

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–10]

Brenton D. Wynn, M.D.; Decision and Order

On February 20, 2020, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC) to Brenton D. Wynn, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1 (OSC), at 1. The OSC immediately suspended Respondent's DEA Certificate of Registration Number BW7210759 (hereinafter, registration or COR) "because [Respondent's] continued registration constitutes an 'imminent danger to the public health or safety.'" *Id.* (citing 21 U.S.C. 824(d)). The OSC also proposed revocation of Respondent's registration, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for any additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's "continued registration is inconsistent with the public interest." *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted on November 16–20, 2020, via video teleconference technology. On December 30, 2020, Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD) to which neither party filed Exceptions. The ALJ transmitted the record to me on January 25, 2021. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein. I issue my final Order in this case following the Recommended Decision.*^A

*^A I have made minor, nonsubstantive, and grammatical changes to the RD and nonsubstantive conforming edits. Where I have added to the ALJ's opinion to include additional information, I have noted the additions in brackets or in footnotes marked with an asterisk and a letter. Where I have made substantive changes, omitted language for brevity or relevance, or where I have modified the ALJ's opinion, I have noted the edits in brackets and have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *^{B 1 2 3}

The issue to be decided by the Administrator is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. BW7210759, issued to Respondent should be revoked, and any pending applications for modification or renewal of the existing registration should be denied, and any pending applications for additional registrations should be denied, because his continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations *^{C 4}

Overview

[The Government alleged Respondent violated federal and California law by issuing numerous controlled substance prescriptions outside the usual course of professional practice and not for a legitimate medical purpose to four individuals between September 2016 and September 2019. ALJ Ex. 1. Specifically, the Government alleged that Respondent violated 21 CFR 1306.04(a) and the following state laws and regulations:*^D

a. Cal. Health & Safety Code § 11153(a), requiring 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";

b. Cal. Health & Safety Code § 11154(a), directing that "no person

and footnotes, the use of the personal pronoun "I" refers to myself—the Administrator.

*^B I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

1 [Omitted pursuant to n.*^B.]

2 [Omitted pursuant to n.*^B.]

3 [Omitted pursuant to n.*^B.]

*^C For brevity, I have omitted large portions of this section that were repetitive of the OSC and have replaced them with a summary of the allegations.

4 [Omitted pursuant to n.*^C.]

*^D However, in its Posthearing Brief, the Government did not address Cal. Health & Safety Code § 11154(a), at all, and seemed to cite to Cal. Bus. & Prof. Code § 2234 to support the legal proposition that the Government does not have to establish that the misconduct was intentional. Because there is not adequate legal support in the Posthearing Brief for a finding regarding either of these state laws, I am not addressing them further herein.

shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition . . .";

c. Cal. Bus. & Prof. Code § 2242, prohibiting the "[p]rescribing, dispensing, or furnishing [of controlled substances] . . . without an appropriate prior examination and a medical indication," the violation of which constitutes unprofessional conduct;

d. Cal. Bus. & Prof. Code § 2234, defining unprofessional conduct to include: "[g]ross negligence"; "[r]epeated negligent acts"; "[i]ncompetence"; or "[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon"; and

e. Cal. Bus. & Prof. Code § 725, further defining unprofessional conduct to include "[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs. . . ."

Additionally, the Government alleged that Respondent issued prescriptions outside of California's applicable standard of care as outlined in the "Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons," Medical Board of California, 7th ed. 2013 (the "Guide"). See ALJ Ex. 1. The Government alleged that these prescriptions fell below the standard of care applicable to the practice of medicine in California, and that therefore, these prescriptions violated federal and California State law.

The OSC provided specific examples of Respondent's alleged failures related to his prescribing controlled substances to the four individuals: D.P., J.K., D.L., and P.S. ALJ Ex. 1, at 4–10. Examples of the Government's allegations as to each patient included that Respondent: (1) Prescribed dangerous controlled substances and combinations of controlled substances resulting in high morphine milligram equivalent (MME) dosages without a medically legitimate basis; (2) failed to resolve red flags of diversion; (3) failed to discuss the risks of the prescribed controlled substances sufficiently to obtain informed consent; (4) failed to appropriately evaluate and monitor his patients; and/or (5) failed to document physical examinations and other information as required by the standard of care. The Government alleged that these failures constituted extreme departures from the standard of care in California. Because of these failures, the Government alleged that Respondent regularly put his patients at significant risk for harm, including overdose or death.]

The Hearing

Government's Opening Statement

The Government argued that the Controlled Substances Act sets up a closed system for distribution of pharmaceutical controlled substances from DEA registrants. Tr. 12. In order for that system to stay closed, the professionals entrusted with DEA registrations are expected and required to be professional. Doctors are expected to know the bounds of their profession, to prescribe within those bounds and rules, to know the dangers of controlled substances, and prescribe them in a manner that reflects those dangers. Tr. 12–13. When doctors fall short of these expectations they are supposed to be up front about it and change course. Tr. 13. The evidence in this case will show a doctor who is prescribing controlled substances in an unsafe manner and without regard to the rules on prescribing pain medication. The Respondent prescribed opioids at extremely high and dangerous levels and the Respondent did not adequately address the risks of combining opioids with other medications, such as benzodiazepines, with his patients. The Respondent also prescribed substances to patients with abnormal drug tests, including tests that were positive for drugs that patients should not have had in their system, or negative for prescribed substances that should have been in their system. The Respondent prescribed controlled substances in a dangerous manner that put his patients' lives at risk.

It is not the Government's burden to prove that every prescription the Respondent issued to every patient was outside the usual course of professional practice. Tr. 13–14. The Government expected that the Respondent would present the Tribunal with testimony from patients and other doctors who believed that Respondent is a good doctor and a good member of the community. Tr. 14. However, on balance, the character testimony and other testimony offered by the Respondent cannot outweigh the fact that the Respondent issued prescriptions that were both outside the course of usual and professional practice in California and not for a legitimate medical purpose.

At the closing of the case, the Government urged this Tribunal to look at the Government's evidence showing a doctor who put his patients in danger by not abiding by the requirements as established by the Controlled Substances Act and the laws of California for issuing controlled substances. The Government argued that

Respondent's professional access to controlled substances is inconsistent with the public interest.

Respondent's Opening Statement

Respondent argued that this case is a reflection of a pain management specialist in San Diego with four patients, who represent less than one percent of his overall practice. Tr. 15. The patients with their high morphine milligram equivalent dosages were patients who came to him from a referral, already on these high doses. None of these patients passed away, of course. In all his years of practice, none of his patients have ever passed away due to an overdose or had to be transported to a hospital under a 911 service because of an overdose. The four patients the Government alleged represent an aberration in the sense of the high amount of opioid medications that they were taking.

The Respondent had evidence from expert witnesses that disputed the Government's case about whether in these particular patients the high amounts represented a breach in the standard of practice and therefore was practicing outside the scope of the law. Respondent said the evidence would show that the Respondent had consistently followed most if not all of the architectural requirements for a pain management doctor to follow patients who are being prescribed pain medication such as having pain management agreements, checking CURES reports, doing urine screens, or other types of screening. Tr. 16. The Respondent's experts told the Court that the Respondent exceeded the standards of practice at the time with how he followed these patients with numerous drug screens, frequent visits, and close monitoring. There was a dispute between the experts about the degree to which these patients should have been on these medications and the Respondent's efforts to try to bring them off those high doses eventually.

Respondent said that the Tribunal would see, upon review of the records, that the documentation from the Respondent's practice throughout the years with his patients had not followed best documentation practices. As a consequence of this, the Government's witnesses have made assumptions that certain things have occurred that did not, in fact, actually occur. The evidence included examples of inconsistent urine drug screen or blood sample screens where Respondent properly decided to continue to prescribe medications to the patients even though the records do not reflect the Respondent's analysis. Tr. 16–17.

The evidence, Respondent argued, would also show that none of the patients were diverting any medications or abusing them, and that the purposes of the Controlled Substances Act, to guard against diversion or abuse by patients, had not been fulfilled here because there was no diversion and no abuse of the medications. Tr. 17.

In the end, "the documentation fails in instances throughout the patients' care and [the Respondent] has taken steps to improve his documentation." Tr. 17. Evidence will show that the Respondent has taken a medical record-keeping course from the University of San Diego. He has also taken a prescribing course from the University of San Diego to enhance his future practice. In the end, the Respondent asked the Tribunal to allow the Respondent to retain his certificate. If monitoring conditions need to be attached to that, then the Respondent said that he would fully follow those conditions. The Respondent argued that he represents a very significant provider in an under-served, under-privileged community in San Diego that needs doctors like him. Tr. 17–18.

Government's Case-in-Chief

The Government presented its case-in-chief through the testimony of two witnesses. First, the Government presented the testimony of a Diversion Investigator. Secondly, the Government presented the testimony of its expert, Timothy Munzing, M.D.

Diversion Investigator (DI)

DI has been a DI for thirty-two years. Tr. 21, 47. As a DI, her duties include the enforcement of the Controlled Substances Act, specifically the CFR, which is the Code of Federal Regulations as they pertain to DEA registrants and controlled substances. Her duties also include regularly inspecting and investigating DEA registrants and their handling and accountability of controlled substances and detecting any diversion from the licit to illicit market.

She investigates any DEA registrant, including doctors and pharmacists, to ensure they are following the requirements of the Controlled Substances Act and California regulations and that they are prescribing controlled substances in the usual course of professional practice and for legitimate medical purposes. Tr. 22, 57–58. As a DI, she is looking for instances or examples of overprescribing as they tend to suggest that the patient may not be taking prescriptions as he should, and oftentimes is diverting them. Tr. 48. She has found that some physicians are

prescribing a lot of opiates and that there is a severe problem with physicians overprescribing and patients diverting drugs.

In order to conduct her investigations, she uses information technology, the computer, for analyzing records. Tr. 22. She uses Excel spreadsheets, computer technology in the tables that she inserts inside the Excel spreadsheets, and subpoenas to obtain records and conduct auditing. Tr. 21–22.

DI first learned about the Respondent when a pharmacist came to the DEA's office in October of 2018. Tr. 22. The pharmacist wanted to report several physicians that she believed were excessively prescribing controlled substances, which included the Respondent. This is just one way an investigation can begin.

After DI looked up the Respondent in the DEA's system and identified his DEA registration, she then accessed California's Prescription Drug Monitoring Program (PDMP), called CURES, and ran a two-year CURES report on the Respondent's prescribing, which included March 17, 2017, to March 19, 2019. Tr. 23. The CURES report showed that the Respondent had dispensed over 590,000 dosage units of schedule II to V controlled substances to patients, which in DI's experience is an extremely high number and warranted further investigation. Tr. 23–24, 51–52. Through this further investigation, she discovered that the most frequent drug the Respondent was prescribing was oxycodone, of various strengths. Tr. 24, 51.⁵ The next highest drug was hydrocodone. Tr. 25, 51. The DI believed that the high dosages warranted further investigation. Tr. 25.

While looking through the CURES report, she relied on the morphine milligram equivalent (MME) that the CDC recommends for the daily dosage amount. Tr. 48–49. For oxycodone, it is currently ninety milligrams a day. Tr. 49. When she did her review, she could tell without even doing calculations that it was going to be extremely high, especially for one particular patient that was receiving almost 200 MME of four different strengths of immediate relief oxycodone every week. She had never seen anything like that. Tr. 49. There is no standard protocol to investigate at a certain level of total MME, rather, investigations are based on various factors. These factors include the fact that a pharmacist reported the Respondent to the DEA, as the DEA

relies on pharmacists or others that regularly fill prescriptions. Tr. 49–50. Other factors include where a patient lives, the distances a patient travelled, criminal history, whether the patient is going to various physicians, how often the patient is going somewhere, and if the same drugs are consistently being prescribed over and over in high quantities. Tr. 50–51.

After reviewing the CURES data, she reviewed a “pivot table” she had created and identified the patients who were obtaining the most prescriptions for controlled substances. Tr. 25. She identified eight patient records to review, but only selected six of those to submit for medical review, as six was sufficient to obtain a meaningful opinion on the Respondent's prescribing. Tr. 52, 53–54. Next, she obtained the medical records and medical charts of the identified patients to have them reviewed by a government expert to determine if the prescribing was appropriate. Tr. 25.

She also reviewed the Respondent's DEA registration, No. BW7210759, which identified his name and his business address or his registered address and the controlled substances for which he has privileges. Tr. 38. She discovered he became registered in April 2001, with an expiration date of May 31, 2022. She also obtained the history of when he initially got the registration, any changes to his registration as far as address, state license, updates, and renewal fees. Tr. 38–39; GX 1.⁶ She looked the Respondent up on the internet and learned that he specialized in pain management. Tr. 51.

On June 26, 2019, DI issued an administrative subpoena to the Respondent, which requested six patients' medical records. Tr. 26–27; GX 16. The Respondent complied with the subpoena within a few days by providing the patients' records in a paper format. Tr. 27–28.

DI issued subpoenas to pharmacies where the subject patients had filled their prescriptions according to the CURES report. Tr. 28. The pharmacies complied with the subpoenas by

providing copies of prescriptions, which DI saved, and they became part of her investigatory file.

DI asked Dr. Munzing if he had time to assist with the investigation by reviewing patient files. Tr. 37. She chose Dr. Munzing because the DEA had used Dr. Munzing in other investigations, he was therefore already in the system and was available. Tr. 54–56. DI provided to Dr. Munzing all the medical records for the six patients listed in the subpoena on a CD, as well as the CURES report for the Respondent. Within a few weeks, Dr. Munzing provided a report that found four of the six patient files were very problematic and that the controlled substances being prescribed were outside the usual course of legal, professional, and medical practice. Tr. 37–38, 56. Dr. Munzing did not believe these prescriptions were medically legitimate and were an extreme departure from the standard of care, putting the patients at risk for side effects including addiction, overdose, and/or even overdose death. Tr. 38.

Dr. Timothy Munzing, M.D.

Dr. Munzing is a licensed physician in California and received his first medical license in approximately 1983. Tr. 61.⁷ He received a Bachelor of Science in Biochemistry at the California State University at Fullerton and received his MD from UCLA in 1982. Tr. 62. From 1982–1985, he attended Family Medicine Residency through the Kaiser Permanent Foundation Hospital, which is now known as the Los Angeles Medical Center. Tr. 62–63. He became Board Certified in Family Medicine in 1985 and remains board certified. Tr. 63. He has been a family physician for about thirty five years and takes care of patients of all ages, from children to the elderly. He currently primarily takes care of adult patients. For the last thirty-two years he has been the founding residency director of a family medicine residency program, where he oversees twenty-four residents and a fairly sizeable faculty. In family medicine, he works closely with people in every specialty, including Internal Medicine, Pediatrics, OBGYN, anesthesia, and pain medicine. As a family doctor, he sees people for chronic pain as well as for high blood pressure, diabetes, and weight issues; he manages all of their conditions, sometimes seeking a subspecialist, when needed. Tr. 319–20.

Dr. Munzing also sits on the National ACGME Family Medicine Review

⁵ This included 1,700 prescriptions or 190,000 dosage units, which was almost thirty-two percent of all the prescriptions the Respondent issued. Tr. 24, 50.

⁶ On cross-examination, the Respondent's counsel asked if DI was referring to notes during her testimony. Tr. 40. DI responded that she was referring to her notes and Dr. Munzing's report. The Respondent's counsel then requested that DI provide him a copy of her notes as well as Dr. Munzing's report. Tr. 41–42. After hearing from both counsel, the Tribunal ordered that the Government provide DI's notes to the Respondent's counsel via email, but did not order Dr. Munzing's be shared as DI's testimony was very general as to Dr. Munzing's findings and did not include anything outside the Order to Show Cause and Prehearing Statements. Tr. 42–47.

⁷ Dr. Munzing's CV was entered into evidence. Tr. 61–62; GX 2.

Committee, as one of twelve individuals that accredits the 600-plus Family Medicine Residency Programs in America, as well as the fellowships under Family Medicine which includes Geriatrics, Addiction Medicine, and others. Tr. 63–64. He has been a Medical Expert Consultant for the Medical Board of California, also known as the Health Quality Investigation Unit for approximately sixteen-years. Tr. 64. He currently holds a DEA COR and maintains a clinical practice. Tr. 64. He typically spends about twenty-five to thirty percent of his time performing clinical work, including seeing patients in the residency office or at after-hours clinics or urgent care, and working as a preceptor. Tr. 64–65, 75–76; 315. When it is indicated and appropriate, Dr. Munzing prescribes controlled substances, such as opioid medications, benzodiazepines, sleeping medications, medications with codeine, and others. Tr. 65. He has treated and provided ongoing medical treatment to thousands of patients for acute and chronic pain throughout this career. Tr. 65. He treated patients in continuity for approximately thirty-years and only stopped this practice in approximately 2016 because he was asked to help develop the Kaiser Permanente School of Medicine, now called the Bernard J. Tyson School of Medicine. He no longer works at this medical school. Tr. 66; 315–16. He primarily works in the Orange County area at the Anaheim Hospital. Tr. 65–66, 76. There are no pain management specialists on cite at the Santa Ana office. Tr. 317–18.

In the course of his professional career, he has been called upon to provide opinions about the professionalism of physicians and the regulation of the practice of medicine. Tr. 66. In approximately his third year of practice, he was elected President of the medical staff and was responsible for overseeing professionalism. He was also on the Quality Improvement Committee and as a residency director he is essentially the person ultimately responsible for the quality and professionalism of the twenty-four residents and faculty. Tr. 66–67. He also precepts residents in their first, second, or third year of residency; Dr. Munzing is ultimately responsible for those patients and must review and countersign those records. Tr. 76. During his career, he has also sat on some national organizations for Family Medicine and Multi-disciplinary care including other specialties, reviewing professionalism. Tr. 67.

For approximately sixteen years, he has provided opinions in approximately 100 cases regarding professional

physicians and the regulation of the practice of medicine regarding prescribing practices, as an expert for the Medical Board of California. Tr. 68, 342. For approximately the last six and a half years, he has provided opinions for a number of federal agencies including the DEA, Federal Bureau of Investigation (FBI), and the Department of Justice. Tr. 67, 341, 454. All of the cases with the federal agencies involved opiate and other controlled substance prescribing. Tr. 68. For Medical Board cases he charges \$200 an hour and for the DEA, FBI, and DOJ, he charges \$400 an hour for his expert work. Tr. 343–44.

He has been qualified as a medical expert in legal proceedings to opine on the standard of care for the legitimate use of opioids to treat pain approximately thirty-times. He has also been qualified as a medical expert in legal proceedings to opine on whether prescriptions were issued with a legitimate medical purpose in the usual course of professional practice “many times.” Tr. 67–68. [Dr. Munzing was qualified in this matter as “an expert in pain management” and in the “standard of care for prescribing controlled substances in California.” Tr. 77.]

According to Dr. Munzing, the standard of care is what a reasonable, prudent physician would do under the same or similar circumstances. Tr. 328. The standard of care generally allows for alternative means of diagnosis, and of treatment amongst reasonably competent, prudent physicians. Tr. 384. Within the field of pain management, there are accepted alternative judgments about what would be reasonable and prudent, or what would be included in a careful pain management plan. An exercise of judgment within the scope of the standard of care, can vary between reasonably prudent, careful physicians. Tr. 385. In fact, some physicians may have not chosen to even try to treat these four patients in this case.

Dr. Munzing became familiar with the standard of care for prescribing controlled substances in California through practicing in California and prescribing controlled substances and also by being a physician leader in California which required he be responsible for overseeing the quality, and standard, of care. Tr. 68–69. There are guides which inform the standard of care in California, including the Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons, which applies to both primary care and specialty care physicians. Tr. 70; GX 3.

Dr. Munzing has reviewed the Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons many times. Tr. 70–73. He has also

studied the Guidelines for Prescribing Controlled Substances for Pain, as a clinician, physician leader, and a medical expert. Tr. 73. Dr. Munzing noted both documents inform the standard of care in California for prescribing controlled substances for pain. Based on his education and professional experience, he believes he can determine whether controlled substances are issued in the usual course of professional practice in California. Tr. 74.⁸

The Medical Board guidelines and Government Exhibits 3 and 4 lay out many of the guidelines that contribute to the standard of care; the guidelines pertain to both primary care physicians as well as physicians managing pain, regardless of specialty. Tr. 77–78, 82–83, 336; GX 3, 4. The standard of care is what a knowledgeable, reasonable physician would do if given the same set of circumstances. Tr. 82.

For each patient, the first thing a provider should do is take a history and perform an examination. Tr. 79, 83; GX 3, at 59. Depending on the specific complaint, the provider must evaluate the patient to decide if any other information is needed through laboratory tests, imaging studies, or other studies and make either a specific assessment diagnoses or likely diagnoses. The provider then does a risk stratification of the patient and determined what other medication problems he might have and how the provider may manage them. The provider then develops a management plan specific to his evaluation. If the plan includes controlled substances prescribing or other potentially dangerous treatments needing informed consent, the provider tells the patient the benefits and risks. Tr. 79–80. Once a provider starts managing the patient, he monitors them on a periodic, regular basis. Tr. 80. The specifics depend on the patient. The provider decides if he needs additional referrals or consultation in general. The provider should try to minimize the risk and maximize the benefits of treatment. All of these things should be documented in detail so that the provider and any future person managing the patient or reviewing the care can look at the documentation and get a detailed, truthful understanding about how the patient was on a particular date and what the reasoning was behind the management of that patient. Tr. 81.

⁸ Without objection from the Respondent, the Tribunal qualified Dr. Munzing as an expert in pain management and also for presenting an expert opinion related to the standard of care for prescribing controlled substances in California. Tr. 76–77.

In continuing care situations for chronic pain management, a physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exams. Tr. 83, GX 3, at 59. When looking at chronic pain, it is not about someone who just twisted an ankle an hour ago with no other pain history. Tr. 83. Instead, a provider should know more about the patient and the chronicity, *i.e.* how did it start, how long has someone had it, what methods were used before, and what limitations the pain imposes. Tr. 83–84. Therefore, getting a detailed current assessment and history to find out what imaging studies, treatments, or physical therapies were performed and what medications were used is helpful for putting the patient's treatment in context. Tr. 84. There is also a lot of crossover between chronic pain and addictive issues [so a drug and alcohol history is needed]. Also, a mental health history is important to get including anxiety, depression, bipolar disease, ADD, etc. Tr. 85. It is also important to put the pain in context of who the patient is, because the provider's pain management may vary dramatically depending on the health or lack of health of the patient. Tr. 85.

A physician/surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver, or guardian. Tr. 85, 456; GX at 60. Again, the patient needs to understand the potential benefits, and the potential risks, as well as available alternatives. Tr. 85–86, 460. [According to Dr. Munzing, “this all has to be well documented in their records.” Tr. 87.] He further testified that, “MME studies show that at 100, the risk of overdose [for a patient] goes up about 8.9-fold and the risk of overdose death is increased.” Tr. 86. When an individual is on a combination of an opiate and a benzodiazepine, the increased risk of overdose death goes up tenfold. There is also a significant risk for addiction in patients that are on only moderate doses of opiates and benzodiazepines. Tr. 86.

Periodic review means the patient needs to be seen on a periodic basis. Tr. 86–87. The frequency of visits is often driven by the circumstances: The severity of pain, the level of medication, and the potential risk for side effects. So an ongoing monitoring would include getting vital signs, blood pressure, heart rate, respiratory rate, and performing an exam on the pertinent area on a regular basis or at every appointment. Tr. 87. The provider should also check CURES and periodically issue urine drug tests to ensure that the patient is taking what

is being prescribed and not taking what is not being prescribed. [According to Dr. Munzing, periodic review also encompasses “periodically reviewing the patient and constantly trying to assess their risk and whenever possible, try[ing] to . . . mitigate the risk by either bringing the dosage of medications down, using alternative strategies, [so] they can still benefit the patient but try to mitigate the risk.” Tr. 87–88.]

In the event a doctor is unable to mitigate risks, and instead of tapering medications he decides to increase a patient's dosage of controlled substances, the doctor must well-document why the increase is necessary despite the increased risk and also note that the patient has been informed of the higher risk. Tr. 88. It is important to keep accurate and complete records when managing a patient, so a provider can look back and see how the patient was at a particular time. Tr. 88–89; GX 3 at 61. Equally important is, if the patient sees another provider for whatever reason, that other provider sees the justification for the patient's prescription and knows that the patient is aware of the risks and accepts those risks. Tr. 89. [According to Dr. Munzing, documentation, “bottom line[,] is a patient safety issue.” Tr. 88.]

To meet the standard of care in California, a provider must ensure that the medical history, examination, other evaluations, treatment plans, objectives, informed consent, treatments, medications, rationale, and agreement with the patient are well-documented in the medical records. Tr. 89–90.

The Medical Board of California also uses the Guidelines for Prescribing Controlled Substances for Pain in determining the standard of care for prescribing controlled substances in the State of California for physicians and other prescribers. Tr. 70, 73, 90–91; GX 4. These guidelines inform a provider's standard of care by laying out the specifics on what needs to be done. Tr. 91. The standard of care requires checking CURES for managing chronic pain, which the Respondent did with the four patients in this case. Tr. 91, 337, 360. The guidelines also require drug testing. The Respondent did urine drug screens on a frequent basis. Tr. 338. These guidelines are relevant for evaluating the Respondent's treatment of patients within the standard of care in California.

