here does not appear to be anything [that is] being done to mitigate this and to try alternative methods that were safer.'' Tr. 388. Dr. Munzing repeated these concerns in support of his opinion that the remaining relevant prescriptions between March 2017 and October 2019 were outside the standard of care. Tr. 405, 407, 409, 411, 415, 433, 438, 444.

Dr. Munzing also opined that the treatment plan lacked clarity as to what conditions Respondent was using controlled substances to treat. Dr. Munzing testified regarding this confusion, ''are we treating lumbar pain, are we treating . . . multiple sclerosis pain, or [are] you treating both? And . . . muscular sclerosis pain . . . typically [does not] respond nearly as well to opiates as with other medications that are focused on neuropathic pain.'' Tr. 390. This confusion is further heightened by the Valium prescription, because, as he explained, Valium, generically diazepam, is ''a longer acting benzodiazep[ine] and which makes it many times more risky because it stays in your system longer. [It has] been used for anxiety, [it has] been used sometimes for muscle relaxation.'' Tr. 391. Dr. Munzing confirmed that it is ''dangerous to prescribe Valium with opioids.'' Tr. 392.

According to Dr. Munzing, there is no real indication in B.G.'s early medical records that Respondent was treating B.G. for his MS and there is no indication of the purpose of the Valium prescription.[37] Dr. Munzing testified that the initial exam lacked details regarding the history of the multiple sclerosis condition and lacked ''information that one would expect if [Respondent was] going to take over management of that condition.'' Tr. 342–43. According to a medical record dated March 16, 2016, B.G. reported to another medical provider, Dr. P., that he was taking Valium for ''irritability and depression,'' not for spasticity. GX 8, at 913. It was not until July 14, 2017, that the medical records include a note stating, ''Valium 10 mg tid × 45 for spasticity,'' with spasticity being an apparent reference to one of B.G.'s multiple sclerosis symptoms.[38] GX 8, 485; Tr. 416. But even with the July note, according to Dr. Munzing, it was not clear that Respondent was treating B.G.'s multiple sclerosis because the neurological examination was insufficient to support the prescription.[39] Tr. 417. Dr. Polston was also left to speculate regarding the Valium's purpose in the beginning, stating ''I think [it is] pretty much for anxiety and depression, but [B.G.] also [has] prior multiple back surgeries and spasms would not be irrelevant here.'' Tr. 782; *see also* 818.

Dr. Munzing explained that, while Respondent reduced B.G.'s opioid dosages, he did not document a

[34] Dr. Munzing testified there is ''no mention of the arms . . . [no] mention [of] anything specific about the legs other than he cannot do a heel or toe walk . . . no listing of the back.'' Tr. 384. In short, Dr. Munzing opined that the performance of the physical examination, assuming it was performed as documented, was still outside the standard of care for the patient. *Id.*

[35] Dr. Polson's testimony on cross-examination seemed to agree.

Q Do you typically see even for chronic pain patients over time, some change in their medical condition?

A Somewhat. Some—sometimes not always.

. . .

Q And even if you were conducting the same physical examinations month after month, you would occasionally see for some variance in the results?

A Yes.

Tr. 717.

[36] Mr. Deshpande testified that ''the number of physical tests copied refers to the discrete number of questions or tests or bullets that are part of the physical exam section that got copied from the previous visit to this visit.'' Tr. 1911.

[37] The ALJ found that ''the failure to timely document that [Respondent] was prescribing Valium to B.G. for spasticity represents a violation of the California standard of care relating to complete and accurate recordkeeping.'' Tr. 207. I agree.

[38] In his Exceptions, Respondent argued that the medical record has enough information generally to determine that the Valium prescription was issued for spasticity prior to the 2017 medical note. I find this argument to be without merit particularly because the lack of clarity in the medical records left both Dr. Munzing and Dr. Polston unsure of the exact purpose of the Valium prescription until July 2017. Additionally, Respondent argued that ''there is no nexus between the alleged failure to *timely* document the reason for . . . [the] Valium, and the stated goals of the DEA to avoid diversion.'' ALJX 30, at 13. I also find this argument, which is based on a misunderstanding of the meaning of ''diversion,'' to be without merit for the reasons set forth in *infra,* n.62.

[39] Put another way, even though the purpose of the Valium prescription is known by July 14, 2017, the subsequent Valium prescriptions remain outside the standard of care for Respondent's failure to perform a proper physical examination. *Supra.*

treatment plan for so doing. On February 14, 2017, the first set of prescriptions for the relevant time period, Respondent prescribed B.G. dilaudid 4 mg, 60 tablets; Valium 10 mg., 90 tablets; and methadone, 10 mg. 600 tablets. GX 24, at 1. Monthly from March 2017 through and including August 2017, Respondent prescribed B.G. dilaudid 4 mg, 30 tablets; Valium 10 mg., 45 tablets; and methadone, 10 mg. 300 tablets. *Id.* For the prescriptions between March 2018 and October 2018,[40] the dilaudid prescription was discontinued, Valium 10 mg. stayed constant at 45 tablets, and methadone 10 m.g. reduced gradually from 270 tablets, to 250, to 230, to 225, and finally to 215. *Id.* Dr. Munzing testified that early in B.G.'s treatment, Respondent had an obligation to ''come up with a management strategy to mitigate the risks, to decrease the risks, to bring [the high doses] down,'' it cannot be ''haphazard.'' Tr. 2041, 1072. Here, Dr. Munzing testified, ''there was an initial drop, and then it was kept stable for an extended period of time.'' Tr. 2045. ''Rather than we'll drop it a little bit, and then continue for six months,'' Dr. Munzing testified, Respondent needed to ''come up with a game plan . . . whether it be a three-month, a six-month plan of action, and then it may need to be tweaked along the way . . . or alter[ed].'' Tr. 2044. Respondent's Exhibit SS, a California Department of Public Health note to providers, confirms Dr. Munzing's testimony about the need for a plan and states, with regard to tapering patients on opioids, that physicians should ''[e]nsure patients understand the risks and benefits of dose maintenance versus dose tapering and develop an individualized plan in collaboration with patients.'' RX SS, at 2. According to Dr. Munzing, while the record occasionally documents that Respondent discussed tapering, Tr. 2098, it does not document what specifically was discussed. And there is no documented individualized treatment plan of action for reducing the controlled substance dosage in the records for B.G. between February 2017 and August 2017. GX 8. For example, between the February 2017 visit and the March 2017 visit, the quantity of all controlled substance prescriptions was cut in half without any explanation for the reduction; both medical record records simply stated ''[p]atient to continue on current medication regimen.'' GX 8, at 625. Beginning in December 2017, Respondent documents a plan to ''bring down [Methadone] 5–10 tabs per visit'' and that plan appears in the records through October 2019. GX 8, at 359; GX 9, at 2–6. Accordingly, I find in accordance with Dr. Munzing's testimony, that the failure to document a treatment plan for the reduction of controlled substance prescribing between February 2017, and August 2017, was outside the standard of care.

