

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–07]

Bradley H. Chesler, M.D.; Decision and Order

On January 8, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Bradley H. Chesler, M.D. (hereinafter, Respondent) of Escondido, California. Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. BC1317165 (hereinafter, COR or registration) and the denial of any pending application to modify or renew the registration and any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's "registration is inconsistent with the public interest." *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

On January 28, 2020, counsel for the Respondent requested a hearing, which, following a series of continuances due to the COVID–19 pandemic, was conducted August 25, 2020, through September 1, 2020, at the DEA Hearing Facility in Arlington, Virginia with parties, counsel, and witnesses participating by video teleconference (VTC). On November 5, 2020, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). On December 2, 2020, the Respondent filed exceptions to the Recommended Decision (hereinafter, Resp't Exceptions) and on December 15, 2020, the Government filed its Response to Government's Exceptions (hereinafter Gov't Response). I address the Respondent's Exceptions in the Recommendation Section, and throughout the relevant portions of the record and I issue the final order in this case following the RD. The ALJ transmitted the record to me on February 19, 2020. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein. *A

*A I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive

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

*B 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 recommendation findings of fact and conclusions of law below.

The Allegations

Although, as discussed in greater detail, *infra*, much of the OSC in this case is burdened with a drafting peculiarity, it is clear that the Government's intent is to seek revocation of the Respondent's COR based on the alleged commission of acts that would render the continuation of his registration status as being inconsistent with the public interest. *See* ALJ Ex. 1 at 1. At principal issue in the case is the Respondent's controlled substance prescribing as it relates to ten patients. Four of the patients (collectively, Board Patients) were the subject of findings by the Medical Board of California, and charts of the other six patients (collectively, Six Patients) were reviewed by the Government's medical expert.¹ On consent of the parties, the OSC in this matter was amended in accordance with a post-hearing order granting partial summary disposition. ALJ Ex. 25.

The Evidence

Stipulations

The parties entered into factual stipulations which were accepted prior to the commencement of the hearing. Accordingly, the following factual matters are deemed conclusively established in this case:

1. The Respondent currently possesses DEA COR No. BC1317165, which expires by its own terms on August 31, 2020.²

changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets 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 Specific patients are referred to by their initials in this Recommended Decision. The Board Patients include Patients A, B, D, and E, ALJ Ex. 1 ¶ 31, while Patients AA, BB, JD, DD, SM, and ET comprise the Six Patients, *id.* ¶¶ 8–30. The Government does not allege that there is any overlap between these two sets of patients. *Id.* at 11 n.14.

² Inasmuch as the parties agree that the Respondent has represented that he has made timely application for a renewal of his COR (ALJ

2. The Respondent was issued California Physician and Surgeon License No. A43963 on August 31, 1987.

3. Alprazolam is a Schedule IV Controlled Substance.

4. Carisoprodol is a Schedule IV Controlled Substance.

5. Fentanyl is a Schedule II Controlled Substance.

6. Hydrocodone is a Schedule II Controlled Substance.

7. Hydromorphone is a Schedule II Controlled Substance.

8. Lorazepam is a Schedule IV Controlled Substance.

9. Morphine is a Schedule II Controlled Substance.

10. Oxycodone is a Schedule II Controlled Substance.

11. Temazepam is a Schedule IV Controlled Substance.

The Government's Case

The Diversion Investigator

The Government presented the evidence of Diversion Investigator (hereinafter, DI). DI testified that he has been a DI for two and a half years, the majority of which has been in DEA's San Diego Field Office. Tr. 45–46. DI was the lead investigator in the case that culminated in the present charges. Tr. 46–47. He testified that the investigation into the Respondent began when DEA received information, around March 2019, from the Medical Board of California that an accusation was filed against the Respondent for over-prescribing controlled substances. Tr. 47. DI's testimony was used to authenticate a number of Government Exhibits,³ consisting of documents

Exs. 39, 40), his registration remains intact pending the conclusion of these proceedings. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