There is an increased risk of overdose death and overdoses when benzodiazepines and opioids are co-prescribed. Tr. 92. In 2016, the Center for Disease Control and Prevention (CDC) highlighted the risk of co-

prescribing these controlled substances and the Food and Drug Administration (FDA) came out with a black box warning highlighting the risk of combining these two medications. Whenever possible, a provider should titrate down the benzodiazepine and if a provider is unable to do that, he should taper the opioid medications; co-prescribing these medications is “significantly increasingly risky.” Tr. 93.

The Patient Evaluation and Risk Stratification requirement addresses: The importance of completing a medical history and physical examination, performing a psychological examination for patients with long-term chronic opioid use for noncancerous pain, and provides examples of screening tools for mental health or potential addiction issues. Tr. 93–94; GX 4 at 12–13. Risk stratification is broken down into two components: (1) The risk of potential addiction or substance use disorder;⁹ and (2) risk stratification as far as the overall health and well-being of the patient. Tr. 94. If a patient has other underlying conditions besides chronic pain that need to be dealt with, those need to be listed in the medical record as a provider is managing a patient as a whole person. Tr. 95. It is also important as it relates to informed consent, because the risk to a patient may be much higher if the patient has other chronic medical problems. Tr. 95–96.

“Ongoing Patient Assessment” or “monitoring” involves following patients whose conditions are dynamic and have varying degrees of pain over time. Tr. 96; GX 4 at 17. A provider should also check CURES, perform point-of-care testing by checking urine screen for consistency, and may perform pill counts or other ways of monitoring. Tr. 97–98. There is also a confirmatory urine test that is much more extensive that looks in much finer detail at medications both prescribed and illegal. However, these tests are not always accurate. Tr. 98. The frequency of these drugs screens based on the standard of care in California is determined on risk stratification. Tr. 99. Different organizations contribute to this opinion, including the American Academy of Pain Medicine and the Agency Medical Directors Group in Washington State. The CDC generally recommends doing urine screens approximately quarterly when the MME is over 90 or 100. Some suggest as often as once a month, while

⁹ According to Dr. Munzing, it has been shown that managing mental health issues appropriately is often a significant tool in decreasing the chronic pain one needs to manage. Tr. 94–95.

others maintain that if there are no inconsistencies or aberrances, quarterly is fine. If there are any aberrances that are unexplained, then the provider needs to strongly document why he is considering continuing prescribing at the same level, and that there was a strong consideration of trying to bring the medication level down. Tr. 99–100. Requiring more urine screens would not exceed the standard of care, but rather just meets the standard of care for that element. Tr. 100.

There are certain things that would drive a provider to taper to a lower, safer dosage, including the level of MMEs. Tr. 102; GX 4 at 20. A provider looks at intolerable side effects, if there is a failure to comply with the pain management agreement, or if there are aberrancies showing up that are not explained. A provider should also look at the overall risk of the treatment. Tr. 102–03. It is necessary to maintain accurate and adequate medical records from both a legal standpoint as well as a patient quality standpoint. Tr. 103; GX 4 at 22.

The CDC issued a fact sheet that gives instructions regarding conversion factors for calculating MMEs, which Dr. Munzing used in informing his opinion on the standard of care and usual course of professional practice in California. Tr. 104–06; GX 5. There is no maximum MME that a provider can prescribe because every patient is different; a provider needs to look at whether an opiate is appropriate and what dosing is appropriate. Tr. 106. However, the CDC and others recommend that providers try not to exceed 90 MME per day. Tr. 107. Although there is no absolute that one can never exceed, the provider should try to reduce the risk; and if a provider is exceeding 90 MME, the provider should provide documented justification for the dosage and document the patient's informed consent of the risk. Tr. 107–08; GX 5.

If a patient presents to a new doctor after having already prescribed at a dosage higher than 90 MME, the new doctor should perform a thorough history, examination evaluation, and whenever possible should get prior medical records to put the prescribing into context and confirm that the patient is really being prescribed that dosage. Tr. 108. The doctor should also look at urine drug tests, CURES, and the PDMP. If the doctor confirms that the patient is indeed taking that high dosage, the doctor should evaluate whether that high dose it is still appropriate at that time and look at the overall risk, including whether alternatives are

available.*^E Tr. 108–09. A doctor should then decide if he is able to reduce the medication of the patient slowly, while also incorporating other pain management strategies that will hopefully decrease the risk to the patient. Simply keeping the patient on the high MME because he was prescribed it before does not meet the standard of care in California.

Continuing high dosages of opioids and controlled substance medications puts a patient at risk; not having side effects in the present does not prevent a patient from having problems with the higher dosage in the future. Tr. 109–10.¹⁰

The FDA document providing the black box warning describing the risks when combining opiate pain medication and benzodiazepines contributed to Dr. Munzing's opinion in the instant case as it relates to the standard of care and usual course of professional practice in California for prescribing controlled substances for the treatment of pain. Tr. 113–14; GX 6. There is a serious increase in risk and potential death when combining opiates and benzodiazepines, and a doctor should try to avoid this combination whenever possible whether he is a primary care physician or a pain specialist. Tr. 114–15; GX 6.

In general, pain patients may not take their pain medications as prescribed, but the pain contract dictates how patients should take their medication. If they are not taking them as prescribed, the provider needs to discuss the resulting risks with them. Tr. 411.

A fast metabolizer is a patient whose body may metabolize a certain medication faster than others so it may potentially not remain in the patient's system as long as it might in someone else's. Tr. 310.¹¹ This would require dosages to be divided more throughout the day, using the same quantity of the drug, but dividing the doses more frequently throughout the day. The standard of care for such patients requires documentation specifically identifying that a fast metabolism is the reason for any aberrant drug screens, because there are many possibilities

why a urine drug screen can be negative. Tr. 310–11. A doctor has several options when resolving aberrant drug screens including actually querying the patient, doing random pill counts, doing more randomized drug screens, and recording the last time a medication was taken. Tr. 312. As to all the patients, there is no evidence in the record that the Respondent took any of these approaches. Tr. 312–13. Although the Respondent may have discussed the risks of combining benzodiazepines and opiates, there was no informed consent in the record. Tr. 415–17.

General Patient Discussion

According to Dr. Munzing, a legacy patient is a patient that comes from another provider or a patient whom a doctor has been following for quite some time who comes in for a certain treatment. Tr. 325–26. It could be within the standard of care to keep a patient on the medications he was prescribed by a previous provider if the current doctor has done an appropriate, independent evaluation and concludes that what was previously prescribed is reasonable, indicated, and medically justified. Tr. 326–28.

Vitals should be taken during each and every visit when patients are on a very high dose of opioids because they are at a greater risk. This is true even if the visits are one day after each other because patients vary day-by-day. Tr. 331–32. Despite the fact that there are no written guidelines that require this, Tr. 338–39, Dr. Munzing based his opinion on discussions with providers who focus on pain management and other specialties, as well as on information obtained at trainings and lectures. There is no maximum MME because a doctor needs to make prescribing decisions within context of each individual patient; prescribing could be a little bit higher than 90 MME depending on the patient. Tr. 332–33.

Dr. Munzing stated that he is “here to help protect patients [by] . . . looking at the standard of care, looking at the dosage of medications, looking at the areas of informed consent, of aberrant urine drug tests, or documentation. . . .” Tr. 341.

According to Dr. Munzing, when a patient reports that his pain is staying at a five on a scale of one-to-ten, that does not necessarily indicate that the treatment plan is working. The provider must look at the complete context of that patient and look at the risk and potential benefits. Tr. 354. However, if the pain number has come down significantly and the patient's function has significantly improved, then a patient may have stabilized at that

*E [Text relocated for clarity.] Dr. Munzing noted there is a condition called Opioid-Induced Hyperalgesia, where higher doses of opioid medications may increase pain rather than decrease pain or may increase a patient's sensitivity to pain. Tr. 109.

¹⁰ Dr. Munzing noted that the CDC guideline was primarily for primary care physicians so his opinion in this proceeding did not completely rely on a strict adherence to the CDC guidelines. Tr. 110–11, 334; GX 5. Furthermore, the CDC guidelines are simply guidelines and not absolute mandates. Tr. 111.

¹¹ Dr. Munzing noted that such patients are relatively rare. Tr. 313–14.

dosage. Tr. 355. One or more of the patients' records infrequently mentioned that their activities of daily living and their ability to function on a daily level was pretty good for them, which could be seen as a potential benefit of the treatment. But this does not necessarily mean that the patient is on the right dosage and the provider still needs to assess the potential risk. Tr. 355–56. A doctor also needs to review where a patient was before prescribing and where he is now, and whether there is potential for continued improvement while simultaneously trying to mitigate the risk. Tr. 356–57.

It is typical for pain to fluctuate in chronic pain patients who have good days and bad days; but patients who are reporting pain at a seven or eight, after having initially reported pain at an eight or a nine, have only minimally changed. This scenario would not be considered a success because this is only a slight improvement at the cost of a significant risk. Tr. 358–59.

If one does not document something and there is no way to verify it, then you cannot infer that it has happened. Tr. 406. Although there may be ways to secondarily find that something was done; [for example, if a physician says they ordered imaging but did not document the imaging, imaging results in the medical record could verify that the imaging was ordered.] *Id.* However, the State of California has stated that a doctor not only needs to prescribe Narcan or Naloxone, but also needs to educate the patient, and both need to be documented. Tr. 407. [Accordingly, Dr. Munzing could not infer that a patient was educated regarding Narcan based solely on the fact that the patient received a Narcan prescription. Tr. 405.]

Dr. Munzing was provided materials to review relating to the Respondent's prescribing of controlled substances including medical records and CURES information for six patients that spanned approximately three-and-half-years. Tr. 116–17, 385–87.¹² He may have spent approximately fifty-to-sixty hours reviewing these records prior to providing his opinion to the DI. Tr. 342. He concluded that the prescribing for two of the patients he was initially presented with was consistent with the standard of care. Tr. 116. He did conclude, however, that the controlled

substances prescribed to J.K., D.P., P.S., and D.L. were not medically justified as prescribed, and were beneath the standard of care in California and outside the usual course of professional medical practice as prescribed. Tr. 117.

Overall, Dr. Munzing generally reached this conclusion based on several factors, including the high morphine milligram equivalent, with one patient's prescriptions being as high as 6,000 MMEs, which is the highest he has ever seen. Tr. 117–18. The patient histories were also limited with little to no mental health history and the use or aberrant use of drugs and alcohol was typically not listed in significant detail. Tr. 118. The examination was absent from the medical records; examinations were sometimes performed fifty-percent of the time and sometimes less. Two or more vital signs were not frequently obtained, oftentimes less than fifty-percent of the time. Tr. 118–19. Urine screens were typically ordered for patients on the first visit and were done as many as two or three times per month, using much more costly confirmatory tests. Tr. 119, 359–60. Furthermore, urine drug tests for three of the four patients had aberrant or even inconsistent values. Resolution of those aberrancies were not typically documented in the medical records, yet the Respondent continued to prescribe the medications. There were a whole host of things that were concerning, including patients continuing on very high dosages of medications and three of the four patients actually had their dosage increased over time. After reviewing the records, Dr. Munzing did believe that all four patients were likely in pain and were not "tricking or faking their pain." Tr. 120, 419.

Dr. Munzing further noted that some of the patients received Narcan or some other form of opioid reversal medication. Dr. Munzing noted that it was possible that the Respondent had a discussion with his patients regarding why the Narcan was being given—that a person could overdose from being prescribed certain medications and this opioid reversal medication could prevent them from dying. Tr. 364–65. However there is no evidence in the records that this was discussed. Tr. 366–67. J.K., D.L., and P.S. had a number of aberrant drug screens. Tr. 309–10. Overall, it was within the standard of care for the Respondent to attempt to pursue a treatment plan with these patients after verifying the pain in some way through studies, etc. Tr. 419–20.

The Respondent reported he tried alternative methods to opioids, including prescribing gabapentin or neuropathic medication, electrical

analgesia, and injections, which Dr. Munzing said were reasonable for the Respondent to pursue at the time. Tr. 351–52. With most, if not all of the four patients, the Respondent either ordered tests or attempted to order tests, and on occasion he made efforts to refer patients to specialists. Tr. 353. Dr. Munzing agreed that this is not a case of a doctor just giving patients pills to control their pain. Tr. 353–54.

Patient D.P.

A Controlled Substance Agreement is separate from an informed consent. An informed consent may be added to a Controlled Substance Agreement. Tr. 120–21; GX 8 at 239. The Controlled Substance Prescription Agreement for Patient D.P., dated April 5, 2017, is adequate as a controlled substances prescription agreement, but is not adequate as an informed consent because it does not lay out for the patient that he/she is at a much higher risk of addiction, overdose, and death. Tr. 121–22, 458. This missing information and lack of informed consent contributed to Dr. Munzing's opinion that the opioid prescriptions were outside the usual course of professional practice. Tr. 122–23.

D.P. was a complex patient. Tr. 321. As to D.P.'s medical record regarding evaluation and monitoring, the medical record shows frequent, expensive urine tests occurring approximately three times a month; this was unnecessary because the patient was fairly consistent in showing that he was taking the prescribed medication. Tr. 123. As discussed previously, doing testing more often than required is not necessarily a good thing and does not mean that a doctor is exceeding the standard of care. Based on CURES, D.P. was receiving an exceedingly high MME dose and high number of pills (approximately 160 tablets per day) over long periods of time that were refilled on a weekly basis. Tr. 123–24. Dr. Munzing has never seen a patient get anywhere near that number of tablets per day. Tr. 123. Over the course of three years, the patient's prescriptions "bounce[d] up and down," between approximately 3,500 to 6,000 MME. Tr. 124, 428. D.P. was receiving somewhere around 1.4 million milligram dosage units per year, sometimes higher than that, which was the highest Dr. Munzing has ever seen. Tr. 119–20.

D.P. then appeared to receive treatment at Pain Management, UC San Diego where the amount dropped to 2,700 MME and the patient was then in and out of the hospital for very serious medical problems unrelated to the pain including a heart attack and kidney

¹² When questioned on cross examination, Dr. Munzing stated that if it appeared that he received insufficient records, he could ask the DEA whether there are additional records available. Tr. 325. He also explained that for the patients not discussed at this hearing, he had done a high level analysis of the CURES report data and did not notify the DEA that he had concerns about patient safety regarding the other patients based on what the DEA had asked him to review. Tr. 388–90.

failure. He began working with other pain management providers and was taken down to 1,000 MME and tapered down. Tr. 124. He was most recently in the 700 range and was continuing to taper down.* F

Overall, the Respondent's documentation for D.P. was "pretty poor" without additional information, it did not reflect adequate attempts to mitigate symptoms or risk over time and did not meet the standard of care. Tr. 125. Furthermore, the medical records show that vital signs were taken at fewer than fifteen-to-twenty percent of the total visits. Tr. 125, 137. Many of the visits lack documented vital signs and a musculoskeletal exam, which is outside the standard of care in California for a doctor who is managing patients at incredibly high dosages. Furthermore, Dr. Munzing opined, the documentation was far below what was necessary and did not justify the incredibly high dosing. Tr. 126.

Comparing the documentation from the Respondent to UC San Diego, it was like "night and day" and D.P.'s pain score was not "all that different" despite the fact that D.P. went down from 6,000 to 1,000 MME. Tr. 126–27. The Respondent's records do not reflect that D.P.'s pain scores and functional level improved when he was on the highest dosages of opiates, which Dr. Munzing would expect to see. Tr. 127. There is a "great difference" between the Respondent's records and those provided by UC San Diego and the other pain management group. The Respondent did not provide records of treatment prior to him establishing care with D.P., which is "vitally important" as it relates to the standard of care. Tr. 127–28.

There were four prescriptions written by Respondent for D.P. on April 18, 2017, to be filled on April 26, 2017; all were for Oxycodone but in four different strengths. Tr. 129; GX 9 at 2. Between the four prescriptions D.P. was prescribed 160 tablets of Oxycodone per day. Tr. 130. Dr. Munzing calculated that the MME for one of the prescriptions alone was 1,200 MME. For all four Oxycodone prescriptions, the total MME was 4,500, which is astronomical and the highest dosage Dr. Munzing has reviewed, including his review of approximately 150 overdose deaths. Tr. 132, 135. There are also medical records dated April 12, 2017,

that provide only a minimal level of investigation, with no vital signs or examination listed; therein Respondent prescribed additional medication, despite there being no justification to do so. Tr. 132–34; GX 8; 246–253. On April 19, 2017, Respondent wrote four prescriptions identical to the four written on April 18, 2017, to be filled on April 19, 2017. GX 9, at 3. It is highly unusual that these two prescriptions were issued to be filled only one week apart, but the Respondent repeatedly prescribes medications over long periods of time on a weekly basis. Tr. 134–35. Dr. Munzing had the same issues with the prescriptions issued on April 19, 2017, and found that they were not issued in the usual course of professional practice or for a legitimate medical purpose. Tr. 135. The Respondent continuously prescribed a combination of 280 tablets of oxycodone 10 milligram, 180 tablets of oxycodone 15 milligram, 280 tablets of oxycodone 20 milligram, and 280 tablets of oxycodone 30 milligram between March 17, 2017, and January 3, 2018. Tr. 136. Rather than tapering, as required by the standard of care, D.P.'s records shows that Respondent periodically added a prescription for oxymorphone, so episodically the MMEs went from 4,500 to 5,100 as the Respondent increased D.P.'s dosage. Tr. 136–37. [Dr. Munzing said that there was no justification in the record for the oxymorphone prescriptions and they were also outside the standard of care. Tr. 137.]

Furthermore, vital signs were taken infrequently, which puts a patient at a high risk; checking blood pressure is important to ensure the blood pressure is not too low or too high, and checking the respiratory rate is important because the medications are respiratory depressants. Tr. 137–38. Furthermore, on July 3, 2017, the Respondent added Opana as an additional opioid prescription that is long-acting, which increases the MME and therefore the risk to the patient. Tr. 139; GX 8 at 372. Any added benefit of this prescription would be minimal as D.P. was already on an astronomically high dose and there was no documented reason why this was added as a prescription. Tr. 140–41. Furthermore, D.P.'s pain level was listed as a "5," which would have made this a great opportunity to start reducing the pain medication. Tr. 141–42. Overall, the Respondent failed to provide adequate justification for why D.P. was prescribed such a high level of MME.¹³ Tr. 142

Dr. Munzing continued to review the Government's exhibits and explained how each prescription did not meet the standard of care for patient D.P. Tr. 142–177. [Dr. Munzing opined that each of the relevant prescriptions to D.P. were issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 146–47, 149, 151–52, 154, 157, 159, 161, 177. He testified in support of that opinion that: Vital signs were not taken and physical examinations were not performed, Tr. 145, 148, 150, 153; the MME bounced up and down but was always "in the [high] stratosphere" without obtaining informed consent or informing the patient of the risks, Tr. 145, 158–59, 163, 171; and there was no plan for tapering medications or assessing withdrawal when the dosages decreased, and there was insufficient justification in the record when the dosages increased. Tr. 146, 148, 150, 152, 156, 172. Dr. Munzing also noted that there is a gap in the medical records between June 25, 2019, and September 30, 2019, but that prescribing continued during that time. He testified, "these are astronomically high levels [of controlled substances] and it's certainly not based on sufficient justification, not usual professional practice, and now there's a big gap, but the prescribing continued. So I have very significant concerns about that . . . [and the patient] ended up being admitted to the hospital on multiple occasions and multiple ER visits, starting in late 2019 and going through the early parts of 2020." Tr. 162–63.]

It appears that D.P. went to a detox facility in September 2019, and his MME was decreased to 60 or 65; there was some discussion in a note from the Respondent that he would not prescribe above 90 MME per day going forward. Tr. 164, 433–34. Dr. Munzing clarified that the detox process (which was not performed by Respondent) was not particularly relevant to his case or his opinions regarding Respondent. Tr. 164.

[Summarizing his opinion of Respondent's prescribing to D.P., Dr. Munzing testified that each of the prescriptions captured in the stipulations were issued without a legitimate medical purpose and were outside the usual course of professional practice. Tr. 177. Dr. Munzing further testified that the prescribing "was incredibly dangerous. The patient is lucky to be alive. It certainly was not [within the] standard of care. The way he prescribed the dosages, the MMEs, were certainly not medically justified and not usual professional practice." Tr. 176.]

*F The Government seems to have offered this evidence as an example of what prescribing and documenting within the standard of care for D.P. could have looked like. However, this information is not material to my decision. I also note that I am not holding Respondent accountable for any actions other than his own.

¹³ [Footnote text moved to the body of the decision.]

Patient P.S.

In reviewing P.S.'s file, Dr. Munzing did not find any documented discussion regarding the specific risks of opioids, including addiction, overdose, or death, and opined that the lack of documentation violated the standard of care. Tr. 178; *but see*, Tr. 390–91 (a note relating to a visit from January 25, 2018, stating generally that the Respondent discussed the risks with P.S. regarding the use of opiates and benzodiazepines and mentions respiratory distress).

On almost every occasion during the relevant period, P.S. was prescribed an opioid and a benzodiazepine, a combination that falls under the FDA warning. Tr. 177–78. Dr. Munzing explained that, curiously, a progress note dated January 9, 2017, mentions that on May 31, 2019, R.R.–G. “discussed that benzodiazepines should not be taken concomitantly with pain medications due to an increased risk of respiratory depression.” Tr. 179. The patient was reportedly advised “not to take both prescriptions at the same time,” and there was a plan to taper down alprazolam or Xanax.” *Id.* Tr. 179; GX 10 at 4. This warning was repeated word for word on several occasions going into the future, but the patient was not really tapered down. Tr. 181. Patient P.S. was switched from 1 milligram of lorazepam to half a milligram of alprazolam; this is not considered a dramatic tapering, and there is no documentation stating why this medication change was made. Tr. 179–81, 193. Furthermore, comparing the two prescriptions is like comparing apples and oranges as there is no definitive data that supports or refutes whether one is more or less risky than the other. Tr. 371–72. Although the patient notes demonstrate that “R.R.–G.”¹⁴ had a discussion with the patient regarding respiratory depression, Dr. Munzing opined that the records did not adequately document informed consent because there is no indication that anyone discussed the specific risks of addiction, overdose, and death. Tr. 182; GX 10. The questionable date of the entry, and the lack of documentation regarding informed consent contributes to Dr. Munzing's opinion that those prescriptions to P.S. were issued outside

the usual course of professional practice.*^G Tr. 183, 374.

According to Dr. Munzing, the Respondent only took vital signs approximately fifty-percent of the time and failed to perform proper musculoskeletal exams. Tr. 183. The records also fail to provide an adequate history of the patient's anxiety or evidence that alternative methods of treatment such as non-controlled substances were considered. Tr. 183–84. There were also no prior medical records in the file and no documented attempt to get them. These failures contribute to Dr. Munzing's opinion that the prescriptions to P.S. at issue did not meet the standard of care. Tr. 184. [Dr. Munzing testified that the “MMEs are fairly consistent [throughout,] in the mid-300 range,” but the patient did not seem to be getting sufficient pain relief to justify the risk of “the high MME and the combination with benzodiazepines.” Tr. 185.]

Dr. Munzing testified that Respondent attempted alternative treatments for P.S. At one point, the Respondent prescribed testosterone to P.S. to help treat the side-effects of opioids, and the patient reported feeling better after receiving the testosterone. Tr. 360–61. Dr. Munzing recalled one of the patients was prescribed a Medrol dose pack, but could not recall if this was for Patient P.S. Tr. 361. At some point in time, Patient P.S. was given injections in the facet joint to help control the pain. Tr. 362–63. The Respondent also attempted to have P.S. see a psychiatrist or psychologist¹⁵ to help with his chronic anxiety problem, which is a reasonable thing for a doctor to do if he is not qualified or competent to deal with that. Tr. 396.

Patient P.S. was prescribed five medications, four of which were controlled substances: Morphine sulfate extended release 30 milligrams three pills a day, morphine sulfate extended release 60 milligrams three pills per day, Dilaudid (hydromorphone), and lorazepam (a benzodiazepine) which is a total MME of 366 (not including the benzodiazepine). Tr. 185–187; GX 11. Dr. Munzing testified that the MME was very high. Tr. 187. Furthermore, Dr. Munzing testified, [“we also have the opioid and the benzodiazepine that both the CDC and the FDA warn against” prescribing together. Tr. 187.] Dr. Munzing testified that these prescriptions were not issued in the

usual course of professional practice or for a legitimate medical purpose. Tr. 189. Dr. Munzing opined that the note for February 17, 2017, was deficient because there is a pop-up warning “from the future, from May 31, 2019,”¹⁶ it did not note alcohol use, and it did not provide a record of an exam being performed despite the patient being prescribed a high dosage of medication and receiving a benzodiazepine, without a diagnosis to justify it. Tr. 187–88. This patient also has significant medical problems, including history of an acute embolism and thrombosis or deep vein thrombosis (DVT), which puts him at an increased risk. Tr. 188–89. Dr. Munzing opined that the opioid prescriptions were not written in the usual course of professional practice or for a legitimate medical purpose because the dosages are high, there are dangerous combinations, there is no informed consent, the exam was deficient, and the documentation had “a whole multitude of parts that were necessary that were missing.” Tr. 189.