Dr. Munzing also explained that where Respondent did create what could be considered a treatment plan for B.G., he did not always follow it. He testified that, at Respondent's initial visit with B.G., he documented that he would not treat B.G. without him having a neurologist to manage the MS. Tr. 1067. On February 19, 2018, the medical records prepared by a different provider state that B.G. ''has been on valium tid[41] for several years for spasticity of the LE. Discussed today with [Respondent], who states that because this is a PMR practice we will continue to prescribe this with the patient's opioid pain medications provided that the patient bring[s] an annual note from neurologist or neurosurgeon who currently sees him for MS if the valium continues to be recommended.''[42] GX 8, 306. Again, the Valium continued to be prescribed throughout the relevant period even though Dr. Munzing agreed that he did not see notes from a neurosurgeon or neurologist appear in B.G.'s records at any time. Tr. 427, *see also* 1728–35. Respondent himself testified that despite the note written by his nurse practitioner, which Respondent admitted ''[he] missed,'' he ''do[es] not require neurology . . . [because] [he is] more specialized than regular neurology to manage spasticity.'' Tr. 1739. This testimony directly conflicts with Respondent's initial medical record for B.G., which stated that if B.G. did not see a neurologist for his MS, Respondent ''would not take over his care.'' GX 8, at 1067. Notably, Dr. Polston testified that he ''would insist'' that a pain patient with MS see a neurologist. Tr. 772. Even if Respondent did not make that note as he contests, it appeared in his treatment plan. Regardless of whether or not a neurological consultation was required, it is clear that the treatment plan is not clearly or consistently documented.

Furthermore, Dr. Munzing opined that Respondent's records for B.G. were beneath the standard of care regarding the requirement to conduct periodic review and monitoring. Dr. Munzing repeatedly criticized that Respondent put ''[B.G.] at significant risk'' by prescribing ''high doses'' of opioids in ''combination with a benzodiazepine'' without any evidence of ''attempting alternative medication that would be less risky.'' Tr. 439, *see also* 434. Moreover, an office visit note for May 31, 2016, stated ''[t]he pt say Dr. [P], psych. About a couple of weeks ago, report is recommending to continue Opioid Medications and taper off benzos.'' GX 8, 797. Tr. 427–28. Dr. Munzing testified that Dr. P's recommendation is a red flag and that the standard of care required that Respondent resolve the red flag and document the resolution, which was not done here. Tr. 359. Additionally, Dr. Munzing testified that the notation regarding Dr. P's recommendation continued to be pasted in the medical record until July 14, 2017, yet Respondent never documented a resolution of the red flag and continued prescribing the valium without change. Tr. 363, 368, 385, 402, 413–14. Dr. Munzing testified that on April 29, 2019, when B.G. stated that he ''[could not] live without Valium,'' it presented yet another red flag, and that Respondent needed to ''explore'' whether that statement meant that B.G.'s ''condition is such that he needs it'' or whether he is ''so dependent on it that if he stops it, he has some symptoms [of] withdrawal.'' Tr. 439; GX 8, at 12.

I note that the record contains many examples of appropriate steps that Respondent took to monitor B.G. including running CURES reports, requiring urinary drug screens, requiring regular follow-up appointments, and administering the opioid risk tool questionnaire;[43] Respondent also referred B.G. to a cardiologist and to a pain psychologist.[44] Tr. 664, 1086, 1094, 1097–98. However, Dr. Munzing testified that ''[s]olely that the fact that [they are] doing urine drug screens and a CURES reports, those alone without the other components . . . [do not] provide medically a justification for prescribing.'' Tr. 422. There were also

[40] The prescriptions between August 2017 and March 2018 were not identified as being at issue in this case. *Id.*

[41] Dr. Munzing testified that ''tid'' means three times a day. Tr. 424.

[42] The record goes on to state ''[d]iscussed this with patient who is upset he needs this note when previously neuro input was no required. Discussed the latest opioid guidelines and the potential for additive respiratory depression when benzodiazepines and opioids are taken together. He verbalized understanding, states he was previously on an additional benzodiazepine for anxiety and this was stopped.'' GX 8, at 306.

[43] Dr. Munzing and Dr. Polston both testified that these are appropriate tools to use for monitoring. *See e.g.* Tr. 605, 664, 1023, 1097–98.

[44] Though, as addressed herein, Respondent did not resolve the red flag arising from the pain psychologist's recommendation to taper off benzos. Tr. 1086–89.

additional inaccuracies with B.G.'s patient record. For example, on June 15, 2017, the medical records for B.G.'s office visit on that date do not include a prescription for Valium, GX 8, at 529, when Valium was in fact prescribed, *id.,* at 524. Tr. 408–09. The impact of this inaccuracy is amplified due to the dangers presented by Respondent's prescribing of Valium, a benzodiazepine, concurrently with opioids. *See supra* II.D.3.b. Also, back in August 2013, during the initial evaluation, Respondent noted that, ''[B.G.] gets 720 pills per month in the last 7 years.'' GX 8, at 1064. This note was repeated verbatim throughout Respondent's treatment of B.G. up-to-and-including the last relevant record dated October 3, 2019. GX 9 (Medical Records for B.G.), at 18). According to Dr. Munzing, while this statement may have been accurate in 2013, Tr. 339, once it got carried over ''year after year,'' it was no longer accurate and created an internal inconsistency within the records. Tr. 332.

In accordance with Dr. Munzing's testimony and the record as a whole, I find that, the forty-three relevant prescriptions issued to B.G. for methadone, dilaudid, and Valium between February 14, 2017, and October 3, 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in California. Particularly, in accordance with Dr. Munzing's testimony, the relevant prescriptions were issued beneath the standard of care and outside the usual course of professional practice, because Respondent failed to perform and/or document a proper physical examination, develop and/or document treatment plan objectives, appropriately monitor and resolve and/or document the resolution of red flags, and maintain accurate and complete medical records.

2. Patient D.B.

D.B. first saw Respondent for pain management on January 3, 2017, when she complained of pain in her low back and hip. Tr. 449, GX 4 (Medical Records for D.B.), at 1. At that time, according to her medical records, D.B. had received ''three total hip revisions,'' the last of which had complications with infection. Tr. 449. On September 8, 2018, Respondent implanted a pain pump for D.B. to address D.B.'s continuing hip pain. Tr. 450–51; GX 4, at 401, 404. Over the course of D.B.'s visits with Respondent, as the expert witnesses testified, Respondent reduced the prescribed controlled substances' overall MME (outside of the pain pump) from 191 to 90 MME per day and her function improved.[45] Tr. 582–83, 625, 1028, 1034.

Dr. Munzing testified that between January 23, 2017, and August 2, 2019, Respondent issued thirty-one controlled substance prescriptions to D.B. beneath the standard of care in California. Tr. 945; GX 24, at 2. The prescriptions included fentanyl 25 mg./ml. in a 10 ml. vial; hydromorphone 50 mg./ml. in a 10 ml. vial; OxyContin 30 mg., 60 tablets issued roughly every other month between January 2017 and May 2017; and finally oxycodone 15 mg. ranging from 135 tablets in January 2017 to 90 tablets in August 2019. GX 24, at 2. Dr. Munzing opined that Respondent failed to satisfy the standard of care with regard to performance of physical examinations, periodic review and monitoring, and recordkeeping.

Dr. Munzing opined that the physical examinations in the record were beneath the standard of care because the Respondent appeared to have copied and pasted the physical examination repeatedly. Dr. Munzing testified that at some point there was ''a documented hip exam which got copied, copied, copied, copied, copied. So we [cannot] confirm that [an exam] was done at all those times because it was a copy forward. And then suddenly a month after the pump goes in, it drops off, which is . . . curious timing . . . [because] [i]f [you are] really treating hip pain, you want to try [to] find . . . some improvement in that.'' Tr. 1294–95. I credit Dr. Munzing's opinion and find that Respondent failed to adequately perform physical examinations as required by the standard of care for prescribing for pain in California. There are additionally times in the records, where, according to Dr. Munzing, ''[d]espite some increase in hip pain, [there is] no documented exam of the hip.'' Tr. 464, 466.