³ Government Exhibit 1 is a print-out of the Respondent's COR. Gov't Ex. 1. Government Exhibit 2 contains medical records for Patient AA. Gov't Ex. 2. Government Exhibit 3 comprises prescriptions for Patient AA, taken from Government Exhibit 2. Gov't Ex. 3. Government Exhibit 4 contains medical records for Patient BB. Gov't Ex. 4. Government Exhibit 5 comprises prescriptions for Patient BB, taken from Government Exhibit 4. Gov't Ex. 5. Government Exhibit 6 contains medical records for Patient JD. Gov't Ex. 6. Government Exhibit 7 comprises prescriptions for Patient JD, taken from Government Exhibit 6. Gov't Ex. 7. Government Exhibit 8 contains medical records for Patient DD. Gov't Ex. 8. Government Exhibit 9 comprises prescriptions for Patient DD, taken from Government Exhibit 8. Gov't Ex. 9. Government Exhibit 10 contains medical records for Patient SM. Gov't Ex. 10. Government Exhibit 11 comprises prescriptions for Patient SM, taken from Government Exhibit 10. Gov't Ex. 11. Government Exhibit 12 contains medical records for Patient ET. Gov't Ex. 12. Government Exhibit 13 comprises prescriptions for Patient ET, taken from Government Exhibit 12. Gov't Ex. 13. Government Exhibit 14 is a CURES report for Patient AA. Gov't Ex. 14. Government Exhibit 15 is a CURES report

obtained during the course of the investigation. Among the exhibits introduced through the testimony of DI was an order (Board Order) issued by the Medical Board of California (MBC or the Board) regarding the Respondent's treatment of the four Board Patients. *See* Gov't Ex. 30.

DI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. In addition to being uncontroverted, the testimony of this witness was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

Dr. Timothy Munzing, M.D.

The Government presented the expert testimony of Dr. Timothy Munzing. Dr. Munzing's *curriculum vitae* (CV)⁴ reflects nearly four decades of experience practicing primary care medicine,⁵ teaching, and serving as a medical expert reviewer for various state and federal agencies in cases involving controlled substance prescribing.⁶ Tr. 72; Gov't Ex. 20. The witness testified that he is (and for thirty-five years has been) a clinical professor at the University of California, Irvine,⁷ and among his published scholarly work is an article published in a peer-reviewed publication regarding controlled substance prescribing. Tr. 74–75, 81; Gov't Exs. 20, 35. Dr. Munzing was tendered⁸ and accepted as an expert witness in the prescribing of controlled substances in the State of California, including for the management of pain. Tr. 89.

Dr. Munzing agreed to confine his testimony to outlining the standard of care for controlled substance prescribing in California, and to avoid conflating the bedrock standards with any discussion of best practices or his view of optimum treatment options. *Id.* at 93–94, 205–06. According to Dr. Munzing, under the

applicable standard in California, the process of controlled substance prescribing must commence with the taking of a patient history. *Id.* at 94. The history must include queries about the length, location, and duration of any pain symptoms, as well as any comorbid medical or mental health conditions, and what (if any) treatment modalities have been deployed to date. *Id.* at 94–95. Any and all controlled and non-controlled medications being taken by the patient must be factored into the history. *Id.* at 96. In Dr. Munzing's view, where controlled substances have been utilized, strong consideration must be given to any indications of historical drug and/or alcohol abuse. *Id.* at 95.

A physical examination that includes the taking of vital signs and a detailed, focused examination of the locus of any discomfort is also a required element that must precede controlled medication prescribing. *Id.* at 96–97. Comorbid physical conditions encountered in a physical exam (*e.g.*, breathing or cardiac issues) may impact prescribing decisions. *Id.* at 97.

The third prescribing prerequisite, according to the witness, is reaching a determination as to whether to order additional objective testing of the patient. *Id.* at 98. Where controlled substances are contemplated by the physician, he/she should query the state prescription monitoring program (PMP), which in California is the Controlled Substance Utilization Review and Evaluation System (CURES). *Id.* at 98–99.