Overall, Dr. Munzing's review of all of P.S.'s medical records indicated there was no proper justification documented for the “very high” and “dangerous” dosage of opioids nor the benzodiazepines that were prescribed to P.S., and they therefore were not issued in the usual course of professional practice or for a legitimate medical purpose. Tr. 190–97. [Dr. Munzing testified that the prescribing was “not appropriate, this is very high, this is dangerous.” Tr. 191. Specifically, he testified “[t]here's no informed consent. The exam is missing on the area [Respondent was] treating. And we don't know really anything about the anxiety that reportedly the Xanax is coming from. . . . [This] patient still is put at significant risk and still the documentation is poor.” *Id.* Dr. Munzing also testified that there was never justification in the medical record for the benzodiazepine prescriptions. Tr. 193.]

Patient P.S. had urine drug screens dated March 17, 2017,¹⁷ April 14, 2017, June 19, 2017, August 7, 2017, September 12, 2017, October 10, 2017, November 3, 2017, September 11, 2018, October 3, 2018, December 21, 2018, and March 26, 2019. Tr. 195–225; GX 10. All of these drug screens showed

¹⁴ The Tribunal later learned that this is the Respondent's nurse practitioner. The Respondent is responsible for his mid-level and lower-level employees. Tr. 220–21, 272. On cross examination, Dr. Munzing elaborated that in California, nurse practitioners are able to see patients, but the Respondent would still be responsible for the overall management of the patient as he continued with the patient's care. Tr. 350–51.

*^G Text omitted for clarity.

¹⁵ Dr. Munzing acknowledged that the Respondent had some challenges getting a psychiatrist or psychology to actually see the patient. Tr. 366–97; GX 10 at 1238–44.

¹⁶ On cross examination Dr. Munzing said it could be possible that this print out may include errors. Tr. 346, 347. However, Dr. Munzing also stated that in his work as an expert, he does not recall ever seeing an issue with an EMR that resulted in a case printing things from the future. Tr. 348–49.

¹⁷ The Respondent documented that there was no aberrant drug screen on this day. Tr. 198.

that Patient P.S. was negative for either lorazepam or alprazolam,¹⁸ an aberrancy, and the later drug screens showed that P.S. was negative for morphine, another aberrancy. Tr. 195–97; GX 10 at 76. Some of the drugs screens also showed alcohol use, [which Dr. Munzing testified “increases the risk to the patient of certainly overdose and overdose death.” Tr. 217.] According to the standard of care, the Respondent should have contacted the patient within a couple of days of receiving these aberrant drug screens to have the patient explain why he was not taking his prescribed medication or why he consumed alcohol. Tr. 198–99. There is no indication that the Respondent documented that he questioned the patient nor that the Respondent resolved these aberrant drug screens. Tr. 199–202.*^H

Despite all of these aberrant results (including P.S.’s evident alcohol use), there were no attempts for the Respondent to either address or resolve these issues with documentation in the medical record, which contributed to Dr. Munzing’s opinion that the prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. [According to Dr. Munzing, following the aberrant drug screens, Respondent needed to explore the reason for the inconsistent result and resolve that reason “before continu[ing] to prescribe.” Tr. 213.] There are several potential dangers posed by these aberrant drug screens, including that the patient is not taking medication some days and taking extra other days, is hoarding the medication, or is illegally diverting the medication. Tr. 199, 211. [Dr. Munzing testified that the inconsistent drug screens and failure to document a resolution contributed to his opinion that the prescriptions issued to P.S. were outside the usual course of professional practice and not for a legitimate medical purpose. Tr. 201–04, 211.]

Ultimately, Dr. Munzing found that the prescriptions prescribed to P.S., which were stipulated to by the parties and listed in the Government’s Prehearing Statement, were far outside the standard of care, were not medically justified, and were outside the usual course of professional medical practice. Tr. 225; GX 4.¹⁹*^I

Patient J.K.

Dr. Munzing testified that the standard of care for patients with chronic migraine headaches, or chronic headaches in general, [such as those for which Respondent was treating J.K.], requires that a provider take an appropriate history and examination, including a neurological examination, in order to narrow down what type of a headache the patient has and rule out certain causes such as a tumor or infection. Tr. 229. If the headaches become more severe, the provider typically does an imaging scan such as a CT scan or an MRI to ensure there is no tumor. Tr. 229–30. The medical records for J.K. do not meet the standard of care because there is no detailed history, no detailed exam, and no evidence of imaging studies, yet the Respondent prescribed opioids, which is not generally a successful treatment for chronic headaches, especially migraine headaches. Tr. 230–31; GX 12.

[Dr. Munzing opined that Respondent did not meet the standard of care for evaluating and monitoring J.K. Tr. 232.] The Respondent’s documentation of J.K.’s medical records did not establish that Respondent met the standard of care because there was no comprehensive history regarding mental health issues or prior alcohol or drug use: there were no prior medical records; there were multiple unresolved aberrant drugs screens; and vital signs were not taken at every visit. Tr. 232–33. There was also limited, vague documentation regarding the patient’s cancer diagnosis with no information regarding oncology doctors, chemotherapy, or treatment for cancer pain. Tr. 233–34. Overall, the medical history done for J.K. did not justify the high dosage of medications that the Respondent prescribed to her. Tr. 234. The standard of care would require a detailed medical history and past medication history, specifically discussing the patient’s breast cancer, and a history regarding the patient’s headaches in general, including any treatments that had been attempted as well as consultations with other doctors. Tr. 234–35. [According to Dr. Munzing, each of these elements was missing. *Id.*] The Respondent also failed to adequately document the risks and attempts to moderate the risks, and

that he was “doing something to explore” the claim. Tr. 391–95.

¹⁸Dr. Munzing testified that “all four of the patients certainly have the likelihood of known pain generators.” Tr. 226. But he made clear in his testimony that having a source of pain alone, without complying with the steps required by the standard of care, was insufficient to justify prescribing controlled substances. Tr. 226–27.

there is no evidence of informed consent in the file. Tr. 235, 446, 448, 458.

The Respondent issued controlled substance prescriptions to J.K. on November 28, 2016, which included: (1) Fentanyl patch,²⁰ 75 micrograms every hour to change every four hours; (2) Percocet 10 milligrams, 180 for 30 days, 6 per day; (3) Soma, a muscle relaxant; and (4) Nuvigil, which is a stimulant. Tr. 235–236; GX 13. The combination of the Percocet and fentanyl patch equals 360 MME. Tr. 237. [Dr. Munzing testified that Soma “is a respiratory depressant . . . [and it is] fairly habit forming or addicting. . . . [I]t is part of a dangerous triad; an opioid, Soma and a benzodiazepine is referred to . . . as the trinity or the holy trinity.”] Tr. 238. In fact, many organizations stopped prescribing Soma ten years ago. Tr. 238–39. The patient’s pain level of four out of ten would not justify a higher level of opioids and in fact, the standard of care would dictate trying other modalities prior to prescribing opioids. Tr. 239–40; GX 13.

[The combination of fentanyl and Percocet was prescribed a number of occasions, but] there was no justification as to why J.K. was prescribed this combination or the very high doses, and therefore these prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose. Tr. 240–41. [Dr. Munzing opined that every time Respondent prescribed a combination of fentanyl and Percocet to J.K., it was outside the usual course of professional practice. Tr. 241.] On January 29, 2017, the Respondent prescribed medications to J.K. that equaled 405 MME, without justification provided in the medical records, and outside the usual course of medical practice and without a legitimate medical purpose. Tr. 242–44; GX 13. On August 18, 2017, the Respondent changed J.K.’s prescription by switching the fentanyl patch and added OxyContin and oxymorphone ER, which would be 450 MME. Tr. 244. J.K.’s opioid prescriptions were therefore being increased without any justification for doing so documented in the medical records [and without trying

²⁰ A fentanyl patch is like a large band aid that works by absorbing through the skin over a period of time, and is really meant to be prescribed on a 3-day basis because when it is used every two days, the MME calculation is higher, but it is a long-acting opioid. Tr. 236–37. Sometimes a patient can have difficulty using the fentanyl patch and in this instance there are several ways to help keep it stuck in the skin, and if they are not successful, the doctor should stop prescribing the patch and instead prescribe oral medication. Tr. 237–38, 452–53.

¹⁸ [Omitted for clarity.]

^H [Omitted repetitive text for brevity.]

¹⁹ On cross examination, the Respondent’s counsel referred Dr. Munzing to a note regarding P.S. seeking an early refill due to leaving his paper prescription in a Lyft and Dr. Munzing confirmed that the Respondent’s note on this date indicated

other treatment options,] which violates the standard of care. Tr. 245. The prescriptions were therefore not issued in the usual course of professional practice or for a legitimate medical purpose. Tr. 244–47.

On November 10, 2017, J.K. had an office visit; the record stated that her pain level was 4 and that the Respondent would continue prescribing her current medications, making these prescriptions outside the usual course of professional practice and not for a legitimate medical purpose. Tr. 247–48. Patient J.K. had another visit on January 8, 2018, but there were no documented vital signs and there was nothing written under the objective assessment plan, which violates the standard of care; therefore, the prescriptions issued at this time were not issued in the usual course of professional practice or for legitimate medical purpose. Tr. 248–49. On February 9, 2018, the Respondent replaced OxyContin with oxycodone without any justification for doing so documented in the patient record,²¹ which does not meet the standard of care. The prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose. Tr. 249–55. GX 13. On October 16, 2018, the prescriptions totaled 330 MME and there was no justification for providing these prescriptions documented in the record. Tr. 255–56; GX 13. Furthermore, there was a note in the record that J.K. was taking leftover pain medication, which means that she was not following the directions of the Respondent and may be receiving a higher dosage than she needed. Such prescribing is contrary to the standard of care. Tr. 256–57.

There is also a note in the file from an incident that occurred on October 12, 2018, when J.K. called the office and stated that she was unsure if she would be alive tomorrow and “she [is] going to drive off the road due to not getting [her] prescription.” Tr. 258. Dr. Munzing noted that this was a very alarming note and that to a reasonable person, this would indicate that J.K. was suicidal. Tr. 258. The standard of care for a doctor with a patient who is on high opioids and has suicidal ideations is to get that patient immediate care, look into the patient’s mental health history, work with other providers such as a psychiatrist, and come up with a

plan. Tr. 259. Typically, a doctor would not continue the medications being prescribed and would work to develop a possible management plan for the patient. The standard of care would also require that the doctor have a discussion with the patient on a subsequent visit, [but Respondent did not.] Tr. 259–60. The October 16, 2018, prescription was therefore written outside the usual course of professional practice and was not for a legitimate medical purpose. [Dr. Munzing explained that it was “dangerous” to continue to prescribe opioids in this manner for a patient with suicidal ideation. Tr. 260. “You may give a three-day dosage or something, recognizing that if this person is suicidal you may be providing them the wherewithal and the means to do it.” *Id.*]

J.K. also had inconsistent urine drug screens on April 27, 2017, February 9, 2018, March 19, 2018, June 4, 2018, and July 31, 2018, which showed the presence of THC, or marijuana, and amphetamine. Tr. 261, 263, 270. This is problematic because it was not a prescribed medication, and taking marijuana, even if it were legally prescribed, while on a high dosage of opioids adds a risk to the patient. Tr. 262–63. J.K. also tested positive for amphetamine, which is a stimulant and can be addictive and dangerous. Tr. 263–64. There is no indication that this was part of J.K.’s management plan with the Respondent, and even if the amphetamine was prescribed by another doctor, it should be very clearly documented in the medical records along with informed consent. Neither controlled substance was in J.K.’s medical records. Tr. 264–66.²² J.K. tested positive for amphetamines again on May 12, 2017, and September 15, 2017. Tr. 267; 269; 270; GX 13. There is no indication in the record that the Respondent discussed any of these aberrant drug screens with J.K. at subsequent office visits. [Dr. Munzing opined that there was no evidence that Respondent addressed J.K.’s inconsistent drug screen results at all. Tr. 267.] There was some indication that Respondent’s nurse practitioner had discussions with J.K. regarding risks on

March 7, 2018,²³ and March 21, 2018,²⁴ [but Dr. Munzing testified that those discussions, as documented, were insufficient to satisfy the requirement for obtaining informed consent.] Tr. 266–67; 268–69; 270; 279. This contributes to Dr. Munzing’s opinion that the prescriptions written for J.K. were outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 266–67; 268–69; 270; 279.²⁵

Dr. Munzing reviewed the medical records that pertained to the treatment of J.K.’s breast cancer, including records from her oncologist. Tr. 279. Reviewing these records informed Dr. Munzing’s opinion that J.K. had been cancer-free for at least four years, so the Respondent was not prescribing opioids to J.K. for end stage cancer.* Tr. 279–81. Overall, Dr. Munzing opined that each of the relevant prescriptions to J.K. were issued outside the standard of care in a “multitude of standard of care elements that should have been done and weren’t done,” were not medically justified as prescribed, and were not within the usual course of professional practice, and they put the patient at a higher risk. Tr. 281.

Patient D.L.

D.L. is a patient who is in her late 60’s/early 70’s. Tr. 287. Overall, Dr.

²³ On cross examination, the Respondent questioned Dr. Munzing about a note from the March 7, 2018 visit with Nurse Practitioner Pasco that mentioned a “discussion” and later stated “patient understandable” and Dr. Munzing stated that it could have referred to describing the risks of combining benzodiazepine and opioid together and in fact was more likely there was a discussion that there is a risk of those medication categories. Tr. 362–64, 67–68.

²⁴ On cross examination, the Respondent questioned Dr. Munzing about a note from the nurse practitioner from March 21, 2018, stating “discussed risk of respiratory depression with concurrent opioid and benzodiazepine use . . . patient verbalized understanding”, which Dr. Munzing stated appears to seem that the nurse practitioner talked about the risk of respiratory depression from P.S.’s combined medications. Tr. 372–73. [But, Dr. Munzing made clear that there were other risks that did not have a documented discussion and that, overall, the discussion of risks was insufficient to meet the standard of care for informed consent. Tr. 374–75.]

²⁵ On cross examination, the Respondent questioned Dr. Munzing about a visit with the Respondent and the note mentioned “discussed to patient current CDC guideline and the need to decrease his opiate dose, his current morphine equivalent is 366 milligrams per day,” which likely means there was a general discussion that the Respondent mentioned the CDC guidelines say 90 MME, and the patient is currently at 366 MME. Tr. 375–76; GX 10 at 544, 550. Dr. Munzing had no objection to the statement in the note itself, [text omitted for clarity] but noted that whether it meets the requirement for informed consent is a different question. Tr. 377.

* Dr. Munzing testified that the standard of care when prescribing for end stage cancer is different. Tr. 281.

²¹ The Respondent’s counsel objected to this questioning and noted that it was a nurse practitioner who met with J.K. regarding the prescriptions for February 9, 2018, and not the Respondent. Tr. 252. The Government clarified with Dr. Munzing that the Respondent should have been aware of these prescriptions that went out under Respondent’s name. Tr. 252–53.

²² On cross examination, Dr. Munzing stated that although he believed that J.K. was seeing a psychiatrist, who was prescribing Adderall and a benzodiazepine, these medications were not listed on the medication list and therefore the medications showing up in the urine screen were not consistent with what the medical records were documenting. Tr. 440–41. However, upon further pressing from counsel he agreed that the test would not be inconsistent if the patient was taking everything in its entirety, but that it would need to be documented. Tr. 442.

Munzing's review of D.L.'s medical records indicated that the evaluation and monitoring the Respondent did for D.L. did not meet the standard of care, and the opioid prescriptions issued to D.L. were not medically justified nor issued in the usual customary medical practice in the State of California. Tr. 282–83. [The medical history was “cursory . . . and lack[ed] detail.” Tr. 282.] Furthermore, the Respondent did not [attempt to obtain] prior medical records, which was mandated by the standard of care. Tr. 283.

The Respondent prescribed D.L. lorazepam, Percocet, morphine sulfate, and oxymorphone, with an initial MME of 455.²⁶ Tr. 283–86; 288; GX 14; 15. D.L. was also prescribed Lunesta, a sleeping agent and respiratory depressant that has the potential risk of habit-forming addiction as well as the increase the risk of overdose when prescribed in combination with opioids. Tr. 286. Furthermore, adding a sleeping medication increases the risk, especially when taking into account D.L.'s age. Tr. 286–87. [Dr. Munzing testified that over the three-year period of treatment, the “extremely high dose medications” did not “show that there was significant improvement” in the pain level. Tr. 289.] There was no justification for prescribing a benzodiazepine (lorazepam) and a sleeping agent, and there was no informed consent. Furthermore, at a visit on May 31, 2018, the Respondent wrote a note indicating that Percocet would be decreased; but in reality, the Respondent increased the Percocet prescription. 295–96; GX 15 at 445. The record also indicated that D.L. had been consulted regarding her MME of 410, which was above the recommended 90 MME dosage by the CDC guidelines, and that the patient would be seen once a week until decreased. Tr. 297. Although the MME was mildly decreased over time, there was no evidence that the MME was significantly decreased and it remained at a dosage well above 90 MME. This note/discussion does not meet the standard of care in California and does not serve as an informed consent [because there was no documentation showing that the “exceedingly high risk of the opioids,” including “addiction, overdoses, [and] death,” were discussed with the patient whose age “adds to the patient's risk.”] Tr. 297–98. Furthermore, the Respondent did not start tapering the patient down slowly and carefully in order to mitigate the

risk, nor did he look at alternative strategies to manage the patient's pain. Tr. 300.

Dr. Munzing found that the relevant prescriptions violated the standard of care and were not issued in the usual course of medical practice or for a legitimate medical purpose. Tr. 287, 290, 292, 294, 299, 301, 308, 309.

D.L. had drug screens on March 23, 2018, (which was negative for oxycodone and lorazepam), April 20, 2018,²⁷ (which was negative for oxycodone and lorazepam), and January 31, 2019, (which was negative for Percocet and Lunesta). Tr. 302–05. Nothing in the record showed that there was any discussion regarding the aberrant drug screens. Tr. 308. [And as Dr. Munzing opined, a physician “needs to address [the reason for the inconsistency] and document the resolution if one is going to continue prescribing.” Tr. 307.]

As to the documented discussion the Respondent had with D.L. regarding using a pain pump, Dr. Munzing testified there was insufficient information to determine whether that was a reasonable alternative because there was not even two full lines of information in the medical record. Specifically, Dr. Munzing testified he could not “even come close to making that determination.” Tr. 407–08. On June 2, 2017, it appeared that the Respondent reviewed an X-ray of the hip and left knee and had a discussion regarding hip injections, but there is nothing documenting what the Respondent discovered from the X-rays. Tr. 408–09.

Respondent's Case-in-Chief

The Respondent presented his case-in-chief through the testimony of five witnesses: (1) The Respondent, (2) D.P., (3) Dr. Wiederhold, (4) Dr. Joseph Shurman, and (5) D.L.

Patient D.P.²⁸

Patient D.P. met the Respondent after a fall that resulted in five compression fractures and five fractured vertebrae in his back. Tr. 507. He was in extreme pain and had several procedures that did not help him. At one point, he was

bedbound and had some pretty dark times lying in bed, sweating through the pain. He saw lots of different doctors, but nothing really happened. At one point his mother recommended her doctor, [not Respondent,] who did not have a “normal medical office;” that physician told D.P. that there was no upper limit on pain medicine, and that as long as D.P. was “breathing [he would] just increase it until [he is] comfortable.” Tr. 507–08. At every visit he would pay that doctor in cash and that doctor would just “kind of double the dosage. . . [of] OxyContin.” Tr. 508. After months of this prescribing, the other doctor “closed up shop” and “went back to Russia.” *Id.* D.P. was then referred to the Respondent from the ER at Paradise Valley Hospital. In the meantime, D.P.'s primary care physician continued to prescribe the same level of opioids for many months until “we kind of got things squared away” and D.P. was able to see the Respondent. Tr. 508–09.

According to D.P., Respondent seemed surprised to learn that D.P. was on such a high dosage and explained to D.P. that opioids can depress breathing, other sensory functions, digestion, libido, and affect pain reception. Tr. 511–13. The Respondent explained that D.P. needed to be brought down [from his high doses] and to be aware of symptoms, such as being tired, indicative of not breathing. Respondent told D.P. that even though D.P. was taking these prescriptions regularly, he could still potentially overdose. Tr. 513, 517. The Respondent gave D.P. a Narcan pack that could be used to reverse the effects of opioids on the body. Tr. 513–15.²⁹ The Respondent also suggested that D.P. try some other treatments including injections and physical therapy, and said that they would “work through this.” Tr. 517–18. Being on the opioids allowed D.P. to work and even volunteer and “function[] like a normal person would.” Tr. 519. D.P. was reluctant to lower his dosage because he was functioning pretty well and his pain range was between 2 and 4. Tr. 520.

The Respondent had D.P. try injections and SANEXAS therapy,³⁰ and physical therapy with his home health. Tr. 521, 522. The SANEXAS therapy, which is a unit that sends electrical stimulation to the body through a computer, helped his back relax a little, but did not help with his bone pain. Tr. 521–22.

²⁹ The Tribunal gave the Government a running objection on leading questions. Tr. 516.

³⁰ The SANEXAS therapy and injections were done in the Respondent's office. Tr. 526.

²⁶ The Respondent also increased D.L.'s dosage of morphine sulfate on February 23, 2018. Tr. 288–89. There was no justification in the records for this increase to a higher MME.

²⁷ The visit subsequent to this drug screen, on May 4, 2018, is silent as it pertains to resolving the aberrant drug screen and instead mentions that the patient had no aberrant behavior and none was reported. Tr. 304–05.

²⁸ The Tribunal ruled that this patient witness could only testify relating to his discussions with the Respondent, his discussions with medical staff at the Respondent's office, treatment received, the regularity of treatment, but nothing relating to the patient's own evaluation of treatment, or efficacy of treatment because such discussion would require medical expertise. Tr. 504.

D.P. was going to the Respondent's office once every week and usually saw the Respondent, but for some visits he saw a nurse practitioner who would always check to make sure he was breathing well. Tr. 522–24. Usually before seeing the Respondent, a nurse would take his blood pressure and weight, and he would usually do a drug screen. Tr. 525. The Respondent would listen to his heart, listen to him breathe, and feel for where the pain was by “like push[ing] on [his] back.” Tr. 525–26. At some point the Respondent explained to D.P. that he would not be able to prescribe to him at the level he was taking, so D.P. tried to go to a detox facility; he was ultimately admitted into Sharp Memorial Hospital and went through detox there. Tr. 528–29. The doctor at that hospital prescribed opioids upon his release. Tr. 529–30. D.P. is currently being treated for pain. Tr. 531.

Patient D.L.

D.L. has been the Respondent's patient for four or five years, maybe longer. Tr. 794. Her primary care physician referred her to the Respondent for her uncontrolled pain. Tr. 795. At that time, she was prescribed Narco or Percocet and lorazepam. The Respondent went into detail with her about the safety of those medications and how the combination could cause respiratory depression, and that she could die or they could lead to addiction. Tr. 797–99, 805. The Respondent also gave her Narcan spray at some point, with prescription refills. Tr. 799–800. The Respondent discussed the importance of taking her medications as prescribed and her son dispenses her prescriptions to her. Tr. 801. She and the Respondent are working to bring her pain medications down and are looking into having an experimental implant in her back to help with the pain. Tr. 802, 806. The Respondent currently prescribes her Percocet, oxycodone, gabapentin, and another medication she could not recall. Tr. 803–04. The nurse practitioners in the office have also discussed the risks and safety issues with her. Tr. 804–05.

Mark Wiederhold, M.D.³¹

Dr. Wiederhold received his Ph.D. in Pathology at the University of Illinois and did a year fellowship in the Special

Life Center for Multiple Sclerosis at the University of Chicago. Tr. 578. He started medical school at Rush Medical College and started his internship and residency at the Scripps Clinic in La Jolla; he finished in internal medicine and critical care. Tr. 578. He then took part in clinical trials and research programs, and he spent some years at the Science Applications International Corporation where he worked on national security issues including work with the DEA. Tr. 578–79, 604–05. He is not board certified because he failed the board exam and did not want to take it again. Tr. 579. He also periodically performs locums work, meaning he fills a temporary position within a medical group. Tr. 595, 594.

He has been seeing patients for thirty years. Tr. 577, 605. He has been in private practice for twenty one years at Virtual Reality Medical Center focusing on managing pain with non-narcotic methods³² for veterans with post-traumatic stress disorder. Tr. 576. He also treats patients with COVID. Tr. 576.

He was on the staff at Scripps for fifteen years doing administrative work on review committees that reviewed charts of other physicians. Tr. 577. At Scripps Clinic, he reviewed patient charts for accuracy and completion, and to ensure that the doctors were meeting protocols. Tr. 579–80. This review included reviewing patients who were treated for chronic pain conditions. Tr. 580, 83.

He was also an expert witness for the State of California in worker's compensation cases, many of which involved chronic pain management. Tr. 577. He said he has testified as an expert witness, but could not recall the name of the court/tribunal. Tr. 583–84. He was an internal medicine physician and ran the intensive care unit for many years; he has treated patients in the emergency room and in the emergent care section, so he has a lot of experience evaluating patients for pain management. Tr. 577–78. [Dr. Wiederhold was qualified in this matter as “an expert in pain management.” Tr. 608.]

At the request of the Respondent's counsel's office, Dr. Wiederhold became involved in the instant case and was asked to review medical records and evaluate the quality of care provided to

four patients.³³ Tr. 584, 606. He evaluated these patients on three levels: (1) He generally made sure that he understood the types of patients that were being seen and the complexity of the patients; (2) he prepared a number of metrics to make some type of objective record; and (3) he made sure he understood the complexities and difficulties of dealing with the Government-supported healthcare system. Tr. 607.