Dr. Munzing testified that an adequate physical examination of D.B.'s hip would entail things like ''look[ing] for any redness, swelling,'' ''palpat[ing] or touch[ing] it,'' ''somewhat of a range of motion . . . rotational exams . . . [there is] a variety of things you can do even when a patient is sitting there in the wheelchair.'' Tr. 1290–91. Dr. Munzing testified that performing a physical examination was important to determine if, as a result of the pain pump, ''the patient may have increased range of motion'' or if ''she may not have pain when [you are] making some maneuvers, or the pain may change.'' Tr. 1296. Dr. Munzing further stressed the importance of a physical exam because, ''[s]he had a history of an infection . . . [i]f an abscess or other infection started happening, she may not recognize that . . . this is infectious pain instead of other pain.'' *Id.*

Regarding the appropriateness of a physical examination of D.B.'s hip, Dr. Polston testified that D.B. ''is a patient who has a lot of pathology in her hip. She's had five surgeries and I would be very cautious about any type of movement with this patient.'' Tr. 601. Dr. Polston testified the physical examination would consist of ''is there an infection there? . . . If the patient is saying . . . the hip is . . . stable or that [she is] responding to some of the medicines . . . [that is] the exam.'' *Id.* However, the physical examination portion of the records subsequent to October 1, 2018, do not include any mention of the hip whatsoever including mention of whether the hip was evaluated for potential infection.[46] *See* GX 4, at 331. Respondent testified that following the October 1, 2018 physical examination of D.B.'s hip, Tr. 1382–83, no further examination was necessary because the patient's condition was ''permanent and stationary,'' and because of her history, an examination could ''potentially cause another [hip] dislocation right in the office.'' Tr. 1386. Based on Respondent's own admission and a review of the medical records, it does not seem that the Respondent conducted even the limited physical examination of D.B.'s hip that Dr. Polston testified would satisfy the standard of care. Regardless, I credit Dr. Munzing's testimony that Dr. Polston's description of the physical examination requirement did not reflect the standard of care. Tr. 1294.

Dr. Munzing also opined that Respondent issued prescriptions for controlled substances beneath the standard of care due to his failure to ''attempt to get prior medical records to confirm the accuracy of what'' D.B. reported regarding ''her multiple surgeries and . . . an infection . . . in

[45] Dr. Polston testified that the MME D.B. was receiving (for the oral medication prescribed, not the medication in the pain pump) ''was cut in . . . more than a half,'' which, he acknowledged, was an example of a ''pain management specialist doing a[n] outstanding job in the reduction of the medication.'' Tr. 625. Dr. Munzing testified that even though ''[it is] great that [Respondent was] tapering down,'' Tr. 1218, prescriptions that are tapered down still must have ''adequate[ ] justif[ication]'' other ''than just the fact they were on a high dose.'' Tr. 1217.

[46] The History of Present Illness portion of the records contain information like ''[t]he patient complains of pain in the Hip pain [sic.] . . . [o]n average the pain is 7/10 . . . [p]t reports increased pain in the mornings'' and arguably contains information regarding the stability of the hip and D.B.'s response to the medication, which Dr. Polston testified was also required.

her hip.'' [47] Tr. 869–70. Dr. Munzing explained that there is ''a history that the patient has had multiple hip surgeries and presumably . . . is being followed by someone else, but we really [do not] know specifics. And [there is] no imaging.'' Tr. 461. Dr. Munzing opined that Respondent had a ''responsibility to do a thorough history'' initially ''to confirm what [the patient was] saying.'' Tr. 1209. Respondent countered this opinion with testimony that he had ''a brief conversation with the patient transferring place, so you have to trust that physician . . . Second, in pain management, . . . you have to trust your patients.'' Tr. 1366. Notably, Respondent later confirmed that his purported call with the referring physician was ''[n]ot documented.'' Tr. 1692. Dr. Polston conclusively opined that Respondent's failure to secure prior records or imaging did not mean Respondent acted outside the standard of care. Tr. 603. However, Dr. Polston later agreed that he has ''had patients who, in [his] opinion, [were] trying to exaggerate their medical condition,'' and that you must ''consider'' what patients tell you regarding their condition, but that you ''just [cannot] take what they tell you at face value.'' Tr. 725. I credit Dr. Munzing's testimony [48] and find that Respondent failed to confirm D.B.'s prior medical history and/or failed to document that confirmation—either way I find that this failure violated the applicable standard of care.

Dr. Munzing opined that Respondent's periodic review and monitoring of D.B. was beneath the standard of care because Respondent failed to resolve red flags arising from D.B.'s inconsistent urine drug screen collected on July 7, 2017, and released on July 17, 2017.[49] GX 4, at 715–16; Tr. 856–62. On July 7, 2017, D.B. was prescribed neither carisoprodol (Soma) nor hydrocodone/codeine, yet, metabolites of those two medications appeared in D.B.'s urine drug screen and were documented as ''inconsistent'' results. Tr. 856, 858; GX 4, at 715. Dr. Munzing confirmed that ''Soma, in particular, can be very dangerous when prescribed with an opioid.'' Tr. 1246. According to Dr. Munzing, it was ''incumbent upon [Respondent] to, in a very timely manner,[[50]] call a patient, talk to the patient.'' Tr. 1249. Respondent needed to figure out ''[what is] going on, and emphasize to the patient that . . . if [she] . . . got some medication through someone else . . . this can be a . . . fatal problem.'' *Id.* Furthermore, he had to ''document specifically what [he] did and [his] reasoning behind a decision to keep on prescribing.'' Tr. 860. Here, as Dr. Munzing confirmed, the medical record did not document any conversation with the patient, Respondent's determination as to what caused the inconsistent results, or what Respondent planned to do about it. *Id.;* and at 1046, 2151–52.

According to Respondent, the aberrancy was addressed on August 3, 2017, as is documented in the note stating, ''MD reviewed LC/MS [liquid chromatography-mass spectrometry] from the DOS of inconsistent 07/07.'' GX 4, at 708, 1053. Respondent testified that he did not need to contact D.B. sooner following the UDS because there were other, less sensitive drug screens run on the same day that did not show aberrant results; therefore, it could have been ''a possible lab error'' and ''[that is] no reason to call a patient to say you could be in danger.'' Tr. 1436. Respondent's argument is contradicted by the record evidence that the other, ''less sensitive drug screens'' run on D.B. on July 7, 2017, make no mention of, and do not appear to have tested for Soma/carisoprodol or its metabolite meprobamate or hydrocodone and codeine or their metabolite norhydrocodone. GX 4, at 719–20. The possibility of a lab error is also less likely, given that, on cross examination, Respondent confirmed that his office was prescribing Soma to D.B.'s daughter around the time of June 7, 2017. Tr. 1687. Respondent agreed that it was hypothetically ''possible that [D.B.] obtained Soma from her daughter's prescription.'' Tr. 1688. However, Respondent avoided a direct answer when asked whether D.B. could have obtained the Soma unlawfully from her daughter. Tr. 1688. He testified, ''Let's put it this way. If [it is] a Soma, if you [are] so close to each other, it could be from a liquid contamination [to] make her urine positive too.'' *Id.* When pressed by the ALJ regarding how Soma could show up in D.B.'s system unless D.B. took it,[51] Respondent explained how the daughter's Soma could accidentally be ingested if the daughter dropped it in D.B.'s food. Tr. 1688–89. The scenario described by Respondent to any logical person strains credulity. Further, there is no evidence on the record that supports the notion that D.B.'s daughter might have dropped her medication in her mother's food. If Respondent had some information that this scenario explained the presence of the Soma after talking to the patient, then in accordance with Dr. Munzing's testimony, that should have been documented. There is no dispute that the medical record did not capture any discussion regarding a conversation with the patient, Respondent's determination as to what caused the inconsistent results, or what Respondent planned to do about it. Tr. 1690.

I credit Dr. Munzing's opinion and find that Respondent failed to appropriately monitor D.B. in accordance with the standard of care when he failed to timely follow up on the inconsistent drug screen; however, even if waiting until the next appointment had been proper, Respondent further issued the next prescription beneath the standard of care by not adequately documenting resolution of the aberrant UDS in the records. I note that the record contains many examples of appropriate steps that Respondent took to monitor D.B. including running CURES reports, requiring urinary drug screens, requiring regular follow-up appointments, and administering the opioid risk tool questionnaire. Tr. 604–05; 1021–25. However, Respondent's actions with regard to this aberrant UDS did not, and I have found his explanation to not be credible. Therefore, I considered Respondent's failure in monitoring in finding that the prescriptions for controlled substances

[47] Dr. Munzing described this as a failure from a ''foundation standpoint'' and explained that this failure applied to all of the relevant prescriptions issued to this patient. Tr. 869–70.

[48] I find that the MBC Guide to the Laws provides further support to Dr. Munzing's testimony in stating that generally, ''[m]edical documentation should include both subjective complaints of patient and caregiver and objective findings by the physician.'' GX 17, at 61. Therefore, the MBC Guide to the Laws makes it clear that a physician has a duty to do more than rely on the subjective position of the patient.

[49] The OSC alleges other aberrant drug screens for D.B, which the Government appeared to drop from its case in its posthearing brief. OSC, at 6; ALJX 27 (Government's Posthearing), at 9–10. Dr. Polston and Respondent both credibly testified that medication infused through a pain pump does not pass through the blood/brain barrier and as a result, will not necessarily show up in urine. RD, at 194–96. Accordingly, D.B.'s UDS that showed a negative result for prescribed substances were not necessarily aberrant. *Id.* I agree with the ALJ and am not sustaining these allegations from the OSC. *See id.*

[50] Dr. Munzing testified that this UDS showed ''potentially serious findings of aberrancies, and so typically one would not wait [until] the next visit'' to discuss them with the patient. Tr. 1042. Rather, ''[o]ne would pick up the phone and call and manage it over the phone.'' *Id.* And the phone call needed to be in ''[s]hort order,'' which could ''be hours or a couple of days'' but not to wait weeks to the next visit. Tr. 1043.

[51] Dr. Munzing testified that the only way a urine drug screen would test positive for a substance is if the patient ingested that substance. Tr. 2066, 2118; RD, at 77.

issued after the aberrant UDS were issued beneath the standard of care.

In accordance with Dr. Munzing's testimony, I find numerous recordkeeping violations on top of those already addressed above, which contribute to my finding that Respondent's controlled substance prescribing to D.B. was beneath the standard of care and outside the usual course of professional practice. For example, on May 12, 2017, Respondent wrote in the medical records that he was prescribing 120 tablets of oxycodone, but he, in fact, prescribed 135 tablets. *Compare* GX 4, at 761 *with* 757 and GX 6b (Prescription Records for D.B.), at 7–8. Dr. Munzing opined that the prescriptions on this date were beneath the standard of care for the above reasons and because ''the amount prescribed is not consistent with what was written in the chart.'' Tr. 497. Second, different medical records dated January 7, 2019, January 21, 2019, and February 2, 2019, all state ''recheck today 1/3/18'' under ''Urine Drug Screening,'' GX 4, at 104, 128, 141, which Dr. Munzing opined was an errant copy forward from prior examinations. Tr. 851–55. Ultimately, Dr. Munzing opined that the ''internal inconsistency even within [D.B.'s] record'' and between the medical record and accompanying prescriptions, demonstrated that the prescriptions were issued beneath the standard of care. Tr. 871.

Dr. Polston, when asked, opined that ''[i]n totality, . . . the standard of care . . . was . . . met by [Respondent] with regard[ ] to record keeping and charting of this patient D.B.'' Tr. 618–19. Respondent similarly testified that ''the totality of overall my charts are good. Of course there [are] some mistakes. [But] I think my chart[s] overall [are] above average.'' Tr. 1607.

I credit Dr. Munzing's more specific opinion, which more accurately relies on the record evidence, and find that Respondent acted beneath the standard of care when he failed to maintain complete and accurate records for D.B. Although some of these mistakes by themselves might not always amount to a particular prescription being issued beneath the standard of care and outside the usual course of professional practice, the fact that these mistakes were made on top of the other failures further demonstrates that Respondent was not maintaining accurate records or documentation. As Dr. Munzing described it, the ''supporting information is just not there.'' Tr. 871.

In accordance with Dr. Munzing's testimony and the record as a whole, I find that, the thirty-one prescriptions for Fentanyl, oxycodone, hydromorphone and OxyContin issued to D.B. between January 23, 2017, and August 2, 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in California. Particularly, in accordance with Dr. Munzing's credible testimony and as supported by California law, the relevant prescriptions were issued outside the standard of care because Respondent failed to perform and/or document a proper physical examination, obtain and/or document an adequate history, appropriately monitor and resolve and/or document the resolution of red flags, and keep accurate and complete records.

3. Patient E.N.[52]

By way of background, E.N. had a history of back surgeries, severe back pain, and weakness in the legs necessitating use of a wheelchair; she became a patient of Respondent in 2006. Tr. 677, 1567. The first medical documentation presented in the record evidence by the Government was dated July 3, 2012, wherein E.N. complained of pain in her low back and knees, complaints, which continued throughout Respondent's treatment of E.N. Tr. 875; GX 12 (Medical Records for E.N.), at 769. Tr. 1145–46; GX 12, at 770. Tr. 877–78; GX 12, p. 766. Over the course of E.N.'s visits with Respondent, for which there are medical records available, the experts testified that Respondent reduced E.N.'s opioid prescriptions from 1,920 MME per day to 960 MME per day [53] and that E.M.'s function improved. Tr. 879, 903, 911, 1147, 1534, 1542.

Dr. Munzing testified that between February 3, 2017, and April 15, 2019, Respondent issued forty-three controlled substance prescriptions to E.N. beneath the applicable standard of care in California. Tr. 945; GX 24, at 3. The prescriptions included prescriptions for Methadone 10 mg. ranging from 360 tablets issued in February 2017 to 120 tablets issued twice a month in April 2019; and a single prescription for Dilaudid 4 mg., 14 tablets issued in January 2019. GX 24, at 3. Dr. Munzing opined that, based on his review of the medical file for E.N., Respondent failed to satisfy the standard of care with regard to performance of a physical examination, periodic review and monitoring, and recordkeeping. Tr. 911, 927–28.

Dr. Munzing credibly testified that the ''extraordinarily high amounts'' of opioids, with a MME ranging from 1440 to 960 per day during the relevant period, Tr. 887, 903, ''would certainly not be medically justified'' by the medical records he reviewed for E.N. Tr. 912–13. Dr. Munzing testified that while the section of the patient records that covers the history of present illness for E.N. is different from visit to visit,[54] the physical examination has ''verbiage that is the same . . . word for word'' continuously between May 25, 2016, and April 15, 2019. Tr. 1173, 1177–78. According to Dr. Munzing, this repeated physical examination is outside the standard of care because ''we [do not] know on any particular date, what truly was the patient's condition at a certain date, and [that is] required to be able to justify, are we going to continue using this, is this the right treatment?'' Tr. 911–12. Dr. Munzing further confirmed that where the physical examination notes were simply repopulated, the ''records do not establish that a physical exam actually occurred.'' Tr. 1237.