He confirmed that he drafted reports with Dr. Shurman, and he has worked with him for five or six years in developing new pain programs. Tr. 589. The two of them discussed their findings from reviewing the record and their opinions and thoughts about the management of these patients. He does not currently practice pain management or see pain patients. Tr. 590. Although he previously prescribed controlled substances, he does not currently prescribe controlled substance at the Virtual Reality Medical Center. Tr. 593–94. He agreed that the standard of care requires sufficient documentation in medical records to justify controlled substance prescriptions to patients, which is for the patient's well-being and also protects the doctors. Tr. 595–96. Doctors are also responsible for reviewing their patient's medical records to ensure they are accurate and complete. Tr. 596.

Dr. Shurman³⁴

Dr. Shurman attended Temple University for his undergraduate education and then attended Temple Medical. Tr. 612. He then went to Mass General, Harvard's residency in anesthesia and intensive care. Tr. 612, 613. He then worked at the University of Washington for four or five years, where the first model pain center for the country started, and then he came to Scripps as a clinical instructor. Tr. 612–13, 615, 616. He believes that he was one of the first full-time pain specialists in the country. Tr. 616, 639. When he

³¹ [The Government objected to the qualification of Dr. Wiederhold as a witness primarily because he was not identified as an expert witness in Respondent's Prehearing Statement. Tr. 596, 604.] The tribunal ultimately found that Dr. Wiederhold's summary in the Respondent's Prehearing Statement dated October 16, 2020, and the summaries filed as exhibits sufficiently described his testimony as an expert. Tr. 596–603. Tr. 603–04, 608.

³² He is currently working with a company that is developing a subcutaneous Naltrexone implant which can be very important for medication assisted therapy. Tr. 581. He is also working with another company that is looking for a way to objectify levels of pain, which involves looking at electroencephalogram (EEG) and other type of physiological signals to try to match those to identifiable levels of pain.

³³ The Respondent's counsel showed Dr. Wiederhold Respondent Exhibits S, T, U, V and he confirmed that he prepared these exhibits in the course and scope of reviewing the patient records for D.P., D.L., J.K., and P.S. respectively. Tr. 586–88. The tribunal later allowed Dr. Shurman to be recalled to testify that the page numbers listed in the exhibits may not actually correspond to the date in the medical records. Tr. 807–816. The Respondent also offered Exhibit F into evidence and the Tribunal admitted the document into evidence over objection. Tr. 817–18.

³⁴ The Respondent's counsel posed hypothetical questions to Dr. Shurman throughout this testimony. The Government's counsel noted this on cross-examination and Dr. Shurman admitted that the questions were posed as hypotheticals because the discussions were not documented in the medical records. Tr. 728–29.

moved to San Diego, he joined the Anesthesia Service Medical Group, where he was the Chairman of Pain Management and head of Medical Research. Tr. 617. He has been the Chairman of Pain Management at Scripps Memorial Hospital for many years; he consults for multiple companies primarily in alternative forms of care, he serves as the co-chair for Palliative Care at Scripps, and he is involved in six or seven research projects to try to address the opioid epidemic, addiction, and the use of alternative forms of therapy. Tr. 610–12, 617. He has been the treating physician for approximately twenty to thirty patients in the last three years prescribed with high dose opioids, including patients who have also been prescribed either benzodiazepines, muscle relaxant medications, or other medications. Tr. 632–33, 635, 638–39. He would slowly taper patients off high doses of opioids, and testified that it should be a long-term goal to attempt to gradually taper patients off high-dose opioid use. Tr. 636, 726. In fact, he opined, it can take as long as three years to gradually and safely taper a patient. Tr. 727. In the last ten years, he has prescribed patients over 1,000 MME. Tr. 637.

He has worked with the California Medical Board as a reviewer and expert and has testified in cases involving pain management as an expert witness. Tr. 628–29. The standard of care is what a reasonable pain management specialist would do when treating patients in the San Diego community. Tr. 629, 733–35. He has met with other pain management specialists at conferences and gatherings. Tr. 643. [Dr. Shurman was qualified in this matter as “an expert in pain management and treatment.” Tr. 640.]

In 2016, there were no upper MME limits if a doctor had a difficult patient that had multiple surgeries. Tr. 630. The guidelines were more for risk stratification and in 2016, the CDC implemented its guidance regarding 90 MME, which was primarily for family practice doctors. If a patient was prescribed above 90 MME, then the recommendation was for the doctor to refer the patient to a pain specialist. Tr. 630–31.

The standard of care requires that a doctor have complete and accurate documentation of patient treatment in the medical records and sufficient documentation to justify controlled substance prescriptions, which protects the doctors as well as the patients. Tr. 720–21. It is also the doctor’s responsibility to review patient medical records and ensure they are complete

and accurate. Tr. 720. [Dr. Shurman agreed that “patients on high-dose opioids are put at a higher risk for other problems.” Tr. 721.]

It was within the standard of care at the time of an initial visit to keep a patient on his existing medication level, even if he was on high-dose pain control medications or a combination of anti-anxiety drugs, benzodiazepines, or muscle relaxants, if the patient was already on these drugs for some time. This is because, according to Dr. Shurman, it is important to get to know the patient and make a plan to slowly taper. Tr. 630–32, 640–41. The standard of care from 2016–2019 did not require that a physician take a patient’s vital signs at every visit when the patient was prescribed above 90 MME. Tr. 642–43. The Respondent’s frequency in taking vitals was within and even above the standard of care for the four patients because the Respondent was using pulse oximetry to measure the oxygen saturation levels of his patients and monitor for respiratory depression. Tr. 644–46.

Dr. Shurman opined that the standard of care does not require that a doctor examine the same area on the body every week or every two weeks; a limited exam every month or two is sufficient [“unless the patient has a complaint . . . or an exacerbation.”] Tr. 648. Pain management agreements are important for the doctor to have a discussion with his patients about the risks of psychological dependency, addiction, physical dependence, and side effects. Tr. 649. Executing a pain management agreement with a patient as a way of having an informed consent discussion was the standard of care. Tr. 650–52. Dr. Shurman reviewed the pain management agreements available in this case, [but he did not clearly testify that the pain agreements here, absent a documented discussion, were sufficient to meet the standard of care for informed consent.] Tr. 652–54.

During the period from 2016 to 2019, the standard of care was to review CURES Reports for patients on high doses of opioids every four months and the Respondent met this standard of care for all four patients. Tr. 665–66. According to Dr. Shurman, addiction is when a patient is “crushing . . . injecting . . . diverting . . . selling and all that.” Tr. 680–82. The standard of care in California allows physicians to have different opinions about the alternative methods of treatment of patients. Tr. 701.

Overview

For this case, Dr. Shurman spent approximately ten hours reviewing the

Respondent’s medical records (which included the time “he dream[ed] about [the case]”) and the summary prepared by Dr. Wiederhold, which assisted in his opinion about this case. Tr. 718–19. Dr. Shurman prepared, signed, and reviewed the reports, which were identified as Respondent’s Exhibits S, T, U, and V. Tr. 618–20.

Dr. Shurman opined that the Respondent met the standard of care in terms of informed consent for all four patients based on the Respondent offering Narcan and performing the oximetry [which, according to Dr. Shurman, reflected that Respondent “was concerned.”] Tr. 655–56. The existence of pain management agreements is very important. Tr. 656. The Respondent’s actual documentation should have been better than it was in some areas for all patients. Tr. 669–71.

Legacy patients are long-term patients who have been brought in on high-dose opioids. Tr. 687–88. [Dr. Shurman clarified that all of the patients at issue in this case are legacy patients and suggested that the standard of care for them was different than for patients who are new to pain management.*^K *Id.* (“When you look at the 2016 guidelines, the focus is really on new patients.”)] The CDC guidelines suggest to slowly taper such patients if possible. Tr. 729.

All of the Respondent’s patients had some organic source for their chronic pain conditions and the Respondent explored alternative means of trying to help these patients with their chronic pain problems. Tr. 695–96. Dr. Shurman opined that it was excellent that the Respondent tried various other avenues besides medications, including electric stimulation, injections, and medications other than opioids. Tr. 696. The Respondent also conducted pharmacogenetic testing, which identified that some patients were rapid metabolizers, which would need to be taken into consideration when reviewing urine screens; such a diagnosis would be important to document in the patient’s medical record. Tr. 696–99, 731. The Respondent closely monitored all his patients. Tr. 707. When treating these four patients who were on high-dose MMEs and combinations of medications such as benzodiazepines, muscle relaxants, or sleep medication, it is a balancing of risks versus benefits in

*^K The CDC Guidelines do address prescribing for patients who are new to opioids; however, they also clearly address patients who use opioids long-term and even patients who are new to the clinician but on long-term opioid therapy. See GX 5. Accordingly, I disagree with Dr. Shurman’s suggestion that the CDC Guidelines do not apply to legacy patients.

deciding how to manage the patient and it depends on the patient. Tr. 711. None of the risks manifested in these four patients while the Respondent was treating them, and Dr. Shurman opined that the Respondent had really good judgment. Tr. 712.

Patient D.P.

Regarding D.P., Dr. Shurman testified that the standard of care would require that, at the initial visit, the doctor have a discussion with the patient and try to taper down his dosage slowly as he had been prescribed approximately 3,000 MME by a previous physician, which is an unusual situation. Tr. 653–54, 657, 660–61, 685. The standard of care would also require that the Respondent talk about the risk of addiction and the risk of overdose. Tr. 654. The records did reflect that D.P. was provided Narcan, which is used to reverse the effects if someone has a severe respiratory depression. Tr. 654. The notes in the medical records also showed that the Respondent had discussions about trying to taper D.P. Dr. Shurman testified there was a risk in quickly decreasing D.P.'s MME as there was a study that forced tapers led to forty-three percent of the patients being hospitalized. Tr. 657–58, 726.³⁵

It was evident that the D.P. remained relatively safe under the Respondent's care because D.P. was clear and alert; his urine screens,³⁶ oximetries, and CURES were appropriate; and he had a quality of life. Tr. 658. D.P. had a painful condition called chronic cellulitis. Tr. 660. He went to a detox center and ultimately ended up with severe withdrawal and pain. Tr. 667–68. When he was at UCSD, the doctors there continued to prescribe him the same medications. Tr. 659. Dr. Shurman

disagreed with Sharp's detox treatment in 2019. Tr. 726–27.

The standard of care requires that a doctor make an attempt to obtain patient records, but in this instance, the Respondent had D.P. as a patient in the past. Tr. 687. It would be a good idea to get records, but it is in the Respondent's judgment if he knows the patient well.^{*L} Tr. 686. It is also better to document any discussion with patients, but Dr. Shurman made inferences that such discussions were had based on the different things Respondent did during exams. Tr. 724–25. Looking at the prescriptions for D.P., [Dr. Shurman opined that] these prescriptions were within the standard of care. Tr. 687.

Patient J.K.

Assuming the Respondent had discussions with J.K. about the urine drug screen reflecting the presence of amphetamine and about her prescriptions for medical marijuana, and assuming he checked CURES to verify the amphetamine prescription,^{*M} Dr. Shurman opined that it was appropriate for the Respondent to continue J.K.'s prescriptions despite the fact that she was taking marijuana. Tr. 672–74. However, such discussions should be in the medical records.^{*N} Tr. 727–28. Dr. Shurman has encountered circumstances where fentanyl patches did not properly adhere to patients, which is a common problem. Tr. 675. J.K. was also on hormone therapy which could cause excessive perspiration. Tr. 709. Assuming the Respondent had discussions with J.K. regarding why the fentanyl derivative was not in her system, it was within the standard of care for him to continue to treat her with medication. Tr. 676. Patients will not always take medications as prescribed and the doctor should look at the average of what their patients are taking.^{*O} Tr. 677–78.

^{*L} Sentence moved for clarity.

^{*M} Sentence modified for clarity.

^{*N} Dr. Shurman testified that, "one of the things [Respondent is] going to improve on [is] to take an abnormal screen, document in his records and in certain cases discuss it with the patients. But [there is] no lapse in his clinical judgment." Tr. 728.

^{*O} Specifically, Dr. Shurman testified, "[t]here are side effects sometimes, nausea, constipation. And sometimes they're having a good day, they may not take it. Or sometimes they're having a bad day and they may take more. And to kind of look at the average of what these patients take, . . . sometimes it may not show up." Tr. 678. He went on to testify that the standard of care did not require that a physician immediately taper medications or refer a patient to an addictionologist following an aberrant drug screen. Tr. 679. Instead, "you talk to them about [the aberrancy]" and if the patient says they are "taking more than they usually take . . . to stabilize their pain . . . [then you] don't consider it aberrant behavior." Tr. 682.

The Respondent attempted to treat J.K.'s migraine headaches with Botox while she was seeing an oncologist for her breast cancer. Tr. 699–700. It is considered a controversial position, but some doctors, including Dr. Shurman believe it is appropriate to use higher doses of opioids to treat resistant or intractable migraines, which is within the California standard of care. Tr. 700–01. Overall, [Dr. Shurman opined that] the Respondent's prescriptions for J.K. were acceptable within the standard of practice under the circumstances. Tr. 702.

Patient P.S.

P.S.'s pain scale reporting did not change much over time and it would have been difficult to taper his prescriptions due to his chronic pain problems. Tr. 689–91; RX U. Regarding the aberrant drug screens, Respondent followed the standard of care of P.S. as long as he had a discussion with him because Respondent followed him closely with CURES, urine screens, etc., to ensure there is not an ongoing problem. Tr. 692–94. Based on a review of P.S.'s medical record, P.S. had an anxiety disorder. Tr. 695. Overall, the prescriptions the Respondent prescribed to P.S. were prescribed within the acceptable standards of practice under the circumstances, as P.S. was a very challenging patient. Tr. 699.

Patient D.L.

The Respondent treated D.L. with opioid medication, benzodiazepines, and a sleep medication, Lunesta.³⁷ Tr. 702, 706. Although there is a black box warning about prescribing "benzos" and opioids, the doctor may still prescribe the combination after considering the risks/rewards and following the patient carefully. Tr. 706. It was within the standard of care for the Respondent to continue D.L. on those medications at the initial visit because she had colon cancer, polyneuropathy, hip pain, and a failed spine surgery. Tr. 702–03. As that was Respondent's first time meeting the patient, the Respondent would not want to promptly start to taper the patient and should "get a feel for them" by getting a history, urine screens, CURES, etc. before making a decision. Tr. 703. The Respondent did pursue these urine drugs screens and CURES reports in this instance.³⁸ Dr. Shurman disagrees with

³⁷ Dr. Shurman clarified that Lunesta, or a sleeping agent, is not part of "the Holy Trinity." Tr. 706. [Text from preceding sentence omitted for clarity.]

³⁸ At this point in the testimony the Government's counsel noted that the document Dr. Shurman was using had highlights and notes. Tr. 704. The

³⁵ [Footnote modified for clarity. On cross-examination, Dr. Shurman stated that he "[did not] find specific documentation of a discussion" between Respondent and D.P. regarding the "various risks associated with him taking opioids at such a high dose." Tr. 722–23. However, he inferred these discussions occurred because the pain management agreement said "he will discuss other side effects with the patient." Tr. 723. And without such a conversation, "why did he use an oximeter, why did he give the patient Naloxone, . . . there's obviously a reason for it." Tr. 723. However, Dr. Shurman ultimately agreed that he "never saw anything in the medical records that documented a discussion about the high risks due to high-dose opioids." Tr. 723–24.]

³⁶ Urine screens are used for multiple purposes including to make sure that a patient is taking his prescriptions and to monitor illicit drugs. Tr. 661. In D.P.'s case, the Respondent went above the standard of care regarding urine screens because it is an undeserved population and such screens only need to be done about every three months. Tr. 662–63, 725. The urine screens for the other three patients were also excellent and above the standard of care, as they were the more costly, confirmatory urine screens. Tr. 663–64.

Dr. Munzing's opinion that every single prescription for patient D.L. was below the standards of practice and in fact [opined that] the Respondent's prescriptions for D.L. were within the standard of care. Tr. 707–08. D.L.'s reported pain level stayed around five or six-of-ten throughout treatment, which is an indication that overall the treatment was effective for her and is in fact a doctor's goal. Tr. 711.

Brenton D. Wynn, M.D. (the Respondent)

The Respondent grew up in San Diego and graduated from UCLA with a bachelor of science in physiological sciences. Tr. 469. He attended Howard University College of Medicine and received his M.D. in 1998. He did his first year of preliminary internal medicine at Good Samaritan Regional Medical Center in Phoenix, Arizona, and started his physical medicine and rehabilitation residency program at Stanford University Medical Center. He then went to the Louisiana State University Health Science Center for a fellowship in musculoskeletal and interventional spine medicine.

In 2004, he went back to San Diego and became the only pain physician affiliated with Paradise Valley Hospital in National City, where he maintained the practice for ten years. Tr. 469, 475. He is board certified in both physical medicine rehabilitation and pain medicine. Tr. 470. He then started with another group in 2014, where his focus was on pain management patients, but left that group in May 2016 to begin the process of rebuilding his own private practice. Tr. 475–76. From 2014–2016, he also worked at the Paradise Valley Hospital Outpatient Senior Health Center, where he did pain management or pain medicine. Tr. 476.

He currently works in outpatient medicine, primarily doing interventional procedures four days a week. He has two nurse practitioners in the practice that assist him with the evaluations and management of the patients. Tr. 477. Eventually, Respondent was able to secure his practice location separate and apart from the Senior Care Facility. Tr. 478. He is currently leasing a space in National City. He is the only pain management doctor that services this area of National City, of approximately 62,000 patients. Tr. 479–80. About sixty percent of the Respondent's patients use Medicare, and the vast majority of the remaining patients are under some sort of IP or managed care plan that is a

Medi-Cal or Medi-Cal-affiliated program. Tr. 480.

When he was at the Senior Health Center, he used the hospital-based electronic record system and his primary entry method was through dictation. Tr. 481. He currently uses Practice Fusion, a free internet-based electronic health record system, which he was using once the four patients came to him at the new location. Tr. 481–82. During this time he worked with a receptionist, an office manager, a practice manager, medical assistants, a biller, and nurse practitioners that were hired and staffed through a management company but were “not technically” his employees. Tr. 483–84. He currently uses a scribe to enter information into the EMR for better record entry, while his nurse practitioners enter the notes themselves. Tr. 484–85.

Since Dr. Wynn received the subpoena for this case, he has tried to enhance his recordkeeping practices and enrolled in courses through the University of San Diego School of Medicine and the PACE Program that focused on recordkeeping and prescribing controlled substances. Tr. 488, 490.*^P He has stayed abreast on current thinking in his area of chronic pain management over the last five years by attending conferences, where there is a PME available, reaches out to fellow colleagues to have dialogues about treatment or new ideas, and attends educational events where pharmaceutical representatives present information. Tr. 567. In 2019, he sat and recertified for his Pain Boards, which required numerous hours of review. Tr. 567. He also attended multiple national meetings.

The Respondent saw all four of the patients at issue in his current practice and had been treating them prior to establishing his current practice. Tr. 491–92. All of these patients were already prescribed opioids when they first met with the Respondent. Tr. 492. When patients enter the Respondent's office, they check in at the front with the receptionist, and there is a process to verify their eligibility, address, and insurance information. Tr. 538. Patients then fill out a pain diagram and sit in the waiting room. Patients then have their height, weight, and temperature taken and are taken to the exam room,

*^P When Respondent was asked whether he had “any thoughts or opinions about whether or not the recordkeeping for these patients in some areas . . . was adequate enough for purposes of good recordkeeping,” he answered “I would say that some areas are appropriate.” Tr. 488. Then when asked whether “there are any areas that in your opinion, looking back now at these records, that you feel are less than adequate for what they should be?” Respondent answered “Yes, I do.” *Id.*

where vitals, including blood pressure and maybe temperature are taken. Medical assistants (hereinafter, MAs) ask some of the questions that are done on the subjective. That information is then discussed with the provider who will see them at the visit. The CURES report and previous drug screen are reviewed if that patient is there for a refill visit prior to the provider entering the exam room. Tr. 538–39. The provider then typically discusses the patient's history and any new or ongoing concerns, performs a physical exam, reviews any documentation such as imaging studies or nerve conduction studies or information from a primary care doctor, and discusses the treatment plan.*^Q Tr. 539. Since COVID, the vast majority of medication refill visits are done through telemedicine. Tr. 539. Prior to COVID, it was his customary routine to do an exam and put his hands on the patient, which could include listening to the heart, lungs, and respiratory rate, observing their gait, and palpating the area of concern. When he prescribed a significant amount of opioids, he also provided Narcan. Tr. 753.

In the beginning of the practice, they were still getting acclimated to the Electronic Health Records (“EHR”), so some things were missing in the medical records, but as time went on, there was improvement with the vitals “actually making it into the chart and the documentation making it into the chart.” Tr. 540. For instance, earlier in the practice, the MAs would write vital signs on a sticky note and the Respondent did not know if they always “ended up in the” medical record. Tr. 540–51. He currently continues to see P.S. and D.F. as patients. Tr. 747. None of his patients, have experienced the risks of overdose, addiction, or significant respiratory distress to the point that they needed Narcan or to call 911 while he was treating them. Tr. 748–49.

As to all his patients, he believed he was within the range of the accepted standard of care, setting aside the issue of documentation, because he conducted a thorough examination at each initial visit, reviewed CURES, gave urine screens, reviewed any documentation provided by previous physicians, discussed the treatment plan, went through a controlled substance agreement, discussed the use

*^Q With regard to the treatment plan's timing for titration down from high levels of opioids, Respondent believed “there's a right time to initiate doing some changes to a patient, and I would prefer to do it when the patient is able to comply and buy in because they're a lot more stable with their current pain or pain and anxiety control.” Tr. 771.

of Narcan, discussed the risks of opioid-use, and discussed the CDC guidelines. Tr. 764–68. Some of the areas of the medical records were less than adequate. Tr. 488.

Respondent agreed that the standard of care requires sufficient documentation in the medical records to justify controlled substance prescriptions to patients [and requires complete and accurate medical records], which protects the doctors as much as it helps the patients. Tr. 778–80. Doctors are also ultimately responsible for preparing those complete and accurate medical records. Tr. 780. He currently serves 600 active patients and has approximately 7,000 patient visits annually. Tr. 830.

Patient D.P.

Patient D.P. was referred to the Respondent for pain management in approximately 2014. Tr. 493. Patient D.P. went to another doctor at some point and then returned to the Respondent's care when he opened his new practice. Tr. 493–94. When D.P. returned, he was on a high level of opioids and the Respondent had never taken care of any patients who were at that high of a level of controlled substances prescriptions. Tr. 494–95. When D.P. came to the Respondent in approximately 2016, the Respondent had reservations about taking him on as a patient because of the high MME, but took him back because he was familiar with D.P., he knew he was a reliable historian, he had worked with the pharmacy where D.P. had received his prescriptions, and D.P. understood that they would establish a plan to safely taper his medication. Tr. 496–97. He and D.P. had a discussion that he was willing to work with him, but discussed the CDC guidelines and D.P.'s opioid load and said that the amount prescribed would need to be decreased to an amount under 1,000 MME. Tr. 496, 544–45. The Respondent is familiar with the concept of informed consent and “in his mind” he had a discussion with D.P. that was adequate informed consent regarding his wound care and the risk of habituation,³⁹ overdose, or death from overdose due to his high MME. Tr. 499–500.

The Respondent initiated titration at some point, but D.P. either would not tolerate it or had withdrawal and there was an incident where D.P. was removed from a plane because he looked ill, which the Respondent attributes to aggressive titration. Tr. 545. After a course of detox, D.P. was placed on Suboxone, which did not manage his pain at all. Tr. 546. D.P. returned to the Respondent and his pain was uncontrolled; the Respondent believes he tried to continue to manage D.P. on the Suboxone, but ultimately had to prescribe oxycodone not exceeding 90 MME. Tr. 546–47, 549. The Respondent stated that there was room for significant improvement in his documentation of D.P.'s care. Tr. 549.

The Respondent testified that he talks to patients about safety issues and diversion prevention and emphasizes the risks of opioid use, including the fact that these patients can be targets for theft, assault, and having their medication stolen if people learned they had those medications. Tr. 500. He typically explains the meaning of MME in a way the patients can understand. Tr. 501.

Patient D.P. admitted to the Respondent that he had over-used some his medications at times. Tr. 541–42. When this happened, with D.P. as well as with other patients, the Respondent would review the controlled substance agreement with the patient and then discuss that is not how the medications were intended to be used; he talked about safety issues, and explained the potential of moving to non-medication options for future management if D.P. could not get back on track. Tr. 542. The Respondent did not discharge D.P. from the practice because they discussed other treatment options including nerve blocks, but ultimately Respondent decided to keep D.P. on his medications. Tr. 542–43. In particular, he had wound care that would be very painful when he received debridement and he would take more medication before and after those debridements. Tr. 543–44. In such cases, however, the Respondent should have discussed and documented this in the medical records. Tr. 781.

If D.P. had problems filling his prescriptions, he would let the Respondent know in most cases. Tr. 782–83. On August 14, 2019, D.P.'s pharmacy started to severely restrict his ability to fill his Oxycodone prescription by only allowing a 48–72 hour fill and there is a note stating “Cardinal would NOT . . . replenish the Oxycodone need for this patient. Therefore as an urgent matter, only do a 48 to 72-hour prescription for all his

four oxycodones until his doctor finds a different solution.” Tr. 783–85.

Patient J.K.

Patient J.K. was referred to the Respondent and she followed him to the group clinic, he “kind of lost care to her directly,” and then she was re-referred to him after he reestablished his own practice. Tr. 549–50. Aside from migraines, she had chronic knee pain and various joint pain that she attributed to her chemotherapy. Tr. 550, 569, 738. The Respondent evaluated whether or not the extent of these problems made it appropriate to use pain medication to treat these conditions. She had previously been prescribed an opioid from another provider to help manage her migraines and the Respondent continued that care. Tr. 550–51. He prescribed a Botox treatment for her, but due to insurance issues he could not get an ongoing authorization approved to treat her migraines with Botox. Tr. 551, 552, 743–44. At some point, the Respondent was treating her while she was uninsured and when she did receive insurance, it was an insurance plan that he had not contracted with so she ended up being treated by another physician. Tr. 551–52.

Respondent testified that J.K. had previous workups with a neurologist in the past and had sinus surgery so the Respondent did not feel as though he needed any imaging studies to treat her for migraine headaches. Tr. 552. She was initially on a fentanyl patch and he continued with that. Tr. 553. She was also prescribed Percocet, (as a short-acting breakthrough medication), Soma (to diffuse muscle spasms), and Nuvigil (to improve excessive daytime sleepiness⁴⁰). Tr. 553–54, 559. It was his custom and practice to discuss any risk associated with combining muscle relaxants with the other pain control medications. Tr. 559. He explained to J.K. that this was not a safe medication combination and that it is habit-forming and addictive and he explained the negative effects of opioids in terms of overdose and potential death. Tr. 559–60, 739. After this discussion, he still continued prescribing the medications because he believed there was a legitimate medical purpose in doing so. Tr. 560. He wanted to reduce the Soma because he was concerned it was not the best medication for her, but it took a while for her to “buy-in on reducing the medication.” Tr. 560. If J.K. reported her pain as being a four or five out of a scale

³⁹ According to Respondent, habituation is a form of physical dependence on a drug. Tr. 503. This term tends to be interchanged with the term “addiction,” which is a behavioral syndrome. Illicit drugs appearing in urine screens is the initial most common thing that indicates a patient is abusing drugs. Tr. 747. Drug metabolites test positive for a longer period of time in urine than blood. Tr. 763. He would go around patients showing drug-seeking behavior, asserting they could not produce a urine sample by taking a saliva or blood sample. Tr. 763.

⁴⁰ At one point the Respondent tried to refer J.K. to a sleep medicine specialist for a sleep lab. Tr. 739–40.

of 10, he saw that as her being stable and her pain being controlled. The plan was that she would remain stable if he did a slow titration. Tr. 561. She also reported that the medication would allow her to maintain her work duties and activities of daily living at home.

He suspected that J.K. had some elements of undiagnosed brain injury based her behavioral issues, continued headaches, and her history of being the victim of physical abuse. Tr. 554. Regarding inconsistencies in J.K.'s urine drug screen, he believed the amphetamine was a prescription medication based on how it appeared. Tr. 553–54, 740. After inquiring, J.K. told him that she was prescribed Adderall from her psychiatrist, which the Respondent also saw in the CURES report. Tr. 555–56. He therefore did not have any issues with J.K.'s drug screen testing positive for amphetamine because he knew it was not an illicit drug. Tr. 557.

The Respondent also recalls times when J.K.'s urine screens lacked the presence of one or more of her prescribed pain medications and he recalls having a conversation with her at a visit. She stated that she was having issues with her fentanyl patches adhering due to excessive sweating so she would replace them before they were due to be changed, which left her short prior to the time of her next refill. Tr. 557. The Respondent considered switching J.K. to an oral medication and at some point he did and prescribed oxycodone and oxymorphone. Tr. 558.

At one point, his office was treating her despite her not having insurance and not charging her for continuity of care. Tr. 561–62. On her last visit the Respondent wrote her a supply of medications that would help her until she could get a new provider with her new insurance, but she was unable to obtain the medications due to an authorization issue. Tr. 562. She did not understand that the Respondent could not fill out the authorization because he was not affiliated with her new insurance plan and acted out of desperation because she was out of medication. Tr. 563. He ultimately authorized some additional prescriptions for her with the understanding that she was actually without her medication. He did not believe she had any intention of following through on her suicide threats. Tr. 564.

The Respondent acknowledged that some drug screens came back positive for THC and [he did not believe it was an inconsistent result] because she had previously been placed on Marinol during her treatment for stage-one breast

cancer. Tr. 564–65, 781. He discussed with her that THC could be a sedative or a stimulant depending on what type she was using and if it did not come from a reputable source, it could be laced or tainted, which could be dangerous. Tr. 565–66. She was getting marijuana from a dispensary and the Respondent did not find that her concomitant use of marijuana was a contraindication for him to prescribe her medications for pain management. Tr. 566–67, 740. Other providers agree with this line of thinking. Tr. 567. Furthermore, the chemotherapy J.K. underwent could cause residual side effects, including prolonged pain syndromes. Tr. 738. The Respondent carefully monitored her to ensure that risks did not develop through frequent visits where her vitals were taken and discussions were had with her, even though these discussions may not be reflected in the record. Tr. 745–46. He testified that his care of J.K. was within the standard of care despite not lowering her MME closer to 90 or 100 because they had a discussion about the overall plan to bring her down, but they had challenges with insurance^{*R} and had various social stressors; he was able to ultimately completely titrate her completely off benzodiazepines. Tr. 744, 770–72. Furthermore, she is currently on close to 200 MME, which is a significant improvement [in safety] and his decisions for her care were made based on his personal judgment and how the patient's overall quality of life is affected. Tr. 772–73.

Patient D.L.

D.L. is still the Respondent's patient. Tr. 751. When she returned to the Respondent as a patient, she was already on [a dose of 100 mg morphine sulfate],^{*S} and he had a discussion with her about what medications she was on and what risks they might pose moving forward, which included a discussion of the 2016 CDC Guidelines. Tr. 751–52; 782. He also provided Narcan and explained how to use it. Tr. 754–55; GX 14 at 37. On a November 2016 visit, a note indicated, "Education," which Respondent testified meant that he would have discussed the combination of medications and the high-dose opioid. 755–57; GX 14 at 40. He also ordered pharmacogenetic testing on D.L. to understand why she may have needed a higher dose of opioids or why there were discrepancies in urine

screens. Tr. 759–60. He learned she had an altered gene expression that related to how she responded to morphine, but he could not change her dose due to insurance reasons. Tr. 760. His management of D.L. was within the range of the accepted standard of care, setting aside the issue of documentation, because they had discussions regarding her treatment goals and she was still having uncontrolled pain. Tr. 764–65, 769–70.

Patient P.S.

The Respondent believes that for P.S., he struck a reasonable balance under the standard of care between his need to have relief, have a quality of life, and the risks associated with his pain levels. Tr. 773–74. He is still the Respondent's patient, and is currently [at a lower MME than he had been]^{*T} and he is open to other therapeutic interventions. Tr. 774. The Respondent resolved P.S.'s inconsistent urine screens by counseling him and reassuring him when he was being compliant. Tr. 776. The Respondent did not think that P.S. was abusing his prescriptions, but instead thought he had good days and bad days with taking his prescriptions.^{*U} The Respondent tried to get P.S. in to see a psychiatrist. Tr. 776–77. Furthermore, sometimes when the Respondent changed a patient's dose, there can be issues with the insurance companies or authorizations with the pharmacies and he would have to "play their insurance games in order to actually get the patients treatment the way we're intending," so sometimes it looked as if some medications were duplicated when they were not. Tr. 778.

In October of 2020, the Respondent prepared a document with the aid of his staff and Dr. Shurman to show ongoing actions that his practice is taking "to improve the quality of documentation and care and compliance with the guidelines." Tr. 822–24; RX W.⁴¹ [Respondent testified that he is implementing the actions currently and intends to continue to so do. Tr. 823.]

^{*T} Modified for clarity.

^{*U} Respondent agreed that for a patient on high-dose opioids, taking a little more than prescribed, even if it is to control pain, can be dangerous. Tr. 781. He further agreed, that if a doctor finds out that a patient is taking more than prescribed, he should discuss that with the patient and document the discussion in the medical records. *Id.*

⁴¹ The tribunal allowed the Respondent's counsel to recall the Respondent to testify regarding this exhibit over the objection of the Government's counsel. Tr. 820–21.

^{*R} Respondent testified that "every time you change a dosing, the insurance requires that you submit an authorization. . . . [s]o that in itself can delay the process of even initiating a titration when you would like to." Tr. 744.

^{*S} Modified for clarity.

*Closing Statement*⁴²

The Respondent acknowledged there was a lack of documentation in this case. Tr. 870–71. However, when balancing whether it would be inconsistent to allow the Respondent to continue with his DEA certificate, Respondent argued that it was important to weigh his experience as a pain management physician overall. Tr. 871. None of his patients had an overdose and there were no particular complications or adverse effects the patients suffered. The record reflects that he monitored patients, reviewed CURES reports, had patients visit frequently, performed frequent urine screens, and tried to find alternative means of treatment, which reflects what is in the public interest and patient safety. Tr. 871–72. The Respondent also served an underserved population. Tr. 872. The evidence shows that even though the Respondent did not keep accurate records regarding informed consent discussions with his patients, these discussions likely took place. Tr. 872–73. Patients D.L. and D.P. also stated that they had informed consent discussions with the Respondent. Tr. 873. In the big picture, there can be a debate between experts about whether the prescriptions were within the balance of reasonable judgment. Tr. 873.

The Respondent has put forth evidence that he has demonstrated efforts to rehabilitate and did not deny anything about the records being lacking. Tr. 874. According to Respondent, the evidence does not support the Respondent having his DEA certificate revoked. Tr. 875.

Rebuttal

Dr. Munzing

After listening to the testimony from Dr. Shurman, Dr. Wiederhold, D.P., D.L., and the Respondent, Dr. Munzing did not change any of the opinions to which he previously testified. Tr. 833–35. Dr. Munzing strongly disagreed with Dr. Shurman's opinion regarding the acceptability of prescribing benzodiazepines and opioids together. Tr. 837. Specifically, there are strong pushes, based on warnings and guidelines from the CDC and FDA that doctors should avoid prescribing benzodiazepines and opioids together and, if it is done, such prescribing requires documentation. Tr. 827–38. Dr. Munzing did agree with Dr. Shurman that keeping a patient on a higher dose when he first begins care is consistent

with Dr. Munzing's testimony.*v Tr. 839. Dr. Munzing's issue with the instant case is that the patients were maintained at high levels over a period of many years. Tr. 839, 856. Dr. Munzing also agreed with Dr. Shurman's assertions that chronic patients should be slowly tapered. Tr. 839–40. Ultimately, Dr. Shurman's assertion that there was no lapse in the Respondent's clinical judgment was incorrect. Tr. 841. Dr. Munzing also reiterated that multiple aberrant drug screens are problematic and must be documented in the medical records. Tr. 844.

Dr. Munzing also reiterated the importance of the Respondent failing to take vitals at each visit, even if visits are weekly, because such frequent visit shows that the Respondent believed his patients needed close monitoring. Tr. 852. [According to Dr. Munzing, "if you believe the patient is unstable enough or tenuous enough that you need to see the patient every week, then you're indicating that you need to more intensively see the patient." Tr. 852.]

Dr. Shurman

Dr. Shurman testified that it would not be extremely dangerous for a patient to take medical marijuana with an opioid and a benzodiazepine, it should just be treated as another medication, and it is common for people to be prescribed to this combination. Tr. 866.

The Facts^{*w}*Findings of Fact*

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me:

During the hearing conducted via video teleconference from November 16–20, 2020, the Government established the following facts through evidence, testimony, or stipulation.

^{*v} On cross-examination, Dr. Munzing testified that it was possible, given Respondent's prior relationship with the patients, that the initial prescriptions at the first visit when the patients returned to Respondent could have been within the standard of care on every element other than appropriate documentation. Tr. 860–62.

^{*w} The parties agreed to Joint Stipulations A–U, Y–Z, BB, CC, EE, FF, HH, and II. See ALJ Ex. 4, Govt Prehearing, at 2–38; ALJX 15, Resp Supp. Prehearing, at 1. The RD included many of the stipulated facts between the parties, but appears to have inadvertently left some out. See RD at 70–110. I have omitted the joint stipulations from the text of this decision in the interest of brevity, but I incorporate fully herein by reference Joint Stipulations A–U, Y–Z, BB, CC, EE, FF, HH, and II.

1. DI has been employed by the DEA as a Diversion Investigator for thirty-two years. Tr. 21:4–6.

2. Respondent came to the attention of the DEA in October 2018, based on a report by a local pharmacist that Respondent was excessively prescribing controlled substances. Tr. 22:11–17.

3. Between March 17, 2017, and March 19, 2019, Respondent dispensed over 590,000 dosage units of schedule 2 through schedule 5 controlled substances. Based on DI's experience, this was an extremely high number of dosage units. Tr. 23:19–25–24:1–8.

4. Between March 17, 2017, and March 19, 2019, Respondent dispensed almost 190,000 dosage units of various strengths of oxycodone, equating to over 1,700 prescriptions. This represented 32% of all Respondent's prescribing over this period. Tr. 24:15–25–25:1–3.

5. Between March 17, 2017, and March 19, 2019, Respondent dispensed almost 123,000 dosage units of various strengths of hydrocodone, equating to over 1,370 prescriptions. This represented 20% of all Respondent's prescribing over this period. Tr. 25:4–7.

6. Between March 17, 2017, and March 19, 2019, Respondent dispensed almost 88,000 dosage units of oxycodone with acetaminophen, equating to over 922 prescriptions. This represented 14% of all Respondent's prescribing over this period. Tr. 25:7–10.

7. Dr. Munzing's curriculum vitae was admitted into evidence as GX 2. Tr. 61:10–25–62:1–15. He is a licensed physician in the State of California, who has worked in the field of family medicine for nearly 40 years. Tr. 89:14–23.

8. Dr. Munzing received his undergraduate degree, a Bachelor of Science in Biochemistry, at the California State University at Fullerton. He received his medical degree from the University of California, Los Angeles, in 1982, and did his residency at Kaiser Permanente Medical Center in Los Angeles. He became Board Certified in Family Medicine in 1985, and that certification still current and active. Tr. 62–63.

9. Dr. Munzing has been a family doctor for 35 years. For the last 32 years he has been the Founding Residency Director of a Family Medicine Residency program, which works in close conjunction with every other specialty, including Internal Medicine, Pediatrics, ObGyn, Anesthesia, and pain medicine. Tr. 63.

10. Dr. Munzing has been working in the family medicine department of Kaiser Permanente, Orange County, for the last 35 years, twice serving as

⁴² The Government deferred its closing statement to the post-hearing brief.

president of the medical staff. In his role as president of the medical staff, he was responsible for overseeing the professionalism and quality of care provided by the staff. Tr. 66.

11. Dr. Munzing has a DEA COR and an active clinical practice, prescribing, *inter alia*, opioids, benzodiazepines, and other controlled substances when indicated. Tr. 64–65.

12. Dr. Munzing also sits on the National Accreditation Board for Family Medicine Residency, which accredits all of the family medicine residency programs in the United States of America. Tr. 63–64.

13. Dr. Munzing has been a Medical Expert Consultant for the Medical Board of California for approximately 16 years. Tr. 64:6–13.

14. Dr. Munzing has been called upon to provide opinions about the prescribing of other medical professionals, and he has been qualified as an expert witness in over 30 cases, including in DEA administrative hearings. Tr. 67–68.

15. As a licensed California physician who has been practicing in California for nearly 40 years, Dr. Munzing is familiar with the standard of care for prescribing controlled substances in California. He also has reviewed publications by the Medical Board of California that inform his understanding of the standard of care, including the “Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons (7th Edition)” (admitted as GX 3, Tr. 71:2–13); the “Guidelines for Prescribing Controlled Substances for Pain,” (admitted as GX 4, Tr. 74:4–15); the CDC guidelines regarding Morphine Milligram Equivalents (GX 5, Tr. 104–108); and the FDA black label warning concerning prescribing opioids and benzodiazepines together (GX 6, Tr. 113–115). Further, Dr. Munzing reviewed several laws and regulations that informed his understanding of the standard of care. Tr. 68–74.

16. Dr. Munzing was qualified as an expert in Pain Management and as an expert in the standard of care for prescribing controlled substances in California. Tr. 77:4–9.

17. Dr. Munzing testified that the standard of care in California first requires that, before prescribing controlled substances, a practitioner perform a sufficient evaluation of the patient, including, a medical history and appropriate physical examination. This includes an assessment of the patient and a determination as to whether any additional information is needed through, for example, laboratory tests, imaging studies, or other studies. Then, the doctor comes up with a

specific assessment or diagnosis or likely diagnosis. After which, a doctor performs a risk stratification of the patient and assesses any other medical problems that may contribute to management of the patient. Then the doctor comes up with a management plan specific to the evaluation. Tr. 79.

18. If the management plan includes prescriptions for controlled substances, a determination needs to be made weighing the potential benefits and risks of such treatment. Once the plan is put into place, a doctor must monitor the patient on a periodic, regular basis. At all times, a doctor is attempting to mitigate risks to the patient by maximizing the benefit of the treatment and minimizing the risk. Tr. 79–80.

19. All of the elements of the management plan must be documented in detail, so in the future, a reviewer can get a detailed and truthful understanding about how the patient was on a certain date and what the reasoning was behind why a patient was being managed in a particular way. Tr. 80:12–21.

20. These rules regarding the standard of care in California apply equally to all practitioners, be it family practitioner or a doctor who specializes in pain management. Tr. 80:22–25.

21. The “Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons (7th Edition)” applies to all physicians in California, regardless of specialty. Tr. 82:11–17; GX3.

22. [The standard of care requires that] a patient should give informed consent regarding the risks and benefits of the use of controlled substances. Patients need to be fully aware of the risks they face and whether any alternatives exist to the proposed treatment, particularly when prescribing opiates. Tr. 85–86.

23. The standard of care in California requires that for patients at the high dosages of opioids, like those in this case, the doctor should obtain vital signs, blood pressure, heart rate, respiratory rate and perform an examination on the pertinent area at every appointment. Tr. 87:1–15, Tr. 85:15–15, 85:2–10.

24. Standard of care in California requires periodic review of the patient and constantly trying to assess the patient’s risk and whenever possible, try to mitigate the risk by either bringing down medication dosages or using alternative treatments. Tr. 87:16–25.

25. When a doctor increases the dosage of a medication, it increases the risk to the patient. As such, the standard of care requires the doctor to well-document why the increase is necessary and document that the patient has been

informed of and is aware that the increased medication poses an increased risk. Tr. 88:1–16.

26. The California standard of care requires that all physicians keep accurate and complete records for all aspects of patient care. GX 3 at 61; GX 4 at 22; Tr. 88–89.

27. The Medical Board of California’s Guideline for Prescribing Controlled Substances for Pain (GX4) applies to all doctors, regardless of specialty. Tr. 90–91.

28. Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression, particularly in elderly patients. Physicians should consider a trial of benzodiazepine tapering in patients concomitantly using opioids or other respiratory depressant medications. If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. GX 4 at 12; Tr. 92–93.

29. As treatment progresses, a physician must monitor the patient. A practitioner must periodically update the patient’s medical history, conduct further physical examinations, and obtain updated information regarding the etiology of a patient’s state of health. The practitioner must periodically review the course of treatment, ascertain how the patient is responding thereto, determine if continued treatment is appropriate or if the treatment plan needs to be modified, and document the rationale for any modifications. The practitioner must also periodically re-inquire into the patient’s urine drug screens. Tr. 96–97.

30. Maintaining a high MME dose of medication for a patient, simply because that patient was on a high MME dose prior to treatment with a particular doctor, does not meet the standard of care in California. Tr. 109:17–21.

31. The standard of care and usual course of professional practice in California for treatment of pain and prescribing of controlled substances does not depend on whether the prescribing physician is a pain care specialist. Tr. 115:9–15. Appropriate documentation is a well-known, fundamental requirement in the medical community. GX 3 at 61; GX 4 at 22.

32. The practitioner must also comply with all relevant California law. Tr. 460–61, 462–63.

33. Between March 13, 2017, and October 29, 2019, Respondent issued Patient D.P. the controlled substance prescriptions stipulated to in ALJ Ex. 4.

34. Dr. Munzing concluded that the prescribing of these controlled substances to Patient D.P. between March 13, 2017, and October 29, 2019, violated the standard of care in

California in numerous ways and was not done in the usual course of professional practice. Tr. 120–77.

35. At times, D.P. was prescribed a dosage in excess of 6,000 MME per day. Dr. Munzing testified he believed it to be the highest MME he has ever seen. Tr. 118:1–5.

36. Between March 13, 2017, and October 29, 2019, Respondent prescribed D.P. approximately 1.4 million milligram dosage units of opioids per year, which was the highest Dr. Munzing has ever seen. Tr. 119:19–25.

37. The Controlled Substance Agreement executed by D.P. is not adequate to demonstrate informed consent by D.P. to the risks associated by Respondent's high-dose prescribing. GX 8 at 239; Tr. 121–22.

38. Over the course of his treatment, D.P. received exceedingly high MME doses and exceedingly high numbers of pills, approximately 160 tablets per day. Dr. Munzing testified he had never seen a patient receive anywhere near that number of tablets per day. Tr. 123:19–25.

39. Between March 13, 2017, and October 29, 2019, D.P.'s MME levels fluctuated between 3,500 MME to over 6,000 MME, at times going down to 4,000 MME and then back up to 6,000 MME. Tr. 124:5–11.

40. Once D.P.'s care was taken over by Pain Management at U.C. San Diego in late 2019, D.P.'s MME dropped fairly quickly to 2,700 MME and has been slowly tapered to 1,000 MME and is now in the 700 MME range. Tr. 124:12–24.

41. The medical histories taken by Respondent for D.P. are poor and do not meet the standard of care in California. The medical records do not contain sufficient information and there is no documentation of attempts to mitigate D.P.'s symptoms or mitigate D.P.'s risk over time. Tr. 125:1–11.

42. Respondent acted outside the standard of care for D.P. by failing to adequately manage a patient on incredibly high doses of opioids and by failing to take vital signs at most of D.P.'s medical visits. Vital signs were taken at approximately 20% of D.P.'s visits, which, for a patient on such high doses of opioids, was outside the standard of care in California. Tr. 125:12–23.

43. Respondent's medical histories for D.P. do not even come close to meeting the standard of care to justify the incredibly high doses of opioids he prescribed to D.P. Tr. 125–26.

44. D.P.'s self-assessed pain score has not changed significantly despite being dropped from Respondent's incredibly

high 6,000 MME to UC San Diego's 1,000 MME range. Tr. 126–27.

45. Dr. Munzing testified that, while there is no upper limit on the amount of opioids a patient can be prescribed by a practitioner, it would be hard to justify a dosage of over 500 MME. Dr. Munzing further testified that he has spoken with many pain management practitioners and lectured to a lot of pain management practitioners, and he has never had any pain management practitioner say that 1,000 MME is medically acceptable, much less two, three, four, five, or six thousand MME. Tr. 128–29.

46. On April 18, 2017, Respondent prescribed D.P. 280 tablets of 10 mg oxycodone, 280 tablets of 15 mg oxycodone, 280 tablets of 20 mg oxycodone, and 280 tablets of 30 mg oxycodone for 4,500 MME per day and 160 tablets per day (do not fill until April 26, 2017). Tr. 129–31; ALJ Ex. 4 at Stip. Y, 5–8; GX 9 at 2. Dr. Munzing testified this level of MME is astronomical. He testified he had never seen a dosage that high, including in his review of over 150 overdose deaths. Dr. Munzing also testified that Respondent's medical records were nowhere close to justifying this level of opioid prescribing. Lastly he testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 132–34; GX 8 at 246–53.

47. D.P. received a second set of prescriptions on April 18, 2017, for 280 tablets of 10 mg oxycodone, 280 tablets of 15 mg oxycodone, 280 tablets of 20 mg oxycodone, and 280 tablets of 30 mg oxycodone that could be filled on April 18, 2017. These are the same dosages as the prescriptions to be filled on April 26, 2017, another 4,500 MME per day and 160 tablets per day. ALJ Ex. 4 at Stip. Y, 9–12; GX 9 at 3. Dr. Munzing testified that Respondent's medical records lacked sufficient information to justify this level of opioid prescribing, including no record of vital signs or an examination. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 134–36; GX 8 at 261–69.

48. Between March 17, 2017, and January 3, 2018, Respondent repeatedly prescribed D.P. a combination of 280 tablets of 10 mg oxycodone, 280 tablets of 15 mg oxycodone, 280 tablets of 20 mg oxycodone, and 280 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 1–105. Each time the MME was 4,500. Dr. Munzing testified these prescriptions were outside the standard of care as there was no attempt to taper D.P.'s

opioid dose, and in fact, Respondent increased the opioid dosage by adding oxymorphone, 40 mg, 150 tablets, and oxycodone prescriptions on numerous occasions, including on May 30, 2017, July 3, 2017, and July 11, 2017. Between March 17, 2019, and January 3, 2018, Respondent acted outside the standard of care by failing to justify either the high doses of opioids or the spikes in MME by adding oxymorphone to D.P.'s prescriptions. Over this time period Respondent acted outside the standard of care by failing to document D.P.'s vital signs. Dr. Munzing testified that the prescriptions written to D.P. between March 17, 2019, and January 3, 2018, were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 136–43, GX 8 at 261–69, 372–78, 534–38.