Dr. Munzing testified generally that, with regard to E.N.'s records, ''large portions of them, and almost entirely the physical exam, appears to get cut-and-paste or are copied forward.'' Tr. 911. Respondent's counsel pointed out and Dr. Munzing acknowledged that on three dates (May 25, 2016, May 16, 2018, and December 27, 2018), ''new information was put in'' alongside the repopulation. Tr. 1263; *see also* GX 12, at 90, 216, 556. Regarding E.N., Dr. Munzing acknowledged that it would be ''fair to say that on dates when new examination notes appear, that [is] probably an indication there was a physical examination [performed] that

[52] Respondent's second Exception challenges the ALJ's finding that Respondent did not re-evaluate the proper course of treatment in the face of E.N.'s reports of increased pain in November 2015. ALJX 30, at 7. Of note, the ALJ found that that re-evaluation did occur, but that it was not documented in the treatment plan. RD, at 216. Regardless, I do not see anything in the record that ties these facts from November 2015 to the legitimacy of the prescriptions from 2017–2019 that are at issue in this case. Accordingly, I consider the matter to be irrelevant and I have not considered the ALJ's finding on this particular matter in issuing my decision.

[53] Dr. Munzing explained that this sort of MME reduction is commendable and reduces the risk to the patient; however, the MME remains ''extraordinarily high'' and is not medically justified. Tr. 912–13; *see also* 681, 702, 1146, 1152–53.

[54] In his Exceptions, Respondent argued that where the medical records reflected changes to the history of present illness, vital signs, and other sections, it ''clearly demonstrated that Respondent, or other physicians or mid-level providers acting on his behalf, had seen and evaluated the patients on a regular basis.'' ALJX 30, at 17. Even assuming that the information establishes that the patient was seen, it does not establish that an adequate physical examination to justify the prescription occurred. *See supra* II.D.2. Therefore, although it is true that parts of the medical record might have met the standard of care, those parts do not impact my finding that, based on Dr. Munzing's testimony, the physical examination records were not adequate.

matches what was described within the notes.'' Tr. 1238. The Government notably did not allege that the prescriptions issued on May 25, 2016 (which were before the time period of the allegations) or the prescriptions issued on December 27, 2018, were issued beneath the applicable standard of care and outside the usual course of professional practice, GX 24, at 3; therefore, I find that Dr. Munzing's acknowledgement of the documented physical examination on May 16, 2018, only affects the prescription issued on that date. The Government did not present any further testimony regarding the adequacy of the note on May 16, 2018, in documenting the alleged physical examination and therefore I am not finding that the prescription for methadone issued on that date was issued beneath the standard of care.

With regard to the applicable standard of care's requirement to conduct a periodic review and monitoring, the record contains several examples of appropriate steps that Respondent took to monitor E.N. that Dr. Munzing acknowledged met the applicable standard of care. Tr. 1165–66, 1544, 1551, 1555. However, the Government alleged that Respondent's prescriptions for controlled substances to E.N. fell beneath the standard of care when he failed to resolve a particular red flag related to an early refill request.[55] OSC, at 12. On February 8, 2019, E.N. visited Respondent for a ''methodone refill. She can not [sic.] get her previous RX filled due to pharmacy issues. It has tried two different pharmacies without help. She is here for new rx for refill.'' GX 12, at 58; Tr. 919. According to Dr. Munzing, this note constitutes a ''red flag'' because it is ''something that catches [Dr. Munzing's] attention that needs further exploration and documentation.'' Tr. 920. Dr. Munzing testified that the pharmacies could have refused to fill the prescriptions for ''suspicious [or] not-suspicious reasons,'' and that it was therefore ''important . . . to find out from the patient why . . . are they not filling it.'' Tr. 920. Dr. Munzing confirmed that the medical record contains no ''notation or documentation resolving that red flag'' and opined that this failure was ''outside the standard of care.'' Tr. 927–28. Dr. Polston opined that Dr. Munzing's opinion was ''very naïve and shows limited experience in the practice of pain medicine,'' because, at the time, pharmacies were ''extremely concerned about prescribing'' and ''sometimes they [do not] have the medicines themselves.'' Tr. 683. Dr. Polston's testimony seems to imply that because there could have been a perfectly legitimate reason that E.N. required the refill, a scenario Dr. Munzing also acknowledged, there was no red flag present. However, Dr. Polston also acknowledged on cross-examination that there could have been suspicious reasons why the prescription was not filled, such as forgery or impairment (intoxication).[56] Tr. 805, 808. Ultimately, Dr. Polston admitted that he does not know why the prescription was rejected by the pharmacies. Tr. 804, 808. I credit Dr. Munzing's opinion that whether or not the reason for the refill request was legitimate, the reason had to be documented, and I find that Respondent's failure to document the resolution of this red flag was beneath the standard of care and outside the usual course of the professional practice.

In accordance with Dr. Munzing's testimony and the record as a whole, I find that forty-two of the forty-three prescriptions issued to E.N. relevant to this case were issued outside of the usual course of professional practice and beneath the applicable standard of care in California. Particularly, in accordance with Dr. Munzing's testimony, the relevant prescriptions were issued outside the standard of care because Respondent failed to perform and/or document a proper physical examination, appropriately monitor and resolve and/or document the resolution of a red flag, and keep accurate and complete records.

III. Discussion

A. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

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

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

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

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

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

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

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (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

[55] The Government also alleged that Respondent failed to resolve a red flag arising from his receipt of a ''Retrospective Drug Utilization Review Program'' letter dated April 27, 2016, that states that ''[E.N.] has filled medication(s) that may be of concern.'' OSC, at 12. Dr. Munzing opined that to resolve this red flag within the standard of care, Respondent would have had to ''document the fact that they . . . received this,'' determine that ''the potential risks of the medications are worth it, based on the potential benefits to the patient,'' and document ''the justification behind what I'm doing moving forward.'' Tr. 924–25. Assuming that the Government established that Respondent failed to resolve this red flag in accordance with the standard of care, the Government has not tied Respondent's failure to resolve this particular red flag to the specific prescriptions at issue in this case, which do not begin until approximately nine months after the date of this letter. Absent explanation as to how this particular red flag ties to whether or not the relevant prescriptions were issued within the standard of care, I decline to consider this allegation.

[56] Dr. Polston's opinion clearly suggests that if forgery or impairment were the reasons why the prescription was not filled, then there would be documentation of that in the record. Tr. 805, 808. The absence of this documentation seems to be what Dr. Polston uses to support his opinion that the reasons why the prescription were not filled were legitimate and his harsh criticism of Dr. Munzing. *Id.* I cannot conclude that the absence of documentation proves the legitimacy of the prescription, especially not in a case as riddled with recordkeeping problems as this one. *Supra* II.E.; *infra* III.A.2.

of the registrant's misconduct.'' *Jayam Krishna-Iyer,* M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

DEA regulations state, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). I find that the evidence satisfies the Government's *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors One and Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Respondent's Conviction Record Under Federal or State Laws Relating to Controlled Substances

Respondent argued that a MBC decision regarding Respondent ''stands in favor of Respondent's continued DEA Registration.'' ALJX 28 (Respondent's Posthearing), at 23. In this case, it is undisputed that Respondent holds a valid state medical license in California. *Supra* II.A. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20,011, 20,018 (2011). It is well established that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chien, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chien* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008).