49. On May 30, 2017, July 3, 2017, and July 11, 2017, Respondent prescribed D.P. 280 tablets of 10 mg oxycodone, 280 tablets of 15 mg oxycodone, 280 tablets of 20 mg oxycodone, 280 tablets of 30 mg oxycodone, and 150 tablets of oxymorphone 40 mg. This was a dosage of 5,100 MME. Tr. 140:9; ALJ Ex. 4 at Stip. Y, 21–23, 25–26, 38–47.

50. On November 13, 2018, Respondent prescribed D.P. a combination of 245 tablets of 10 mg oxycodone, 270 tablets of 15 mg oxycodone, 285 tablets of 20 mg oxycodone, and 260 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 259–62. This represents an increase in Respondent's opioid dosage for D.P., which Dr. Munzing testified was “astronomically high.” Tr. 149–50. Dr. Munzing testified that in issuing these prescriptions, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids, failing to properly taper D.P. off such high opioid doses, and failing to document vital signs. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 149–51; GX 8 at 1352–57; ALJ Ex. 4 at Stip. Y, 259–62.

51. On December 18, 2018, Respondent prescribed D.P. a combination of 280 tablets of 10 mg oxycodone, 309 tablets of 15 mg oxycodone, 325 tablets of 20 mg oxycodone, and 297 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 259–62. This represents an increase in Respondent's opioid prescribing to D.P., which Dr. Munzing testified was “astronomically high.” Tr. 149–50. Dr. Munzing testified that in issuing these

prescriptions, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids, failing to properly taper D.P. off such high opioid doses, and failing to document vital signs. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 151–52; GX 8 at 1447–52; ALJ Ex. 4 at Stip. Y, 259–62.

52. On January 10, 2019, Respondent prescribed D.P. a combination of 245 tablets of 10 mg oxycodone, 270 tablets of 15 mg oxycodone, 285 tablets of 20 mg oxycodone, and 260 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 291–94. Dr. Munzing testified that in issuing these prescriptions, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids, failing to properly taper D.P. off such high opioid doses, failing to document informed consent, failing to document an appropriate medical examination, and failing to document vital signs. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 152–54; GX 8 at 1480–84; ALJ Ex. 4 at Stip. Y, 291–94.

53. Between December 11, 2018, and April 30, 2019, Respondent consistently prescribed D.P. a combination of at least 245 tablets of 10 mg oxycodone, 270 tablets of 15 mg oxycodone, 285 tablets of 20 mg oxycodone, and 260 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 275–378.

54. On February 11, 2019, Respondent prescribed D.P. a combination of 245 tablets of 10 mg oxycodone, 270 tablets of 15 mg oxycodone, 285 tablets of 20 mg oxycodone, 260 tablets of 30 mg oxycodone, 105 tablets of 10 mg oxycodone, 114 tablets of 15 mg oxycodone, 120 tablets of 20 mg oxycodone, and 114 tablets of 30 mg oxycodone. ALJ Ex. 4 at Stip. Y, 311–18. This amounts to approximately 6,144 MME. Dr. Munzing testified that in issuing these prescriptions, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids, failing to document the reason for the eight oxycodone prescriptions, failing to properly taper D.P. off such high opioid doses and instead significantly escalating his MME level, failing to document informed consent, failing to document an appropriate medical examination, and failing to document vital signs. Dr. Munzing testified that these

prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 155–57; GX 8 at 1543; ALJ Ex. 4 at Stip. Y, 327–42, 361–68.

55. Respondent continued this level of prescribing on March 4, 2019, March 13, 2019, and April 15, 2019. ALJ Ex. 4 at Stip. Y, 327–42, 361–68. This amounted to 6,000 MME per day. Tr. 158:3–6. Dr. Munzing testified that Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 157–59; GX 8 at 1607; ALJ Ex. 4 at Stip. Y, 327–42, 361–68.

56. Between April 2019 and June 2019, Respondent prescribed D.P. combinations of 10 mg oxycodone, 15 mg oxycodone, 20 mg oxycodone, and 30 mg oxycodone that caused D.P.'s daily MME to bounce between 4,000 MME and 6,000 MME. Tr. 159:4–19; ALJ Ex. 4 at Stip. Y, 351–423. Dr. Munzing testified that on each occasion, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 159; ALJ Ex. 4 at Stip. Y, 351–423.

57. On July 8, 2019, Respondent prescribed D.P. a combination of at 233 tablets of 10 mg oxycodone, 265 tablets of 15 mg oxycodone, 115 tablets of 20 mg oxycodone, 103 tablets of 30 mg oxycodone, 100 tablets of 10 mg oxycodone, 111 tablets of 15 mg oxycodone, 270 tablets of 20 mg oxycodone, 240 tablets of 30 mg oxycodone, 14 tablets of oxymorphone 40 mg, and 6 tablets of oxymorphone 40 mg. ALJ Ex. 4 at Stip. Y, 429–38. This is over 6,000 MME per day. Tr. 160:7–23. Dr. Munzing testified that in issuing these prescriptions, Respondent acted outside the standard of care by failing to document a reason to continue to prescribe D.P. this level of opioids. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 160–61; ALJ Ex. 4 at Stip. Y, 429–38.

58. There is a gap in Respondent's medical records for D.P. from June 25, 2019 until September 30, 2019. Tr. 161–162; GX 8 at 1847.

59. Respondent continued to issue prescriptions for 10 mg oxycodone, 15 mg oxycodone, 20 mg oxycodone, and

30 mg oxycodone in July and August 2019. Stip. Y, 424–76. During this time, Respondent acted outside the standard of care by failing to taper D.P.'s opioid levels, which ranged between 3,000 and 6,000 MME. Tr. 163:4–17. Respondent acted outside the standard of care by issuing prescriptions to D.P. without any medical record documentation. Tr. 162–63. Dr. Munzing testified that due to these failures, these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 162–63; ALJ Ex. 4 at Stip. Y, 424–76.

60. UC San Diego doctors described Respondent's opioid prescribing to D.P. as “massive amounts,” “very high amounts,” and “exorbitant amounts.” Tr. 165:2–6. Over time, UC San Diego stabilized D.P.'s multitude of medical conditions and was then able to put him on a steady tapering program which reduced his MME to 1,000 and then down to the 700 MME range. Tr. 165, 167.

61. Respondent acted outside the standard of care by prescribing extremely high doses of opioids without referring D.P. for a mental health evaluation. Tr. 175:12–25.

62. Dr. Munzing testified that the overall care provided by Respondent for D.P. was incredibly dangerous and certainly not within the standard of care. In fact, Dr. Munzing testified D.P. is lucky to be alive. Tr. 176:17–23.

63. Dr. Munzing testified that, based on the extremely high MMEs, the failure to provide a medical justification, and the failure to properly document treatment including vital signs and appropriate physical examinations, all of the stipulated prescriptions Respondent issued to D.P. were issued outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 176–77.

64. Dr. Munzing testified that Respondent acted outside the standard of care in prescribing to P.S. because he found no evidence in the medical records that Respondent had informed consent discussions with P.S. to make him aware of the specific risks from taking high dose opioids, including addiction, overdose or death. Tr. 178, 182.

65. Respondent failed to take or document vital signs in approximately 50% of his visits with P.S. and performed or documented a musculoskeletal examination less than 20% of the time; these were necessary because P.S. was being treated for musculoskeletal complaints with opioid medications. Tr. 183:12–21. Respondent failed to obtain a significant medical history regarding P.S.'s anxiety before

prescribing him anti-anxiety medications, lorazepam and alprazolam, and failed to try non-controlled substances to treat P.S.'s anxiety. Tr. 183–84.

66. Respondent acted outside the standard of care in California by prescribing P.S. high dose opioids, mid-300 MME range, in combination with a benzodiazepine; these prescriptions did not correlate to any significant improvement in P.S.'s condition, but the combination put P.S. at significant risk. Tr. 184–85.

67. On February 17, 2017, Respondent prescribed to P.S. 45 tablets of morphine sulfate ER 30 mg, 45 tablets of morphine sulfate ER 60 mg, and 45 tablets of Dilaudid (hydromorphone), 8 mg and 30 tablets lorazepam 1 mg. This was a dosage of 366 MME. GX 11 at 1; ALJ Ex. 4 at Stip. BB, 1–4; Tr. 185–86. Dr. Munzing testified that 366 MME is classified as very high; four times the CDC's recommended high of 90. Tr. 185:5–15; GX 5.

68. Dr. Munzing testified that in issuing these prescriptions, Respondent acted outside the standard of care by failing to document a reason to prescribe P.S. this level of opioids, failing to document a reason for prescribing the dangerous combination of high dose opioids with a benzodiazepine, failing to document informed consent, failing to document an appropriate medical examination, failing to properly perform a psychiatric examination, and failing to assess the increased risk to P.S. due to his age and history of acute embolism and deep venous thrombosis. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 187–189; GX 10 at 46; ALJ Ex. 4 at Stip. BB, 1–4.

69. Between February 17, 2017, and September 16, 2019, Respondent prescribed to P.S. 45 tablets of morphine sulfate ER 30 mg, 45 tablets of morphine sulfate ER 60 mg, and 45 tablets of hydromorphone 8 mg, and a benzodiazepine (either lorazepam 1 mg or alprazolam 0.5 mg). ALJ Ex. 4 at Stip. BB, 1–175.

70. Based on a review of P.S.'s entire medical record Dr. Munzing testified that Respondent acted outside the standard of care by failing to document a reason to prescribe P.S. this level of opioids, failing to document a reason for prescribing a benzodiazepine, failing to document a reason for prescribing the dangerous combination of high dose opioids with a benzodiazepine, failing to document informed consent, failing to taper P.S. off of high dose opioids,

failing to document an appropriate medical examination, failing to properly perform a psychiatric examination, and failing to use a non-benzodiazepine to treat P.S.'s anxiety. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 190–95; ALJ Ex. 4 at Stip. BB, 1–175.

71. P.S. had an aberrant urine drug screen on March 3, 2017, (GX 10 at 67–78) when P.S. tested negative for lorazepam, which was inconsistent with P.S.'s February 17, 2017 lorazepam prescription. Tr. 196–97; ALJ Ex. 4 at Stip. BB, 4. Respondent acted outside that standard of care by failing to address or resolve the aberrant result. Tr. 198–200; *see also*, e.g. GX 10, at 89.

72. P.S. had aberrant urine drug screens on the following dates:

a. April 14, 2017, (GX 10 at 106–08) when P.S. tested negative for lorazepam, which was inconsistent with P.S.'s March 29, 2017 lorazepam prescription. Tr. 200–01; ALJ Ex. 4 at Stip. BB, 8.

b. June 19, 2017, (GX 10 at 195–97) when P.S. tested negative for lorazepam, which was inconsistent with P.S.'s June 5, 2017 lorazepam prescription. Tr. 201–02; ALJ Ex. 4 at Stip. BB, 15.

c. August 7, 2017, (GX 10 at 275–77) when P.S. tested negative for lorazepam, which was inconsistent with P.S.'s July 25, 2017 lorazepam prescription. Tr. 202–03; ALJ Ex. 4 at Stip. BB, 32.

d. September 12, 2017, (GX 10 at 324–26) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s August 16, 2017 alprazolam prescription. Tr. 203–04; ALJ Ex. 4 at Stip. BB, 40.

e. October 10, 2017, (GX 10 at 359–61) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s September 12, 2017 alprazolam prescription. Tr. 209–10; ALJ Ex. 4 at Stip. BB, 44. P.S. also tested negative for morphine, which was inconsistent with P.S.'s morphine prescriptions on September 12, 2017. Tr. 210:7–12; ALJ Ex. 4 at Stip. BB, 41–43.

f. November 3, 2017, (GX 10 at 389–91) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s October 23, 2017 alprazolam prescription. Tr. 211–12; ALJ Ex. 4 at Stip. BB, 48. P.S. also tested negative for morphine, which was inconsistent with P.S.'s morphine prescriptions on October 23, 2017. Tr. 212:18–23; ALJ Ex. 4 at Stip. BB, 45–47.

g. September 11, 2018, (GX 10 at 754–56) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s August 28, 2018 alprazolam prescription. Tr. 213; ALJ Ex. 4 at Stip.

BB, 114. P.S. also tested negative for morphine, which was inconsistent with P.S.'s morphine prescriptions on August 14, 2018. Tr. 213–14; ALJ Ex. 4 at Stip. BB, 111–13.

h. October 3, 2018, (GX 10 at 793–95) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s September 25, 2018 alprazolam prescription. Tr. 214–15; ALJ Ex. 4 at Stip. BB, 122. P.S. also tested negative for morphine, which was inconsistent with P.S.'s morphine prescriptions on September 25, 2018. Tr. 215:6–11; ALJ Ex. 4 at Stip. BB, 119–21. P.S. tested positive for alcohol, which is an aberrant result because the P.S.'s Controlled Substance Agreement stated a patient should not be drinking alcohol with these medications. There is an increased risk to a patient for overdose or death when combining alcohol and controlled substance medications. Tr. 217:7–25.

i. December 21, 2018, (GX 10 at 911–13) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s December 10, 2018 alprazolam prescription. Tr. 222–23; ALJ Ex. 4 at Stip. BB, 132. P.S. also tested negative for morphine, which was inconsistent with P.S.'s morphine prescriptions on December 10, 2018. Tr. 212:18–23; ALJ Ex. 4 at Stip. BB, 133–35.

j. March 26, 2019, (GX 10 at 1105–07) when P.S. tested negative for alprazolam, which was inconsistent with P.S.'s March 1, 2019 alprazolam prescription. Tr. 224; ALJ Ex. 4 at Stip. BB, 144.

78. Respondent acted outside that standard of care by failing to address, resolve, and document each of the above aberrant drug screen results. Tr. 198–204, 211, 213–14, 218–21, 224; *see also*, e.g. GX 10 at 807–11.

79. Dr. Munzing testified that P.S.'s numerous aberrant drug screens and Respondent's failure to address or resolve those aberrant drug screens contributed to his opinion that Respondent's prescriptions to P.S. were outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 200–04, 211, 222.

80. Respondent acted outside the standard of care in prescribing controlled substances to J.K. by failing to provide appropriate treatment and examinations for her migraine pain. Respondent prescribed controlled substance but failed to do a proper neurological examination, including imaging scans, CT, or MRI, to ensure that other diagnoses are not being missed. Tr. 229–31.

81. Respondent acted outside the standard of care when prescribing the

relevant controlled substances to J.K. by failing to take a comprehensive medical history including an examination of mental health issues, failing to address and document J.K.'s use of alcohol and other drugs in the past, failing to perform a neurological exam or refer to a neurological subspecialist for J.K.'s migraine treatment, failing to take vital signs, and prescribing controlled substances without resolving numerous aberrant drug screens. Tr. 232–33.

82. Respondent's medical records for J.K. did not document that she was being treated for cancer pain, as her cancer treatment ended in 2014. Tr. 233–34.

83. Dr. Munzing testified that Respondent acted outside the standard of care when prescribing opioids to J.K. by failing to properly document justification for the high dosages of opioids he prescribed to J.K. Tr. 234:2–7.

84. Dr. Munzing testified that Respondent acted outside the standard of care when prescribing opioids and benzodiazepines to J.K. by failing to obtain and document proper informed consent for the risks of high dose opioids (300 to 400 MME), as well as the increased risk posed by Respondent prescribing a combination of opioids and benzodiazepines. Tr. 235:7–22.

85. On November 28, 2016, Respondent prescribed to J.K. a fentanyl patch, 75 micrograms per hour (change every 4 hours), 180 tablets of Percocet 10/325 mg, and 30 tablets of Soma 350 mg. This is 366 MME. GX 13 at 1; ALJ Ex. 4 at Stip. EE, 1–3; Tr. 236–37. Dr. Munzing testified that 366 MME is classified as very high, four times the recommended CDC limit of 90. Tr. 185, 237; GX 5.

86. Dr. Munzing testified that in issuing the November 28, 2016 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, failing to document informed consent, and failing to document an appropriate medical examination. Dr. Munzing also testified that J.K.'s expressed pain level of 4 did not justify this high dose of opioids and possibly not even a low dose of opioids. Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 235–41; GX 13 at 1; GX 12 at 3–8; ALJ Ex. 4 at Stip. EE, 1–3.

87. On January 19, 2017, Respondent prescribed J.K. a fentanyl patch with 12 micrograms per hour, a fentanyl patch

with 50 micrograms per hour, a fentanyl patch with 75 micrograms per hour, 90 tablets of Percocet 10/325 mg (two week supply), and 15 tablets of Soma 350 mg. GX 13 at 2; ALJ Ex. 4 at Stip. EE, 4–8. This was 440 MME. Tr. 242–43; GX 12 at 30. Respondent failed to document a justification for the increase in opioid medication prescribed to J.K. GX 12 at 29–34; Tr. 242–43. Dr. Munzing testified that Respondent failed to perform an appropriate examination, failed to document J.K.'s present illness, and put J.K. at much higher risk based on minimal information. *Id.* As such, Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. *Id.*; ALJ Ex. 4 at Stip. EE, 4–8.

88. Respondent prescribed J.K. a combination of fentanyl patch, Percocet 10/325 mg, and Soma 350 mg, on a number of occasions between November 28, 2016, and March 14, 2017. ALJ Ex. 4 at Stip. EE, 1–14; GX 13 at 1–5. Dr. Munzing testified, based on a review of all of J.K.'s medical records, that on each occasion, Respondent failed to justify the very high doses of opioids prescribed to J.K. and failed to justify the dangerous combination of opioids with Soma. As such, Dr. Munzing testified that these prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. *Id.*; Tr. 240–46.

89. On August 18, 2017, Respondent prescribed J.K. 180 tablets of Percocet 10/325 mg, 60 tablets of oxymorphone ER 40 mg, 60 tablets of OxyContin 40 mg, and 60 tablets of Soma, 350 mg. ALJ Ex. 4 at Stip. EE, 19–22; GX 13 at 9. This is approximately 450 MME. Tr. 244:1–15.

90. Dr. Munzing testified that in issuing the August 18, 2017 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to taper J.K. off high dose opioids and in fact increasing her dosage, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, failing to document informed consent, failing to document an appropriate medical examination, and a failing to document a justification for switching J.K. from a fentanyl patch to oxymorphone and OxyContin. As such, Dr. Munzing testified that the August 18, 2017 prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 243–47; GX 13 at

9; GX 12 at 109–16; ALJ Ex. 4 at Stip. EE, 19–22.

91. On November 10, 2017, Respondent prescribed J.K. 180 tablets of Percocet 10/325 mg, 60 tablets of oxymorphone ER 40 mg, 60 tablets of OxyContin 40 mg, and 90 tablets of Soma 350 mg. ALJ Ex. 4 at Stip. EE, 23–26; GX 13 at 10–12. This was approximately 450 MME. Tr. 244, 247.

92. Dr. Munzing testified that in issuing the November 10, 2017 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to taper J.K. off high dose opioids, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, and failing to document informed consent. Dr. Munzing also testified that J.K.'s expressed pain level of 4 did not justify this high dose of opioids and possibly not even a low dose of opioids. As such, Dr. Munzing testified that the November 10, 2017 prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 247–48; GX 13 at 10–12; GX 12 at 129–35; ALJ Ex. 4 at Stip. EE, 23–26.

93. On January 8, 2018, Respondent prescribed J.K. 180 tablets of Percocet 10/325 mg, 60 tablets of oxymorphone ER 40 mg, 60 tablets of OxyContin 40 mg, and 90 tablets of Soma 350 mg. ALJ Ex. 4 at Stip. EE, 29–32; GX 13 at 14–16. This was approximately 450 MME. Tr. 244, 248.

94. Dr. Munzing testified that in issuing the January 8, 2018 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to taper J.K. off high dose opioids, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, failing to provide an objective assessment and plan, failing to record vital signs, and failing to document informed consent. Dr. Munzing also testified that Respondent failed to record a pain level for J.K. As such, Dr. Munzing testified that the January 8, 2018 prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 248–49; GX 13 at 10–12; GX 12 at 144–48; ALJ Ex. 4 at Stip. EE, 29–32.

95. On February 9, 2018, Respondent prescribed J.K. 180 tablets of Percocet 10/325 mg, 60 tablets of oxymorphone ER 40 mg, 60 tablets of oxycodone 36 mg, and 120 tablets of Soma, 350 mg. ALJ Ex. 4 at Stip. EE, 33–36; GX 13 at 17–20. This is 430 MME. Tr. 250:14–18.

96. Dr. Munzing testified that in issuing the February 9, 2018 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to taper J.K. off high dose opioids, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, failing to record vital signs, failing to document an objective assessment, failing to provide information about alcohol use, failing to document the subjective/objective assessment and plan in the medical records, failing to document reasoning for changing J.K.'s opioid medications, and failing to document informed consent. As such, Dr. Munzing testified that the February 9, 2018 prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 249–55; GX 13 at 17–20; GX 12 at 149–56; ALJ Ex. 4 at Stip. EE, 33–36.

97. On October 16, 2018, Respondent prescribed J.K. 10 fentanyl patches 75 mg, 120 tablets of morphine sulfate IR 15 mg, 120 tablets of Soma 350 mg, 180 tablets of Percocet 10/325 mg, and 60 tablets of morphine sulfate ER 60 mg. ALJ Ex. 4 at Stip. EE, 54–57; GX 13 at 36–37. This is 330 MME. Tr. 255:9–23.

98. Dr. Munzing testified that in issuing the October 16, 2018 prescriptions to J.K., Respondent acted outside the standard of care by failing to document a reason to prescribe J.K. this level of opioids, failing to taper J.K. off high dose opioids despite J.K. having left-over opioids from previous prescriptions, failing to document a reason for prescribing the dangerous combination of high dose opioids with Soma, failing to record vital signs, failing to document an appropriate examination, failing to address the fact that J.K. indicated she is not following Respondent's dosing instructions as she was taking left-over medications, failing to provide information about alcohol use, failing to provide an objective assessment or plan, failing to document informed consent, and for prescribing controlled substance despite J.K. having possible suicidal ideations. As such, Dr. Munzing testified that the October 16, 2018 prescriptions were written outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 255–61; GX 13 at 36–37; GX 12 at 272–75; ALJ Ex. 4 at Stip. EE, 54–57.

99. [J.K. had aberrant urine drug screens on the following dates:]

a. April 27, 2017, (GX 12 at 62–64) when J.K. tested positive for THC and amphetamines, neither of which were

prescribed to J.K. by Respondent. Tr. 261–66.

b. May 12, 2017, (GX 12 at 74–76) when J.K. tested positive for amphetamines, which were not prescribed to J.K. by Respondent. Tr. 267–68.

c. September 15, 2017, (GX 12 at 109–11) when J.K. tested positive for amphetamines, which were not prescribed to J.K. by Respondent. Tr. 269:5–13.

d. February 9, 2018, (GX 12 at 159–61) when J.K. tested positive for THC and amphetamines, neither of which were prescribed to J.K. by Respondent. Tr. 270–71.

e. March 19, 2018, (GX 12 at 180–82) when J.K. tested positive for THC and amphetamines, neither of which were prescribed to J.K. by Respondent. Tr. 273:5–14.

f. June 4, 2018, (GX 12 at 221–23) when J.K. tested positive for THC and amphetamines, neither of which were prescribed to J.K. by Respondent. Tr. 274, 276.

g. July 31, 2018, (GX 12 at 241–43) when J.K. tested positive for THC and amphetamines, neither of which were prescribed to J.K. by Respondent. Tr. 277–78.

100. Respondent acted outside that standard of care by failing to address or resolve the above aberrant results. Tr. 198–200, 247–50, 266–67, 268–73, 277–79; GX 12 at 67–70, 80–83, 125–28, 165–68, 185–92, 227–31, 247–50.

101. Dr. Munzing testified that each of J.K.'s [unresolved] aberrant drug screens contributed to his opinion that Respondent's prescriptions to J.K. were outside the usual course of professional practice and not for a legitimate medical purpose. Tr. 267, 279.

102. Based on Dr. Munzing's review of J.K.'s oncology records, he was able to confirm that Respondent's opioid prescriptions to J.K. were not related to [treatment of end stage cancer]. Tr. 279–81.

103. Dr. Munzing testified that Respondent's prescribing to D.L. did not meet the standard of care in California. The controlled substance prescriptions issued to D.L. were not medically justified as prescribed and were not issued in the usual course of professional practice. Further, Respondent's medical histories for D.L. were not consistent with the standard of care due to their brevity and lack of detail. The histories did not include even limited information regarding a mental health or alcohol and drug use. The medical history also lacks necessary details regarding any chronic medical problems D.L. has and how they might

interact with the controlled substances prescribed by Respondent. Tr. 282–83.

104. On January 23, 2018, Respondent prescribed D.L. 60 tablets of lorazepam 1 mg, 240 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 90 tablets of morphine sulfate IR 30 mg, 21 tablets of oxymorphone HCl 5 mg, and 30 tablets Lunesta 3 mg. ALJ Ex. 4 at Stip. HH, 1–6; GX 15 at 12–17. This is 455 MME. Tr. 285–86.

105. Lunesta poses a risk of habit forming addiction. It is also a respiratory depressant, which, when added to an opioid prescription, increases the risk of overdose or overdose death. Tr. 286:13–21.

106. Combining opioid, Lunesta and benzodiazepine prescriptions creates an even greater risk to a patient due to the combination of multiple respiratory depressants. Tr. 287:1–11.