In determining the public interest, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020); *see also Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002).

In this case, neither the MBC nor any other state entity has made a direct recommendation to DEA regarding whether the Respondent's controlled substances registration should be suspended or revoked. There is evidence on the record that effective January 31, 2020, the MBC found, amongst other things, that Respondent had violated state law by committing gross negligence in violation of Cal. Bus. & Prof. Code § 2234 when he failed to recognize the risk to patients associated with concurrent use of high dose opioids, benzodiazepines, and Soma, and failed to perform ongoing patient assessments, GX 26 (MBC Decision Involving Respondent), at 161–162; repeated negligence in violation of Section 2234 when he failed to document certain prescriptions and failed to maintain adequate records documenting his treatment of a patient, *id.* at 163–64; and acted in violation of Sections 2234 and 2266 when he failed to maintain adequate and accurate records of his care and treatment of the patients at issue, *id.* at 165. However, the evidence demonstrates that the matter before the MBC involved entirely different patients during an earlier time frame and was therefore different from, the conduct alleged in this case. GX 26; 21 U.S.C. 823(f)(1). Following its evaluation, the MBC took disciplinary action against Respondent, suspending his license and then probating the suspension, which permitted the Respondent to practice medicine without restriction. GX 26; ALJX 28, at 3–4; RD, at 233.

The evidence before me is different than what the MBC had at the time that it made its decision because it demonstrates that Respondent engaged in additional violations of state and federal law with respect to his prescribing practices. Further, the fact that the MBC did not choose to revoke Respondent's state medical registration carries minimal to no weight under Factor One, because there is no evidence that the MBC would have made the same decision in the face of the continued misconduct found herein involving different patients and continued recordkeeping violations.[57] Accordingly, the terms of the MBC Order have been considered, but I find that they have little impact on the public interest inquiry in this case.[58] *See Jeanne E. Germeil,* 85 FR 73,786, 73,799 (2020); *see also John O. Dimowo, M.D.,* 85 FR 15,810. In sum, while the terms of the MBC Order are not dispositive of the public interest inquiry in this case and are minimized due to the differences between the evidence in the MBC Order and the record evidence before me, I consider the MBC's Order's reprimand of Respondent's California medical license and give it minimal weight in Respondent's favor, because the charges could have resulted in the suspension or revocation of his medical license. *See Jennifer St. Croix,* 86 FR 19,010, 19,022 (2021).

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 Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[57] In *Dimowo,* the Acting Administrator found that ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state;'' however, *Dimowo* also limited the ''recommendations'' DEA would consider to the ''actions of an appropriate state entity on the same matters, particularly where it rendered an opinion regarding the practitioner's medical practice in the state due to the same facts alleged in the DEA OSC.'' *John O. Dimowo,* 85 FR at 15,810. Although the same ''matters'' may include similar types of violations, in this case, I have no indication that the MBC would have made a similar decision in the face of these additional violations and continued misconduct.

[58] In his exceptions, Respondent argued that the ALJ, who found that the MBC decision weighed slightly in Respondent's favor, RD, at 233, should have given greater weight to the MBC's decision and allowed Respondent to continue prescribing. ALJX 30, at 24. For the reasons contained in this analysis, I disagree. I have weighed this factor slightly in his favor, but I find that the fact that the state permitted him to continue to practice of medicine is not dispositive as to whether Respondent's continued controlled substances registration is in the public interest.

2. Factors Two and Four—the Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

(a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice

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

I found above that the Government's expert credibly testified as supported by California law, the MBC Guide to the Laws and Guidelines for Prescribing, that the standard of care in California requires a physician to, amongst other things, perform and document a physical examination, develop and document a treatment pan, conduct periodic review and monitoring of the patient, and have complete and accurate records in order to prescribe controlled substances. *See supra* II.D. I also found above that Respondent issued one-hundred and fifteen controlled substance prescriptions, often extremely high doses of opioids, to three patients without performing or documenting adequate physical examinations, developing or documenting adequate treatment plans, resolving or documenting resolution of red flags, and/or keeping complete and accurate records as required by the standard of care. *See supra* II.E.

Respondent repeatedly issued prescriptions without complying with the applicable standard of care and state law thus demonstrating that his conduct was not an isolated occurrence, but occurred with multiple patients.[59] *See Kaniz Khan Jaffery,* 85 FR 45,667, 45,685 (2020). For example, Respondent's medical records for all three of the individuals at issue had verbatim language repeated throughout the relevant time frame (with very few exceptions) regarding the physical examination allegedly performed.[60] Dr. Munzing opined that the verbatim records ''do not establish that a physical exam actually occurred'' and they prohibited us from ascertaining truly what ''the patient's condition [was] at a certain date'' and whether the prescribing was ''justif[ied].'' Tr. 911–12, 1237; *supra* II.E.3. The California standard of care clearly and indisputably requires a physical examination including ''an assessment of pain, physical and psychological function,'' and requires physicians to ''keep accurate and completed records . . . including the . . . physical examination.'' GX 17, at 59, 61. In his exceptions, Respondent acknowledged that ''the repopulation of his physical exam findings created inaccuracies and were thus deficient. . . . [And] because of the repopulation of physical exam findings [Respondent] cannot identify which portion or portions of the physical examinations he conducted during his visits with the patients.'' [61] ALJX 30, at 23.

Agency decisions highlight the Agency's interpretation that ''[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.' '' *Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,464 (2011). DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that he prescribed a controlled substance—adequate documentation is critical to that assessment. *See Kaniz-Khan Jaffery,* 85 FR 45,686. Here, Respondent's verbatim recordkeeping, failure to document justification for the treatment plan, failure to document resolution of red flags, and other errors, made it impossible to evaluate Respondent's prescribing practices in any meaningful way. *See Mark A. Wimbley, M.D.,* 86 FR 20,713, 20,726 (2021). Further, as Dr. Munzing stated, complete and accurate ''[m]edical records are incredibly important for physicians'' and inaccurate records could jeopardize ''patient safety'' particularly if the ''patient rolls into the ER.'' Tr. 705, 1197. Therefore, recordkeeping is not only important for compliance, but also for the safety of the patients.

DEA decisions have found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28,643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998). Diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .' '' *Id.* (citing *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014)).[62] In this case, I have found that Respondent issued controlled substance prescriptions without complying with his obligations under the CSA and California law. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010)).

Respondent's additional arguments likewise lack merit. In his Exceptions, Respondent argued that he has not

[59] And, as I discussed above, Respondent was disciplined by the MBC for similar conduct against different patients than those involved in this case during a prior timeframe. *Supra* III.A.1.

[60] I have chosen this example because it was Respondent's most frequently repeated and pervasive violation of the standard of care. However, each and every instance where I found a violation of the standard of care above, *supra* II.E.1–3, supports my decision in this case.

[61] In the same brief, Respondent took exception to the ALJ's finding that he had ''rampantly neglected his recordkeeping obligations by carrying forward verbatim entries for physical exam findings.'' ALJX 30, at 14–18; RD, at 224–26. I note that ''rampant neglect'' is not the applicable legal standard applied here—the question is whether the records were sufficiently accurate and complete to establish that the relevant prescriptions were issued within the standard of care. They were not. Second, all of Respondent's arguments regarding this exception are repetitive of arguments Respondent has already made and that I have already addressed. For example, Respondent argued the patients' physical examinations would not be expected to change because of their chronic conditions, addressed at *supra* II.E.1; argued Respondent properly monitored the patients, addressed at *supra* II.E.1–3; argued that updates to the history of present illness sections and vital signs demonstrated that the patients were evaluated, addressed at *supra* n. 54.