107. Dr. Munzing testified based on his review of D.L.'s medical records that the high MME, the combination of the controlled substances, and the risks associate with prescribing these combinations to an elderly patient makes the January 23, 2018 prescriptions issued to D.L. outside the usual course of professional practice and not for a legitimate medical purpose. Tr. 287; ALJ Ex. 4 at Stip. HH, 1–6; GX 15 at 12–17.

108. On February 23, 2018, Respondent prescribed to D.L. 60 tablets of lorazepam 1 mg, 240 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg, and 30 tablets Lunesta 3 mg. ALJ Ex. 4 at Stip. HH, 7–11; GX 15 at 18–22; Tr. 288:1–8.

109. In issuing the February 23, 2018 prescriptions to D.L., Respondent acted outside the standard of care by failing to justify the increase in morphine sulfate 30 mg from 90 to 120 tablets, failing to document an appropriate examination, failing to justify the overall level of opioid prescribing to D.L., failing to justify the lorazepam prescription, and failing to document informed consent for the significant risk to the patient with this combination of controlled substances. As such, Dr. Munzing testified that the February 23, 2018 prescriptions to D.L. by Respondent were prescribed outside the usual course of professional practice and were not for a legitimate medical purpose. ALJ Ex. 4 at Stip. HH, 7–11; GX 15 at 18–22; Tr. 289–90; GX 14 at 355–60.

110. On March 23, 2018, Respondent prescribed to D.L. 60 tablets of lorazepam 1 mg, 240 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg, and 30

tablets of Lunesta 3 mg. ALJ Ex. 4 at Stip. HH, 12–16; GX 15 at 23–27.

111. In issuing the March 23, 2018 prescriptions to D.L., Respondent acted outside the standard of care by failing to justify in the medical records the high level of opioid prescribing to D.L., failing to document a justification for the combination of high dose opioids with the Lunesta and the benzodiazepine, failing to document a physical exam and the fact that D.L. described her pain level only at a 5. As such, Dr. Munzing testified that the March 23, 2018 prescriptions to D.L. by Respondent were prescribed outside the usual course of professional practice and were not for a legitimate medical purpose. ALJ Ex. 4 at Stip. HH, 12–16; GX 15 at 23–27; Tr. 289–90; GX 14 at 368–73.

112. On May 4, 2018, Respondent prescribed to D.L. 60 tablets of lorazepam 1 mg, 210 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg, and 30 tablets Lunesta 3 mg. This was approximately 420 MME. ALJ Ex. 4 at Stip. HH, 17–21; GX 15 at 28–31; Tr. 293–294.

113. In issuing the May 4, 2018 prescriptions to D.L., Respondent acted outside the standard of care by failing to justify in the medical records the high level of opioid prescribing to D.L., failing to document a justification for the combination of high dose opioids with the Lunesta and the benzodiazepine, failing to make any efforts to taper D.L.'s morphine levels, and in fact, increasing those levels since 2016, and failing to document a physical exam. As such, Dr. Munzing testified that the May 4, 2018 prescriptions issued to D.L. by Respondent were outside the usual course of professional practice and were not for a legitimate medical purpose. ALJ Ex. 4 at Stip. HH, 17–21; GX 15 at 28–31; GX 14 at 405–09; Tr. 294.

114. On May 31, 2018, Respondent prescribed to D.L. 240 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg. This was approximately 435 MME. ALJ Ex. 4 at Stip. HH, 22–24; GX 15 at 32–34; Tr. 295.

115. In issuing the May 31, 2018 prescriptions to D.L., Respondent acted outside the standard of care by failing to justify in the medical records the increased number of Percocet tablets, failing to justify in the medical records the high level of opioid prescribing to D.L. particularly because D.L.'s pain was only at a pain level of 5 out of 10, failing to taper D.L.'s high level of

opioids, and failing to document a physical exam. As such, Dr. Munzing testified that the May 31, 2018 prescriptions issued to D.L. by Respondent were outside the usual course of professional practice and were not for a legitimate medical purpose. ALJ Ex. 4 at Stip. HH, 22–24; GX 15 at 32–34; GX 14 at 440–45; Tr. 295–98.

116. On July 31, 2018, December 4, 2018, and January 3, 2019, Respondent prescribed to D.L. 60 tablets of 210 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg, and 30 tablets Lunesta 3 mg. On July 31, 2018 (OK to fill August 9, 2018), Respondent prescribed to D.L. 60 tablets of 210 tablets of Percocet 10/325 mg, 60 tablets of morphine sulfate ER 100 mg, 120 tablets of morphine sulfate IR 30 mg. ALJ Ex. 4 at Stip. HH, 25–39.

117. In issuing these prescriptions to D.L., Respondent acted outside the standard of care by failing to justify in the medical records the high level of opioid prescribing, failing to document a justification for the combination of high dose opioids with the Lunesta, failing to make any efforts to taper D.L.'s morphine levels, failing to document vital signs for each visit, and failing to document a physical exam. As such, Dr. Munzing testified these prescriptions to D.L. were issued outside the usual course of professional practice and were not for a legitimate medical purpose. ALJ Ex. 4 at Stip. HH, 25–39; Tr. 298–301.

118. D.L. had an aberrant urine drug screen on March 23, 2018, (GX 14 at 379–81) when D.L. tested negative for oxycodone, which was inconsistent with D.L.'s February 23, 2018 oxycodone prescription. Tr. 302; ALJ Ex. 4 at Stip. HH, 9. D.L. also tested negative for lorazepam, which was inconsistent with D.L.'s lorazepam prescription on February 23, 2018. Tr. 302; ALJ Ex. 4 at Stip. HH, 7. Respondent acted outside that standard of care by failing to address or resolve the aberrant results. Tr. 302–03; GX 14 385–90.

119. D.L. had an aberrant urine drug screen on April 20, 2018, (GX 14 at 395–97) when D.L. tested negative for oxycodone, which was inconsistent with D.L.'s March 23, 2018 oxycodone prescription. Tr. 303; ALJ Ex. 4 at Stip. HH, 14. D.L. also tested negative for lorazepam, which was inconsistent with D.L.'s lorazepam prescription on March 23, 2018. Tr. 303–04; ALJ Ex. 4 at Stip. HH, 12. Respondent acted outside that standard of care by failing to address or resolve the aberrant results. Tr. 304–05; GX 405–09.

120. D.L. had an aberrant urine drug screen on January 31, 2019, (GX 14 at 577–79) when D.L. tested negative for oxycodone, which was inconsistent with D.L.'s January 3, 2019 oxycodone prescription. Tr. 305–06; ALJ Ex. 4 at Stip. HH, 38. Respondent acted outside that standard of care by failing to address or resolve the aberrant results. Tr. 307–08; GX 588–93, 609–13.

121. Dr. Munzing testified that D.L.'s aberrant drug screens and Respondent's failure to address or resolve the aberrant drug screens were facts that contributed to his opinion that Respondent's prescriptions to D.L. were outside the usual course of professional practice and were not for a legitimate medical purpose. Tr. 211, 303.

122. Due to the importance of ensuring a patient has given informed consent regarding treatment, including prescriptions for controlled substances, the standard of care in California requires that practitioners document in the medical records specifically what was discussed with a patient and specifically what risks and benefits the patient was informed of prior to the patient's agreement to the treatment or receipt of controlled substances. Tr. 460–62.

123. Respondent testified that in his medical practice, his documentation of certain areas of patient care did not meet the standard of care. Tr. 488, 490.

124. Patient D.P. testified that, when seen by nurse practitioners at Respondent's practice, they did not necessarily discuss the risks or issues with taking high dose opioid medications. Tr. 524:12–22.

125. Patient D.P. testified that he did not have his vital signs taken at every medical visit with Respondent. Tr. 525:8–11.

126. Patient D.P. testified that Respondent did not conduct a full physical exam at each of D.P. visits. Tr. 525:15–20.

127. Patient D.P. testified he was able to calculate the MME for his opioid prescriptions. He calculated that his MME with the doctor treating him prior to Respondent was between 4,500 and 4,800. Tr. 534–35.

128. Patient D.P. testified he did not know how high his MME level was with the opioid medications prescribed by Respondent. Tr. 535:9–12.

129. Patient D.P. testified his knew his current MME level to be 752. Tr. 535:16–17.

130. Respondent testified he suspected J.K. to have an undiagnosed brain injury, and he admitted that he

did not assess or treat the brain injury.^{*X} Tr. 554:2–16.

131. Dr. Mark Wiederhold, Dr. Joseph Shurman, and Respondent all confirmed that the standard of care requires a doctor to have complete and accurate documentation of the patient's treatment in the patient's medical records. Tr. 595, 719–20, 779.

132. Dr. Mark Wiederhold, Dr. Joseph Shurman, and Respondent confirmed that the standard of care requires patient medical records to contain sufficient documentation to justify controlled substance prescriptions issued to that patient. Tr. 595, 720, 779–80.

133. Dr. Mark Wiederhold, Dr. Joseph Shurman, and Respondent confirmed that the standard of care requiring complete and accurate documentation in a patient's medical record is for the protection, not only of the patient, but for the protection of the doctor as well. Tr. 595, 720, 780.

134. Dr. Mark Wiederhold, Dr. Joseph Shurman, and Respondent confirmed that a doctor is ultimately responsible for preparing complete and accurate medical records. Tr. 595–96, 720, 780.

135. Dr. Mark Wiederhold, Dr. Joseph Shurman, and Respondent confirmed that doctors are responsible for reviewing their patient's medical records to assure that the records created by the doctor are accurate and complete. Tr. 596, 780.

136. Dr. Joseph Shurman testified that it is much easier to taper off immediate release opioids than off the extended release opioids. Tr. 685:16–20.

137. Ultimately, Dr. Shurman testified he spent approximately 10 hours reviewing over 4,000 pages of medical records in this case. Tr. 719:7–15; GX 8, 10, 12, 14.

138. Dr. Joseph Shurman confirmed that doctors must justify their use of high dose opioids in the medical records. Tr. 721:1–4.

139. On the basis of his review of the D.P. medical records, Dr. Shurman found no evidence that Respondent documented any discussions he had with D.P. regarding the various risks associated with taking high dose opioids, including the risk of death. Tr. 722–24.

140. Dr. Shurman testified that a long term goal for a patient on high-dose opioids would be to attempt to gradually taper the patient off the high-dose opioids. Tr. 725:12–16.

141. Dr. Shurman testified that the standard of care for a pain doctor in San

Diego is measured by what a reasonable pain specialist would do in the San Diego area. Tr. 733:13–25.

142. Dr. Munzing, Respondent's two experts, and Respondent all agreed that the standard of care in California requires sufficient documentation in the medical record to justify controlled substance prescriptions. Tr. 89–90, 245, 595, 720, 779–80.

143. In May 2019, D.P. was seen by Respondent or someone in Respondent's office on a weekly basis. Tr. 782:19–22. D.P. went to Respondent's office on May 21, 2019, May 29, 2019, June 4, 2019, June 11, 2019, June 17, 2019, and June 25, 2019. Tr. 782–83.

144. D.P. would notify Respondent if D.P. had any problems filling any of his prescriptions. Tr. 783:2–5.

145. In August 2019, D.P.'s pharmacy began to severely restrict his ability to fill oxycodone prescriptions at that pharmacy. Tr. 783:6–10; GX 9 at 397.

146. As of August 14, 2019, the pharmaceutical distributor Cardinal would not replenish the Respondent's oxycodone prescriptions issued to D.P. GX 9 at 397; Tr. 784–85.

147. Due to Cardinal's refusal to replenish Respondent's oxycodone prescriptions to D.P., the pharmacy would only fill a 48–72 hour prescription for all four oxycodone prescriptions issued by Respondent. *Id.*

Analysis

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked and any applications should be denied, because as recently as September 16, 2019, Respondent violated federal and California law by issuing prescriptions for controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. ALJ Ex. 1, p. 3, ¶ 6. The Government further alleges that the Respondent's conduct reflects negative experience in prescribing with respect to controlled substances under 21 U.S.C. 823(f)(2), and shows that Respondent has failed to comply with applicable federal and state laws relating to controlled substances under 21 U.S.C. 823(f)(4). ALJ Ex. 1, p. 2, ¶ 2.

In the adjudication of a revocation or suspension of a DEA COR, the DEA bears the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e).^{*Y}

^{*Y} Remaining text moved to the Sanctions section *infra* or omitted for brevity and clarity.

California Law

The applicable laws in this case include:^{*Z} Cal. Health & Safety Code § 11153(a), requiring that a “prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner practicing in the usual course of his or her professional practice;” Cal. Bus. & Prof. Code § 2242(a) which includes in the definition of unprofessional conduct subject to sanction, “[p]rescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication”); and Cal. Bus. & Prof. Code § 725(a), which includes in the definition of unprofessional conduct subject to sanction, “[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs”

Failure To Maintain Complete and Accurate Records

[The “Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,” requires that a practitioner “keep accurate and complete records, including but not limited to, records of the patient's medical history, physical examinations of the patient, the treatment plan objectives and the treatments given, and the rationale for any changes in treatment.” GX 3, at 59. Not surprisingly, the failure to maintain accurate and complete patient records itself is outside the usual course of professional practice and represents a violation of the California standard of care. Tr. 89.] The Respondent concedes, [though not unequivocally,] that he failed to maintain complete and accurate patient charts [in “some areas,”] which he agreed is required by the standard of care. Tr. 488, 779. Beyond the lack of detail, there is evidence of missing records. He has acknowledged [at least some recordkeeping] failures, has taken steps to educate himself as to this critical aspect of the standard of care, and has credibly vowed to correct this failure. Tr. 822–24; RX W.

Dr. Munzing's opinions and conclusions regarding the Respondent's failure to appropriately document within the charts are fully credible. [Dr. Munzing opined that to meet the standard of care in California, a provider must ensure that the medical history, examination, other evaluations, treatment plans, objectives, informed consent, treatments, medications,

^{*Z} Omitted text pursuant to *supra* n. *D.

^{*X} This fact is not material to my decision in this matter; it appears to assert failures in Respondent's medical treatment of J.K. that extend beyond Respondent's failures with regard to prescribing controlled substances.

rationale for prescribing, and agreement with the patient are well-documented in the medical records. Tr. 89–90. He further testified that the standard of care required the resolution of aberrant drug screens to be well documented before continuing to prescribe. Tr. 99, 310–11. Dr. Munzing repeatedly opined that Respondent acted beneath the standard of care with regard to documentation in many of the categories where documentation was required for each of the four individuals. For D.P. alone, Dr. Munzing testified that the documented medical history was “actually pretty poor,” Tr. 125, that “the documentation was far below what was necessary [to] justify the incredibly high dosing,” Tr. 126, “there’s no vital signs, there’s no examination, there’s [a] limited amount of information . . . [and] the documentation is inadequate . . . and we still don’t have an informed consent.” Tr. 132, 154.]

I find that the Government has proven the allegations as to the Respondent’s failure to appropriately document within the patients’ medical records as to each of the subject patients.⁴³ The failure to document is closely related to a practitioner’s responsibility to establish informed consent.⁴⁴

The Government expert, Dr. Munzing, appropriately based many of his opinions on the absence of supporting notes in the patient chart, applying the truism, “if it is not documented, it did not happen.” Tr. 406. [Dr. Munzing testified, that “[i]f one doesn’t document something and there’s no other way to verify it, then you can’t necessarily infer that it’s happened.” Tr. 405–06. This opinion is consistent with prior DEA decisions, stating, based on credible expert testimony, 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 57749, 57760 (2019). The RD stated that, because in this case there was] credible testimony from patients and credible testimony from the Respondent regarding aspects of undocumented but otherwise appropriate treatment protocol, [the ALJ was] not prepared to accept the blanket conclusion that because Respondent failed to include treatment notes in the record, such treatment was not provided.⁴⁵ [I do not agree with the ALJ’s suggestion that because a few undocumented actions

were corroborated by testimony, all of the undocumented actions must have occurred in accordance with Respondent’s testimony. Here, the testimony from the two testifying patients was limited and corroborated only a few of the undocumented actions, such as obtaining informed consent. The vast majority of Respondent’s actions remained uncorroborated by either documentary evidence or testimony.]

The Government argues that the failure to document alone renders the resultant prescriptions illegitimate under the standard of care, and therefore unjustified. Although the Respondent may indeed have performed certain treatment protocols that were not documented in the medical records, I accept the Government’s conclusion that the failure to document alone violates the standard of care. The Government also alleges a number of clinical failings by the Respondent. These will be addressed as well.

Discussion as to Patient D.P.^{*BB 45}

The major dispute between the parties regarding D.P. was the Respondent’s failure to titrate D.P. from the astronomical levels of opioids on which D.P. came to the Respondent, 3,000 MME per day. As D.P. was a returning patient and well-known to the Respondent, the Respondent decided to provide treatment even though he had never treated a patient who was prescribed such high levels of opioids. The Respondent and his expert, Dr. Shurman, both recognized the importance of reducing D.P.’s MME. D.P. testified that he was “reluctant[t]” to lower his dosage because he was functioning pretty well and his pain range was between a two-to-four out of ten. Tr. 520. The Respondent testified that D.P. did not tolerate titration, either suffering withdrawal or manifesting physical reactions when attempts were made. The Respondent attempted alternative treatment, and took positive measures, such as providing D.P. with Narcan, but ultimately decided to continue D.P. on the opioid medication regimen. Additionally, there was an admission by D.P. to the Respondent that he had taken medication not as prescribed. An insurance company stepped in and greatly restricted the

pharmacy’s ability to fill the subject prescriptions. Rather than re-evaluating his treatment strategy, the Respondent adjusted his prescribing schedule to work around that restriction. Ultimately, although Sharp Hospital’s attempt at titration failed as too rapid, UC San Diego Pain Management successfully titrated D.P. down to 700 MME.^{*CC}

[Dr. Shurman and Dr. Munzing both testified that the standard of care required Respondent to try to taper down D.P.’s dosage slowly. Tr. 146–48, 653–54. Instead of attempting titration as required by the standard of care], the patient chart reveals a sporadic treatment strategy, with MME levels [first increasing] and then alternating between 3,500 and 6,000 MMEs.^{*DD} [Dr. Munzing testified that Respondent’s prescribing was beneath the standard of care because “rather than tapering, [he] episodically increases the dosages,” and there was no documented titration plan. Tr. 137, 145–46. Dr. Shurman excused the high MME levels Respondent prescribed to D.P. without titrating because he concluded Respondent’s monitoring of D.P. was sufficient to ensure D.P. remained relatively safe. Tr. 658. This position is not convincing over Dr. Munzing’s credible testimony. I cannot find that monitoring, assuming for the sake of argument that it was sufficient, can overcome Respondent’s failure to document medical justification for prescriptions as high as 6,000 MME and failure to document a treatment plan for titration. Dr. Munzing testified that these levels were the highest MME that he had ever seen. Tr. 117. He further described this level of prescribing to be “incredibly dangerous.” Tr. Tr. 177.]

I find that the evidence supports [Dr. Munzing’s opinion] that the Respondent’s [prescribing to] D.P. was dangerous and outside the standard of care. Dr. Munzing’s opinions relating to the Respondent’s evaluation and monitoring of D.P. and the Respondent’s overall [prescribing to] D.P. as being outside the standard of care are accepted.⁴⁶

The Government has sustained its burden as to the allegations relating to the Respondent’s [issuance of the prescriptions at issue to] D.P.

^{*BB} The RD included an extensive write up of the OSC’s allegations pertaining to each of the four individuals at issue prior to discussing each individual. The allegations are set forth clearly in the OSC, *see* ALJ Ex. 1, and are summarized above; therefore, for brevity, I have omitted each of the four sections outlining the allegations pertaining to each of the four individuals. The ALJ’s analysis of those allegations remains.

⁴⁵ [Omitted pursuant to n.*BB.]

^{*CC} Some text has been moved or omitted from this paragraph for clarity.

^{*DD} Sentence relocated and additional text omitted for clarity.

⁴⁶ Although disputed during the hearing, even with the use of oximetrics at visits, I accept Dr. Munzing’s opinion that vital signs should have been taken at each of D.P.’s visits, due to the high levels of MME and his concurrent medical issues.

⁴³ [Omitted for brevity and relevance.]

^{*AA} Remaining text omitted for legal clarity.

⁴⁴ [Text from the body and from the footnote omitted for legal clarity.]

Discussion as to Patient J.K.

There were several disputes as to the propriety of [the prescriptions issued to] J.K. Again, Dr. Munzing's conclusions are based on his review of the medical chart. Dr. Munzing criticized Respondent for failing to order a neurological exam to determine if J.K.'s migraines could be caused by a tumor or other organic issue. This was confronted by the Respondent's memory, undocumented in the chart [and not supported by other testimony or evidence], that J.K. had a "workup with a neurologist" in the past. The Respondent had seen J.K. when he worked for a medical group prior to reopening his own practice. It seems unusual that the Respondent did not obtain J.K.'s medical records from the prior group, which requires the tribunal to assume that she had this prior workup. I will give him the benefit of the doubt that he properly evaluated her need for further testing.*^{EE}

The next controversy relates to the Respondent's use of opioids to treat intractable migraines, which Dr. Munzing characterized as being beneath the standard of care [because "opioids are not generally a very successful treatment for chronic headaches." Tr. 231.] Dr. Shurman presented the opinion that some physicians, including himself, believe opioids are an appropriate treatment for migraines within the standard of care. The Respondent testified that he treated J.K. with Botox, but her insurance eventually failed to cover these injections. Without further detail or explanation from the experts, I [decline to decide whether or not the prescribed opioids were appropriate to treat J.K. migraines.] *^{FF}

The next dispute relates to Dr. Munzing's assertion that J.K.'s ongoing pain could not be attributed to cancer pain as J.K. had been cancer free for four years. The Respondent counters that chemotherapy can produce residual pain syndromes, which can extend after treatment has ended. Dr. Munzing did not address whether the treatment for cancer can produce ongoing pain issues. Therefore, I credit the Respondent's explanation. [However, I also credit Dr. Munzing's testimony that regarding

cancer pain, "[t]here really wasn't anything in [J.K.'s medical records]. The focus of the treatment was not anything related to cancer per se." Tr. 233–34. To prescribe to J.K. within the standard of care for pain stemming from cancer or cancer treatment, Dr. Munzing testified that Respondent's "medical history certainly should have included more specifics in regards to the diagnosis of breast cancer." Tr. 234.]

The next controversy relates to J.K.'s abnormal urine drugs screens (UDS). J.K.'s UDS failed to reveal the fentanyl she had been prescribed in the form of a patch. According to the Respondent, when confronted with this discrepancy, J.K. explained that the patches would fall off prematurely due to her perspiring. She would then put on a new patch prematurely, and run out of her prescribed patches prior to her next medical visit. Dr. Shurman confirmed this scenario was not uncommon and noted that J.K. was on hormone replacement. I accept Dr. Shurman's opinion that this abnormal UDS was properly investigated and found to be reasonably explained. [However, I also agree with Dr. Munzing that the required documentation showing that Respondent addressed and resolved the aberrant results was missing from the medical records, which is itself beneath the standard of care. Tr. 266–67; 268–69; 270; 279.]

The next UDS controversy relates to THC appearing in J.K.'s UDS, which had not been prescribed by the Respondent. Dr. Munzing noted the danger in combining marijuana with J.K.'s prescribed medications. The Respondent testified that J.K. had been prescribed Marinol during her cancer treatment, and she apparently continued to take it after obtaining it from a dispensary. The Respondent testified that he cautioned her about potential side effects and contraindications in conjunction with the other medications she was taking, but the testimony was not supported by documentation in the medical records. Dr. Shurman opined that marijuana derivatives were commonly prescribed now and did not present a significant danger to J.K. [Even assuming that the aberrant result was investigated and handled appropriately, I find in accordance with Dr. Munzing's testimony that Respondent's failure to document that he investigated and resolved the aberrant results was beneath the standard of care. Tr. 266–67; 268–69; 270; 279.]

The next abnormal UDS relates to the appearance of amphetamine, which was not prescribed by the Respondent. The Respondent recognized that the UDS results indicated the dose was likely

pharmaceutical. The Respondent remembered that J.K. was being seen by a psychiatrist, who prescribed Adderall. The Respondent testified that he cautioned J.K. regarding taking her medications as prescribed. I find that the Respondent investigated and properly handled this UDS. [Even assuming that the aberrant result was investigated and handled appropriately, I find in accordance with Dr. Munzing's testimony that Respondent's failure to document that he investigated and resolved the aberrant results was beneath the standard of care. *Id.*]

The next issue related to J.K. taking in excess of the opioid dosage prescribed. Tr. 256–57. The Respondent testified that he counseled J.K. regarding the dangers of doing so. However, no further cautionary steps were taken. J.K. had a dosage of approximately 400 MME at this time and the MME had been increased by the Respondent. [With regard to patients who are not taking medications as prescribed, Dr. Munzing testified that "there are significant risks of either taking too much [and] potentially overdosing [or] taking too little and potentially going through withdrawal." Tr. 411. Accordingly, Dr. Munzing testified, when "a prescriber learn[s] about it, you need to counsel the patient and document that." *Id.*] Dr. Shurman suggested that it was normal for patients to take medications other than as strictly prescribed, and it was appropriate to average their compliant versus noncompliant behavior. That position is contrary to common sense, and I must reject it. At such high levels of MME, taking an opioid as prescribed must be more than a suggestion [in light of the risks identified by Dr. Munzing]. Allowing a patient to increase [or decrease] dosages on his own can be dangerous. I find the Respondent's [failure to take action and/or document the action taken with regard to addressing J.K.'s admission that she did not take the medication as prescribed] was insufficient to satisfy the standard of care.