[62] In his Exceptions, Respondent argues that the Government has not made a *prima facie* case because there was ''no evidence of diversion nor the risk of diversion of controlled substances.'' ALJX 30, at 20. Respondent supports this argument with Dr. Munzing's testimony regarding a variety of red flags that were not present in this case (such as patient reports of lost or stolen medication, requests for early refills, inappropriate physical appearance). *Id.* at 21. The Government, however, is not required to prove that diversion resulted from the unauthorized issuance of prescriptions. *Arvinder Singh, M.D.,* 81 FR 8247, 8249 (2016). Rather, when a practitioner violates the CSA's prescription requirement, set forth in 21 CFR 1306.04(a), by issuing a prescription without a legitimate medical purpose and outside the usual course of professional practice, the DEA [essentially] considers the prescription to have been diverted. *George Mathew, M.D.,* 75 FR 66,146. I find Respondent's argument to lack merit.

committed acts that render his Registration inconsistent with the public interest. ALJX 30, at 21–22. He argued that there were no ''departures from the standard of care with the clinical decision-making and prescribing; the only departures were found relating to documentation.'' *Id.* Respondent also argued that because the ALJ found that ''Respondent's care and treatment and prescribing to each patient [was] appropriate and [met] the standard of care,'' it was ''puzzling'' that the ALJ then found that the ''record-keeping violations delegitimize the controlled substance prescriptions the subject records sought to justify.'' ALJX 30, at 19; RD, at 229.

The question at issue is whether the relevant prescriptions were issued beneath the standard of care and outside of the usual course of professional practice. In assessing whether the issued prescriptions violated 21 CFR 1306.04, it is not essential to count how many elements of the standard of care were violated for each prescription. The ALJ determined that the relevant prescriptions were issued outside of the standard of care due to incomplete and inaccurate record keeping, and that defect cannot be cured by the fact that Respondent, as the ALJ found, complied with other elements of the standard of care. DEA has previously made clear that ''a physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained patient records.'' *Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019). This principle was echoed in Dr. Munzing's testimony stating that ''you have to be treating it [in] real time[,] [y]ou have to document it [in] real time,'' you cannot say ''because of this [justification] three years from now, everything before must be that.'' Tr. 1233. What is essential in this case is whether at the time Respondent issued each prescription for a controlled substance, he met the standard of care in issuing that prescription—he had conducted the physical examination, had a treatment plan, monitored the patient, and documented such. California law and guidance emphasizes the importance of documenting crucial aspects of the rationale for prescribing to ensure that a practitioner is doing so in a manner that is transparent and recorded and adequately cares for the patient. Dr. Munzing testified that such practice is of particular importance where the prescriptions for controlled substances are in such high dosages. Tr. 281; *see also id.* at 389, 348–39, 768, 912–13.

The expert testimony demonstrates repeatedly that the accurate documentation of a physical examination and treatment plan that justify the continued prescribing of these high volume controlled substances is not merely a check-the-box exercise. And as explained above, it is impossible for the Agency or anyone to assess the legitimacy of a particular prescription without adequate recordkeeping. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,772 (finding that ''documentation is critical to effective enforcement of the CSA.'') With a regulated community of nearly two million registrants,[63] DEA must be able to rely on physicians to maintain complete and accurate medical records justifying their prescribing decisions.

Additionally, I find that Respondent's actions as they are documented in the medical records, not the actions he claimed with limited credibility that he performed, provide the best evidence to determine whether or not Respondent acted within the standard of care in issuing these prescriptions. California's standard of care makes clear that complete and accurate recordkeeping is tied to each other element of the standard of care in California. *See* GX 17, at 60. Ultimately, it is impossible to determine whether, as Respondent claims, he did conduct the physical examinations, did have appropriate treatment plans and did adequately address red flags, because he did not document any of these things as he was required to do under state law and the standard of care. Therefore, I cannot find definitively, as Respondent suggests, that the prescriptions he issued were within the usual course of professional practice and within the standard of care. In fact, the record evidence demonstrates that he did not prescribe within the standard of care. The standard of care in California for prescribing controlled substances cannot be met if the justification for those controlled substances is not properly documented.[64]

Respondent repeatedly argued that the individuals ''were never harmed and because [of Respondent's] care, all achieved positive results.'' ALJX 30, at 26. Instead, Respondent claimed, the evidence shows that Respondent significantly lowered each individual's opiate dosage levels ''while allowing the patient[s] to maintain adequate pain control and functionality.'' ALJX 30, at 21. I acknowledge that the record evidence supports a finding that Respondent, in the big picture, reduced the relevant individual's opioid levels with the benefits that Respondent espoused. Respondent does not, however, cite legal authority for the proposition that I must find harm occurred before I may suspend or revoke a registration. And as Dr. Munzing testified, ''I would say not only in pain manage[ment] but in medicine in general, you [cannot] look back and say, based on the fact that there was no documented harm, whatever happened before must be okay.'' Tr. 1298. Moreover, the documentation is too deficient to conclusively determine that no harm occurred. Dr. Munzing testified that he had ''significant concern[s]'' with the documentation, ''[s]o there may very well be things in this case that we [do not] know . . . concerns that [do not just] go away because the patient [has not] overdosed and you [do not] document that [there are] adverse effects.'' Tr. 1034. Furthermore, the violations of the standard of care in this case are not limited to one patient nor are they limited to a specific timeframe. The record evidence demonstrates that for B.G. for example, from February 14, 2017, to May 8, 2018, twenty-one physical tests were copied forward, verbatim from prior medical visits without any new information being added. Tr. 1920–22; GX 29b (Bizmatics Subpoena Response), at 4–5. Eight physical tests were added on May 8, 2018, and then all twenty-nine of those physical tests were copied forward verbatim until October 3, 2019. *Id.* Additionally, each of the patients at issue in this case had many instances of required recordkeeping copied forward. These recordkeeping violations were not isolated: They were systematic; they spanned patients; they spanned years; they spanned different elements of the standard of care in California.

[63] *See* DEA FY 2020 Budget Request *available at https://www.justice.gov/jmd/page/file/1142431/download.*

[64] In his Exceptions, Respondent argued that ''[r]evoking Respondent's certificates based upon recordkeeping violations alone is not supported by Agency precedent,'' and he attempted to distinguish his case from the cases the ALJ cited for the proposition that ''record-keeping violations associated with controlled substance prescriptions may render such prescriptions outside the usual course of professional practice.'' ALJX 30, at 25–26. Respondent's point was that each of the cases the ALJ cited had more going on than record-keeping violations. *Id.,* at 27–28. Respondent's argument fails for the reasons set forth in this paragraph. The Government has established that Respondent's record-keeping violations rendered the relevant prescriptions outside the standard of care, which is sufficient to determine a violation of 21 CFR 1306.04. Once the Government has established a *prima facie* case, I will assess whether the Respondent has presented adequate evidence that he can be entrusted with a registration. *See infra* IV.

Additionally, the act of copying forward the examination made it more difficult for the Agency to determine whether Respondent had violated his legal obligations—the copy and forward served to hide the truth of whether these important aspects of care had occurred. In this case, the repeated and systematic violations of Respondent's obligations to document required elements of the standard of care when prescribing high dosages of opioids manifests a disturbing pattern of indifference that weighs heavily against a finding that Respondent's continued registration would be consistent with the public interest. Overall, I find that in issuing one-hundred and fifteen prescriptions beneath the applicable standard of care and outside the usual course of professional practice in California, Respondent violated 21 CFR 1306.04(a) and these violations of law weigh against Respondent's continued registration under Public Interest Factors 2 and 4.

(b) Violation of State Law

In addition to finding a violation of 21 CFR 1306.04(a), I also find that the Government has proven by substantial evidence that Respondent's prescribing violated state law. California law, just like federal law, requires that a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a). Therefore, for the same reasons I found a violation of 21 CFR 1306.04(a), I find that the record contains substantial evidence that Respondent violated this state provision with respect to the relevant prescriptions issued to B.G., D.B., and E.N. *Supra* III.A.2.a.

Cal. Bus. & Prof. Code § 2242(a) states that it is unprofessional conduct to ''prescribe[ ] . . . without an appropriate prior examination and a medical indication.'' Dr. Munzing testified that it means prescribers ''cannot prescribe controlled substances without an appropriate medical examination and without medical indication.'' Tr. 285. Consistent with my findings above, *supra* II.A.2.a., I find that Respondent issued the relevant controlled substance prescriptions without documenting an appropriate physical examination and/or legitimate medical indication justifying the high prescription doses in violation of Cal. Bus. & Prof. Code § 2242(a).

I am not issuing a finding on the alleged violations of Cal. Health & Safety § 11154(a); Cal. Bus. § Prof. §§ 725(a)[65] and 2234; or California Health & Safety Code § 11190(a) because neither the Government's Expert, nor the Government fully explained their application to this proceeding.

Ultimately I find that the record contains substantial evidence that Respondent issued multiple prescriptions of controlled substances to multiple patients beneath the applicable standard of care and outside the usual course of the professional practice and in violation of state law over the course of several years. I therefore find that Factors Two and Four weigh in favor of revocation.

B. Summary of Factors Two and Four and Imminent Danger

As found above, the Government's case establishes by substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice. I, therefore, conclude that Respondent engaged in misconduct which supports the revocation of his registration. *See Wesley Pope,* 82 FR 14,944, 14,985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has ''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 evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice establishes ''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 registration. *Id.* The risk of death was established in this case. There was ample evidence introduced to establish that ''combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system has resulted in serious side effects including slowed or difficult breathing and deaths.'' GX 20, at 1; Tr. 317–19, 1278.

Respondent argues in his Exceptions that the ''Government did not prove, at any point, that [Respondent's] continued registration constituted any danger to patients, or any threat of harm, much less imminent danger or harm.'' ALJX 30, at 21. Dr. Munzing's testimony was critical of the conclusion that these patients were not harmed. Dr. Munzing testified, ''[we need to be cognizant whether [it is] prescribing opiates, benzodiazepines, or anything else in medicine is we need to recognize what the potential harms are. And even if that patient so far [has not] experienced harm from whatever your management is, one still needs to be cognizant that that risk is there and not say, 'Well, nothing's happened yet. So that means that everything must be okay.' That certainly is not . . . the case.'' Tr. 1267. He further stated that the patient could be ''stable, stable, stable, stable, stable until they [did not] wake up.'' Tr. 1266.

Thus, as I have found above, at the time the Government issued the OSC/ISO, the Government had clear evidence of violations of law based on the one-hundred and fifteen controlled-substance prescriptions Respondent issued without complying with the California standard of care. *See supra* III.A.2.a.

IV. 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, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made minimal effort to establish that he can be entrusted with a registration.

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 259 (2006). A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that he can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that

[65] The ALJ evaluated Cal. Bus. § Prof. §§ 725(a).

where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR 23,853; *John H. Kennedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here, I agree with the ALJ's statement: ''I cannot find that the Respondent has unequivocally accepted responsibility for his proven deficiencies.'' RD, at 240. In his exceptions, Respondent claimed that ''consistently throughout these proceedings . . . [Respondent] recognized that his medical recordkeeping needed improvement.'' [66] However when testifying in his own words, Respondent admitted there were ''some mistakes'' in his recordkeeping, seeming to accept responsibility in one breath, but then in the next maintained that ''overall [his] charts [were] good'' and ''above average.'' Tr. 1607. Respondent's Exceptions also state, ''Respondent accepts that the repopulation of his physical findings created inaccuracies and were thus deficient.'' ALJX 30, at 23. This claim is not supported by Respondent's own testimony that the physical findings were not repopulated, but rather, Respondent conducted the same examination and made the same selections every visit, which simply produced an identical narrative. *See supra* II.C.; Tr. 1775–79; 1799–1801. I do not credit the acknowledgment of responsibility made in Respondent's Exceptions over Respondent's actual testimony, and I find that any of Respondent's testimony that could be considered to be an acknowledgment of responsibility in this case was both equivocal and not credible.

In all, Respondent failed to explain why, in spite of his misconduct, he can be entrusted with a registration. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ''magic words'' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,973 (2019). Here, having considered Respondent's case and statements, I am still left with no confidence in Respondent's future compliance with the CSA.

The Agency also looks to the egregiousness and extent of the misconduct, which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR 18,910 (collecting cases). In this case, the ALJ found, and I agree, that the record-keeping was so deficient that it ''delegitimize[d] the controlled substance prescriptions the subject records sought to justify.'' RD, at 229. Furthermore, the record evidence contains testimony from the Government's expert that explains exactly why recordkeeping is so important. In particular, Respondent was prescribing a dangerous combination of high dose controlled substances to a patient and his compliance with the state legal requirements regarding recordkeeping was so egregiously bad that it is difficult to determine what steps Respondent was taking to ensure this patient's safety, or even why a particular controlled substance was being prescribed. These are not solely recordkeeping requirements—these requirements are in place to ensure that practitioners are actively considering the safety of their patients and documenting that they did so. As Dr. Munzing stated, the patient could be ''stable, stable, stable, stable, stable until they [did not] wake up.'' Tr. 1266.

Respondent argues that the sole findings of departures are related to documentation and therefore warrant a sanction less than revocation. ALJX 30, at 25. Respondent's cavalier assumptions about his documentation responsibilities and the fact that he did not undertake this responsibility with seriousness weigh against my ability to entrust him with a registration. *See Singh, M.D.,* 81 FR 8248 (''[U]ntil . . . [a] Respondent can convincingly show he accepts the authority of the law and those bodies charged with enforcing it and regulating his activities, granting [ ] a DEA registration will gravely endanger the public.''). The truth is that it is not possible to tell whether Respondent's care was as appropriate as he claims because his recordkeeping was so abysmal.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent's behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration be revoked 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 Nos. FQ7186174, FQ7906968, and BQ7364970. 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 deny the pending application for a new DEA Certificate of Registration, Application No. W18124091C, for John X. Qian, M.D., and hereby deny any pending application of John X. Qian, M.D. to renew or modify these registrations, as well as any other pending application of John X. Qian, M.D. for registration in California. This Order is effective March 14, 2022.

Anne Milgram,

Administrator.

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[66] Respondent also argued that he had taken steps to mitigate and remediate his recordkeeping issues. ALJX 30, at 22. One example of these efforts included taking a course on medical recordkeeping in 2013. *Id.* This does not seem to have been an effective remedial effort given that the recordkeeping violations at issue in this matter took place years later. *Id.* Regardless, where, as here, the Respondent has not credibly accepted responsibility for his misconduct, I do not generally consider evidence of remedial measures. *See Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,202–03. Even if he had adequately accepted responsibility, I cannot find that these remedial measures are adequate such that I could entrust him with a registration.

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