The next controversy relates to attempts to titrate J.K. down on her opioids, Soma, and benzodiazepine. In reviewing the record, the Respondent described his efforts to get J.K. to "buy in" on the idea of titrating her off the high level MME she was on and off her benzodiazepine dose.*^{GG} The Respondent also defended the medication regimen as it allowed J.K. to work and to complete her ADLs. However, according to Dr. Munzing, the standard of care requires practitioners to

*^{EE} I do question how Respondent could credibly testify both that J.K. had previous workups from a neurologist such that no other imaging studies were necessary, and that Respondent suspected that J.K. had some elements of undiagnosed brain injury based her behavioral issues, continued headaches, and her history of being the victim of physical abuse. Tr. 552, 554. Ultimately the evidence on this issue was not fully developed by expert testimony and is not material to my decision in this matter.

*^{FF} Text modified for clarity.

*^{GG} Text omitted for clarity.

reduce the MME to the level that balances the highest level of activity with the least MME. Dr. Munzing described the danger inherent in the combination of controlled substances that J.K. found herself on, “the Holy Trinity,” as prescribed by the Respondent. When J.K. returned to the Respondent as a patient, she was on a fentanyl patch, which the Respondent continued. He also prescribed a short-acting opioid for breakthrough pain, and Soma to diffuse muscle spasms. He later concluded that Soma was not the right medication for J.K. and attempted to have her “buy in” to titrate off of it. Even crediting the Respondent’s explanation for prescribing, which is not documented in the record, I credit Dr. Munzing’s opinion that having J.K. on that dangerous combination was unjustified and contrary to the standard of care.

As to J.K.’s threat of suicide, Dr. Munzing opined that the Respondent’s actions fell below the standard of care. Dr. Munzing testified that the standard of care for a doctor with a patient on high-dose opioids and has suicidal ideations is to get that patient immediate care, review the patient’s mental health history, work with other providers such as a psychiatrist, and come up with a plan. Tr. 259. Typically, Dr. Munzing testified, a doctor would not continue the medications being prescribed and would work to develop a possible management plan for the patient. The standard of care would also require that the doctor have a discussion with the patient on a subsequent visit. Tr. 259–60. [Dr. Shurman did not offer an opinion on this issue.] The Respondent testified that he believed that J.K. [had no intention of following through on her] threat, which he believed was based solely on her fear that she would be without her medication. Tr. 564. Accordingly, the Respondent continued her prescription regime. I agree with Dr. Munzing’s [credible opinion] that the Respondent’s reaction, [particularly his continued prescribing without modification following J.K.’s suicide threat,] was outside the standard of care.

[In addition to the above areas, Dr. Munzing testified that with regard to prescribing to J.K., Respondent failed to take an appropriate history and examination to narrow down the cause of the headaches, Tr. 229; failed to adequately document the risks and attempts to moderate the risks, Tr. 235, 446, 448, 458; failed to obtain informed consent, *id.*; failed to medically justify the high levels of opioids or the dangerous combinations of opioids with Soma and a stimulant, Tr. 235–40; failed

to document justification for increased dosages and changes to prescriptions, Tr. 244–45; and failed to take or document vital signs at multiple visits, Tr. 248–49. Based on these failures, I find in accordance with Dr. Munzing’s testimony that each of the relevant prescriptions issued to J.K. were issued outside the usual course of professional practice and beneath the standard of care. Tr. 281.]

Discussion as to Patient P.S.

The following issues were controverted by the parties. The most significant controversy was related to P.S.’s repeated abnormal UDS. He tested negative for lorazepam and alprazolam several times, which were prescribed controlled substances. He also tested negative for morphine, a prescribed pain medication. Dr. Munzing faulted the Respondent for not immediately contacting P.S. to investigate and to monitor him more closely. The Respondent believed that P.S., who suffered from chronic pain and an anxiety disorder, had good days and bad days and would refrain from taking his medications some days, but was not abusing his medication. The Respondent also tried to refer P.S. to a psychiatrist. Dr. Shurman viewed P.S. as a challenging patient. He viewed the abnormal UDS, as long as they were not ongoing, as something which at least requires the practitioner’s attention. Dr. Shurman believed the Respondent followed the standard of care with P.S. because he had a discussion with him and followed him closely with CURES, urine screens, etc., to ensure there was not an ongoing problem.^{*HH} Tr. 692–94.

I find Dr. Munzing’s testimony more credible in this instance. P.S. was prescribed dangerous combinations of medications with serious concurrent medical issues. He also suffered from mental health issues, but was not under psychiatric care. He demonstrated a propensity to refrain from taking his medication if he felt he did not need it and had fifteen abnormal drug screens, including several evidencing alcohol use. [As Dr. Munzing testified, there are significant risks for taking too much or too little medication. Tr. 411. And here, there is no indication that the Respondent documented that he investigated the aberrant results, counseled P.S. regarding them, or resolved the aberrancies; Dr. Munzing testified Respondent acted beneath the standard of care. Tr. 198–202.] I

^{*HH} Again, this position is not convincing. I cannot find that monitoring, assuming for the sake of argument that it was sufficient, can overcome Respondent’s other failures, here, the failure to resolve repeated aberrant drug screens.

therefore find that the Respondent continuing prescribing to P.S. without modification, despite multiple aberrant drugs screens, fell below the standard of care.^{*II}

The next matter in controversy was the justification for prescribing opioids and a benzodiazepine together. The Respondent prescribed P.S. morphine, hydromorphone, and a benzodiazepine at 366 MME per day. P.S. had serious concurrent health issues, including an embolism and DVT. The Respondent did not address these issues at the hearing, either through his own testimony or through his expert’s testimony, except in the most general terms that his prescriptions were within the standard of care. As noted by Dr. Munzing, the patient’s medical record does not reveal Respondent’s rationale for issuing these prescriptions. Dr. Munzing’s opinion is rational, logical, consistent with his other opinions and with the credible facts of the case, and was uncontroverted. Accordingly, I accept Dr. Munzing’s opinion. I therefore find that the Respondent’s actions to prescribe opioids and benzodiazepine fell below the standard of care because the Respondent failed to justify this dangerous medication regimen for P.S.

[In addition to the above areas, Dr. Munzing testified that with regard to prescribing to P.S., Respondent failed to obtain an adequate medical history, Tr. 183–84; failed to adequately document the full range of risks of using opioids and a benzodiazepine, Tr. 178; failed to obtain informed consent, Tr. 183, 374; failed to medically justify the controlled substance prescriptions, Tr. 190–97; failed to document justification for changes to prescriptions, Tr. 179–81, 193; failed to take or document vital signs at multiple visits and failed to perform proper musculoskeletal exams, Tr. 183. Based on these failures, I find in accordance with Dr. Munzing’s testimony that each of the relevant prescriptions issued to J.K. were issued outside the usual course of professional practice and beneath the standard of care. Tr. 193.]

Discussion as to Patient D.L.

The first matter in controversy relates to the Respondent’s inability to taper D.L. down from the high doses of medication. Despite acknowledging the importance of reducing the MME, D.L. would eventually reach 455 MME under the Respondent’s care. Dr. Munzing explained that although the patient’s chart suggests her opioid dosage was going to be reduced, the medical records

^{*II} Text omitted for legal clarity.

reflect that the opioid dosage was actually increased over time. [Dr. Shurman opined that “at the time she [first] came to Dr. Wynn” it would not have been appropriate for Respondent to immediately taper D.L. from her dosages without “getting a feel for [her], get[ting] a history, urine drug screens, CURES, etc.” Tr. 703. Dr. Shurman went on to testify that D.L. continued getting the same combination of medications for a while, *id.*, but then never offered further testimony regarding the appropriateness of tapering after the first visits.] I credit Dr. Munzing’s opinion that the [prescriptions issued to] D.L. were not consistent with the standard of care. Documenting an intent to reduce an opioid dosage, yet increasing it, is troubling. The Respondent provided no justification for increasing D.L.’s MME to such a high level.

The next matter in controversy relates to the indication of abnormal UDS. Dr. Munzing notes there is no explanation in the file for the aberrancies, nor any indication the Respondent investigated the matter or discussed any aberrant drug screens with D.L. The Respondent testified that he had ordered pharmacogenetic testing for D.L. and discovered she had an altered gene expression that related to how she responded to morphine. He explained this condition was the reason for her aberrant UDSs, although nothing in the record showed that there was any discussion regarding the aberrant drug screens. Tr. 308. I therefore find that the Respondent did investigate and address the abnormal UDS results [but did not document resolution of the aberrant drug screens appropriately.]

Dr. Munzing cited D.L.’s age as an aggravating factor relative to Respondent’s prescribing as she was in her late 60’s/early 70’s. Tr. 287. She presented with a history of colon cancer, then experienced uncontrolled pain due to polyneuropathy, hip pain, and a failed spine surgery. The Respondent testified that he investigated hip injections and a pain pump as possible alternatives. Dr. Shurman noted that throughout treatment, D.L.’s subjective pain scale remained at a five or six out of ten. He considered this a success. [Dr. Shurman also offered his opinion that Respondent’s prescribing to D.L. was appropriate because of “how he handled it;” specifically that “he followed [her] closely, CURES, urine screens, kept an eye on [her] mentally” Tr. 708.]⁷⁷

⁷⁷ Again, this position is not convincing. Based on Dr. Munzing’s credible expert testimony, I cannot find that monitoring, assuming for the sake of argument that it was sufficient, can overcome Respondent’s other failures.

[In addition to the above areas, Dr. Munzing testified that with regard to prescribing to P.S., Respondent: Failed to obtain an adequate medical history, Tr. 283; failed to adequately document the full range of risks of using opioids with a benzodiazepine and a sleeping agent, Tr. 286; failed to obtain informed consent, Tr. 297–98; failed to consider or document consideration of alternative strategies to manage D.L.’s pain, Tr. 300; failed to medically justify the controlled substance prescriptions, Tr. 289; and failed to take or document vital signs or perform proper musculoskeletal exams at multiple visits, Tr. 294, 296, 300. Based on these failures, I find in accordance with Dr. Munzing’s testimony that each of the relevant prescriptions issued to J.K. were issued outside the usual course of professional practice and beneath the standard of care. Tr. 287, 290, 292, 294, 299, 301, 308, 309.]

Government’s Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a)(4). At the outset, I find that the Government has demonstrated and met its burden of proof in support of its allegations relating to Respondent’s prescribing of controlled substances to patients D.P., J.K., D.L., and P.S.

Public Interest Determination: The Standard

[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.” ^{KK} 21 U.S.C. 824(a)(4).] ⁴⁷ Evaluation of the following factors has been mandated by Congress in determining whether maintaining

^{KK} Respondent argued that his continued registration is consistent with the public interest because he provides medical services to a community that is “very under-served, under-privileged and in need of doctors like him.” Tr. 18. The CSA requires me to consider Respondent’s controlled substance dispensing experience, among other things, not whether Respondent’s practice of medicine as a whole was beneficial to the community. 21 U.S.C. 823(f)(2); see *Frank Joseph Stirlacci, M.D.*, 85 FR 45229, 45239 (2020) (declining to accept community impact arguments); see also *Richard J. Settles, D.O.*, 81 FR 64940, 64945 n.16 (2016).

⁴⁷ [This text replaces the ALJ’s original text and omits his original footnote for clarity.]

such registration would be inconsistent with the “the public interest”:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
 - (2) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.
 - (3) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
 - (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
 - (5) Such other conduct which may threaten the public health and safety.
- 21 U.S.C. 823(f). “These factors are . . . considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003).

Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant’s registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); see also *Morall* at 173–74; *Henry J. Schwarz, Jr., M.D.*, 54 FR 16422, 16424 (1989). Moreover, the Agency is “not required to make findings as to all of the factors,” *Hoxie*, 419 F.3d at 482; see also *Morall*, 412 F.3d at 173. [Omitted for brevity.] The balancing of the public interest factors “is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009).

The Government’s case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of the Respondent’s COR based primarily on conduct most aptly considered under Public Interest Factors Two and Four.⁴⁸

⁴⁸ 21 U.S.C. 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding [Respondent’s prescribing practices] (Factor One). [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. See *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011) (“The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent’s DEA certification is consistent with the public interest.”)] Likewise, the record contains no evidence that the 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,

*[Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances]*LL*

According to the Controlled Substances Act's implementing regulations, a lawful controlled substance order or prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).⁴⁹

Respondent has demonstrated substantial experience as a licensed California doctor since 2000; he has been board certified in Physical Medicine and Rehabilitation since 2004, and has maintained a subspecialty certification in Pain Management since 2006. RX 1, at 1. Respondent has practiced pain medicine in a variety of settings including in affiliation with hospitals, in group settings, and most recently rebuilding his preexisting private practice since 2016. Tr. 469–76. At the time of the hearing, Respondent testified that he served 600 active patients, and handled a total of approximately 7,000 medical appointments a year. Tr. 830. The Agency assumes that Respondent has prescribed legally, except where the Government has established violations of the law. Here, Respondent's treatment of the four patients as alleged in the OSC demonstrates that his prescribing practices fell beneath applicable standard of care.

I find that the Government's expert credibly testified, as supported by

there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay*, M.D., 75 FR 49956, 49973 (2010). 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.* The Government does not identify Factor Five as being relevant.]

*LL The ALJ evaluated Factors 2 and 4 in separate sections and I have combined and expanded on his analysis herein.

⁴⁹ [Footnote omitted along with original text for legal clarity.]

California law and California's Guide to the Laws and Guidelines for Prescribing, that the standard of care in California for prescribing controlled substances requires a physician to, amongst other things, obtain a detailed medical history, perform and document a physical examination, come up with a diagnosis, perform a risk stratification, and develop and document a customized management plan. Tr. 79. Thereafter, the physician must monitor the patient on a periodic and regular basis, which includes obtaining vital signs including blood pressure, heart rate, and respiratory rate at every office visit for patients on high dose opioids. Tr. 79–80, 87, 851–52. The standard of care further requires that physicians maintain complete and accurate records documenting all of the above steps in detail. Tr. 79–80. The standard of care requires that patients be notified of the risks and benefits of the use of controlled substances and the availability of any alternatives, that patients give informed consent, and that the notification of risks and informed consent be documented. Tr. 85–86.

I also found above, in accordance with Dr. Munzing's testimony, that Respondent issued each of the relevant controlled substance prescriptions to the four patients at issue without taking a proper medical or mental health history; conducting a sufficient physical, mental, or neurological examination; recording pain levels; documenting an appropriate treatment plan; documenting medical justification for the high levels of prescribed opioids; documenting discussion of the risks of the prescribed controlled substances and informed consent; monitoring the patient including taking key vital signs; and/or resolving inconsistent urine drug screen results. *See supra* Findings of Fact. I further found that each of the relevant prescriptions Respondent issued to the four individuals were issued without a legitimate medical purpose, outside the usual course of professional practice and beneath the standard of care in California. Accordingly, I find that Respondent violated 21 CFR 1306.04(a).

Indeed, 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. *See Kaniz Khan Jaffery*, 85 FR 45667, 45685 (2020). For each of the four individuals, Respondent repeatedly, amongst other things, failed to have medical justification for issuing high dosages of opioids often in combination with other dangerous controlled substances, failed

to properly obtain or document obtaining informed consent, and failed to properly monitor by taking or documenting the taking of vital signs.

Agency decisions highlight the concept 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 19450, 19464 (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 at 45686. Dr. Munzing testified that complete and accurate records are necessary because "bottom line[,] it's a patient safety issue [I]f this patient ends up seeing another provider, whether it be the primary care provider, another subspecialist, or the emergency room . . . they know . . . how the patient was, here's why they were taking what they're taking as far as a justification, and the patient is aware of the risk and accepts those risks." Tr. 89. The extreme failures in Respondent's documentation extended to each of the four individuals.

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 28643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51592, 51601 (1998)). "Diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA'" *Id.* (citing *Roy S. Schwartz*, 79 FR 34360, 34363 (2014)). 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 66138, 66148 (2010)).

With regard to California law, just as I found a violation of 21 CFR 1306.04(a), I find that Respondent repeatedly issued controlled substance prescriptions what were not "for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice," in violation of

Cal. Health & Safety Code § 11153(a). California law also prohibits “[p]rescribing, dispensing, or furnishing” controlled substances “without an appropriate prior examination.” Cal. Bus. & Prof. Code § 2242(a). Crediting Dr. Munzing’s testimony, I have found that the Respondent failed to conduct an appropriate prior physical, mental, and/or neurological examination with regard to his prescribing to each of the four individuals at issue, which I find violates Cal. Bus. & Prof. Code § 2242(a). Crediting Dr. Munzing’s testimony, I find that Respondent acted outside the bounds of these laws with regard to his prescribing to each of the four patients.

Finally, California law prohibits “[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs.” Cal. Bus. & Prof. Code § 725(a). The Government cited to the sheer volume of prescriptions issued by Respondent to the four individuals at issue as its only proof of a violation of Cal. Bus. & Prof. Code § 725(a). While I note that the prescriptions were voluminous, the Government did not elicit testimony from its expert to establish that Respondent’s prescribing to the four individuals at issue constituted clearly excessive prescribing in California. Accordingly, the Government has not met its burden of establishing a violation of Cal. Bus. & Prof. Code § 725(a).]

Here for the reasons discussed *supra*, I find the Government has proven by substantial evidence that Respondent violated California Business & Professional Code § 2242(a), California Health & Safety Code § 11153(a), and 21 CFR 1306.04(a).^{*MM}

[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 that supports the revocation of his registration. *See Wesley Pope*, 82 FR 14944, 14985 (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 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, comas, and deaths. GX 6, at 1. Dr. Munzing testified that “[w]hen an individual is on a combination of an opiate and a benzodiazepine, the increased risk of overdose death goes up approximately tenfold.” Tr. 86.

I credit Dr. Munzing’s repeated testimony that Respondent was prescribing “astronomical” and “incredibly high doses” of individually dangerous drugs; one patient was prescribed over 6,000 MME which Dr. Munzing testified was “the highest [he had] ever seen.” Tr. 118, 125, 132. Moreover, many of the prescriptions at issue were issued in dangerous combinations including the “holy trinity” the “new holy trinity” and other dangerous combinations as have been discussed. Tr. 189, 238, 264. Dr. Munzing testified that for D.P. alone, the prescribing “was incredibly dangerous. The patient is lucky to be alive.” Tr. 177. In contrast, Respondent testified that he was not aware of any of his patients having suffered the consequence of an overdose due to medications he prescribed. Tr. 748. Even if I credit Respondent’s testimony that none of his patients overdosed, I cannot rule out the real potential for addiction. Dr. Munzing testified, that “addictive issue[s] with benzodiazepines and opiates is a very real risk and potentially life-altering risk.” Tr. 458. Even the individuals’ exposure to the increased risks caused by the dangerous combinations of the controlled substances Respondent prescribed could be harmful.

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 many controlled-substance prescriptions Respondent issued without complying with the California standard of care. *See supra* Factors Two and Four.]

[Sanction^{*NN}

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 18882, 18910 (2018) (collecting cases). Here, Respondent has not established 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 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.*, 53 FR 21931, 21932 (1988)). “‘Moreover, because “past performance is the best predictor of future performance,” *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.’” *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009) (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); *see also Jackson*, 72 FR at 23853; *John H. Kennedy, M.D.*, 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the

^{*MM} Sentence modified to remove findings regarding California laws that were either dropped from the Government’s case, *see supra* n.*D, or not established.

^{*NN} I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

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, [the ALJ found that] the Respondent had accepted responsibility that his record-keeping was not appropriate or sufficient.⁵⁰ [At the hearing, Respondent agreed with his attorney's question that "looking back now at these records, [there were areas that he felt were] less than adequate." Tr. 488. But he also testified, "I would say that some areas are appropriate." *Id.* The testimony does not contain sufficient detail for me to determine that Respondent fully understands the documentation requirement in the applicable standard of care and which "areas" were appropriate and which were not. Moreover, this limited acceptance of responsibility cannot be said to be unequivocal, or even complete.] Respondent has taken remedial steps to improve his documentation, including taking courses/trainings to bring himself into compliance with the critical documentation standard and hiring a scribe to help draft his patient notes, [but I find these remedial measures to be insufficient, without an unequivocal acceptance of responsibility, to convince me that Respondent's documentation failures will not recur]. Moreover, as to all of the allegations [unrelated to documentation failures], such as the dangerous prescribing of opioids in conjunction with benzodiazepines, failure to timely titrate, and ongoing failure to sufficiently monitor some of his patients, he has not accepted any responsibility.⁵¹

Egregiousness and Deterrence

[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 at 18910 (collecting cases). As Dr. Munzing testified, not all of Respondent's prescribing practices were beneath the standard of care.] Dr. Munzing conceded he believed each of the subject patients likely had genuine pain, and testified that the Respondent either ordered tests or attempted to

order tests, conducted UDS, prescribed Narcan, and made efforts to refer patients to specialists. Tr. 353. Dr. Munzing agreed that this is not a case of a doctor limiting treatment to merely giving patients pills to control their pain. Tr. 353–54. However, I find that [there were still substantial deviations from the standard of care such that each of the relevant prescriptions were issued in violation of the CSA and California law.] The proven misconduct is egregious and deterrence considerations weigh in favor of revocation. The proven misconduct involved the Respondent's repeated failure to maintain complete and accurate patient charts. The proven misconduct also involved the medically unjustified increase and maintenance of extraordinarily high MME levels for years at a time and combinations of dangerous medications.⁵² [For example, Respondent prescribed D.P. opioids reaching 6,000 MME, which Dr. Munzing testified "was incredibly dangerous. The patient is lucky to be alive." Tr. 176.]

I further find that deterrence considerations weigh in favor of revocation. [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 10083, 10095 (2009); *Singh*, 81 FR at 8248.] Allowing the Respondent to retain his COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite their wholesale failure to maintain accurate and complete records, increase MME levels to dangerous levels, and maintain those levels without documenting appropriate medical justification.⁵² Revoking the Respondent's COR communicates to registrants that DEA takes all failings under the CSA seriously and that severe violations will result in severe sanctions.

Lack of Candor

The degree of candor displayed by a registrant during a hearing is "an important factor to be considered in determining . . . whether [the registrant] has accepted responsibility" and in formulating an appropriate sanction. *Hills Pharmacy, LLC*, 81 FR 49816, 49845 (2016) (citing *Michael S. Moore*, 76 FR 45867, 45868 (2011)). The

Government has established that the Respondent lacked candor during his testimony by claiming the term "education" within a prescribing order reflected that the Respondent had then admonished the patient as to the risks of the subject medications. [The record at issue states in relevant part: "2. Medication refill Norco 10/325 . . . 3. Medication refill OxyContin 20 mg . . . 4. Education refill morphine sulfate ER 200 mg . . . 5. Medication refill morphine sulfate ER 30 mg" GX 14, at 40.] The context of term within the sentence makes it much more likely that the term "education" was a scrivener's error for the intended term, "medication." Tr. 756; GX 14 at p. 40.] This was a lapse in candor by the Respondent [which weighs against my ability to entrust him with a registration].

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. In evaluating Factors [Two and] Four of 21 U.S.C. 823(f), I find that the Respondent's COR is inconsistent with the public interest. Furthermore, I find that the Respondent has failed to overcome the Government's *prima facie* case [and that the sanction of revocation is warranted].⁵³

Therefore, I recommend that the Respondent's DEA COR No. BW7210759 should be *revoked*, and that any pending applications for modification or renewal of the existing registration, and any applications for additional registrations, be *denied*.⁵⁴

Mark M. Dowd,

U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C.

⁵⁰PP Remainder text omitted consistent with my findings above.

⁵¹PP The ALJ went on to state: "I note that Dr. Shurman has agreed to shepherd the Respondent in his future practice, and the Respondent has represented he is more than amenable to a conditional allowance of his registration. Dr. Munzing observed that this is not a case of a doctor limiting treatment to merely giving patients pills to control their pain. The Respondent either ordered tests or attempted to order tests and on occasion made efforts to refer patients to specialists. As the violations by the Respondent do not appear wanton and may have been more the result of inexperience, as the Respondent is a relatively young physician, and with relatively limited experience, the Administrator may consider permitting the Respondent to retain his registration with the

Continued

⁵⁰ [Omitted for clarity.]

⁵¹ Where a registrant has not accepted responsibility, it is not necessary to consider evidence of the registrant's remedial measures. *Id.* at 5498 n.33.

⁵² Sentence modified for clarity.

⁵³ [Omitted for legal clarity.]

requirement of weekly review and certification of his prescribing practices by Dr. Shurman, for a one year period.” As an initial matter, I cannot agree with the ALJ’s characterization that Respondent is inexperienced where he has been board certified in a pain management subspecialty for approximately sixteen years and has been a licensed practitioner in California for approximately twenty-two years. Regardless, with a regulated community of more than 1.8 million registrants and fewer than two-thousand Diversion Control Employees (See DEA FY 2022 Budget Request available at <https://www.justice.gov/jmd/page/file/1399016/download>), DEA must be able to rely on physicians to maintain

824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. BW7210759 issued to Brenton D. Wynn, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any other pending

complete and accurate medical records and otherwise comply with the CSA without overseeing weekly monitoring. Accordingly, I agree with the ALJ that revocation is the appropriate sanction.

applications for renewal or modification of this registration, as well as any other pending application of Brenton D. Wynn, M.D., for registration in California. This Order is effective May 23, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–08514 Filed 4–21–22; 8:45 am]

BILLING CODE 4410–09–P