According to Dr. Munzing, the fourth step in the prescribing process is to assess the patient based on the information acquired in the other steps. *Id.* at 100. The physician must process available information to formulate a differential diagnosis of the etiology of the symptoms. *Id.* at 100–02. An important element of the assessment stage is to stratify the patient's risks of opioid or other substance abuse attendant upon utilizing controlled substances. *Id.* at 99, 102–04. The risk stratification piece of the equation remains an ongoing evaluation throughout the treatment of a patient as an aspect of meeting the applicable standard of care. *Id.* at 108–10.

Once the assessment has been conducted, the next step in the process is to individualize the treatment of the patient by setting objectives and procuring informed consent for the designated treatment modalities. *Id.* at 104–05. Informed consent includes “[n]otifying the patient about the common potential side effects or adverse effects,” as well the additional risks posed by taking controlled

substances as prescribed, to include addiction or substance use disorder, overdose, and death. *Id.* at 131–N; *see also id.* at 205–06.

Dr. Munzing stressed that throughout the process, “clear[,] true, and . . . appropriate documentation” is a required element of the standard of care for controlled substance prescribing in California. *Id.* at 105–07. The witness explained the documentation requirements this way:

Document . . . the history . . . , document the exam, document the vital signs, document . . . how you came up with the risk stratification, document the assessment. If you've done laboratory imaging, document those, and then document an appropriate management plan including either in the [progress] note or separate from the [progress] note an informed consent, especially sharing the most serious potential problems of the management figure. *Id.* at 106–07.

Dr. Munzing's view is that treatment risk stratification, coupled with periodic informed consent, is a process that must continue throughout the treatment of the patient. *Id.* at 111. A high-risk patient should be re-stratified and get renewed informed consent annually, whereas a lower risk patient can be addressed less frequently in this regard. *Id.* at 111, 204.

The Government's expert testified that he reviewed patient charts corresponding to the Six Patients⁹ from the Respondent's practice and determined that the Respondent's controlled substance prescribing did not meet the applicable standard of care in California.¹⁰ Tr. 120. There were numerous observations that Dr. Munzing offered in support of his position. For example, the progress notes showed no indicia that the Respondent or his staff conducted a physical examination, gauged heart or lung function, performed an abdomen check, [on AA] or took any vital signs from the other patients [over the majority of time period covered by the allegations].*^C Gov't Exs. 2, 4, 6, 8, 10; Tr. 165–66, 182, 191, 193, 231–32

⁹Patients AA, BB, JD, DD, SM, and ET.

¹⁰Some of the prescriptions reviewed by the Government's expert included those issued by physician assistants (PAs) who worked within the Respondent's practice. Dr. Munzing's testimony that the Respondent was responsible for the prescriptions issued by these PAs, *see* Tr. 174, is in accord with California Business and Professions Code § 3502.1(d).

*^CI have amended this sentence based on Respondent's Exceptions, which noted that Dr. Munzing's testimony regarding the lack of physical examination and lack of heart and lung function and abdomen check were limited to Patient AA—the patient who died of an overdose, and which noted that Respondent began taking vital signs from his patients in 2018. Resp't Exceptions at 12.

for Patient BB. Gov't Ex. 15. Government Exhibit 16 is a CURES report for Patient JD. Gov't Ex. 16. Government Exhibit 17 is a CURES report for Patient DD. Gov't Ex. 17. Government Exhibit 18 is a CURES report for Patient SM. Gov't Ex. 18. Government Exhibit 19 is a CURES report for Patient ET. Gov't Ex. 19. Government Exhibit 30 is a decision by the California Board concerning the Respondent. Gov't Ex. 30. Government Exhibit 31 is a report from the Medical Examiner for Patient AA. Gov't Ex. 31. Government Exhibit 37 is a portion of a CURES report concerning the Respondent, from November 2019 to August 2020 and pertaining to Patient SM. Gov't Ex. 37.

⁴Gov't Ex. 20.

⁵Dr. Munzing testified that most pain management treatment in the United States is conducted by primary care physicians. Tr. 88–89.

⁶Dr. Munzing testified that he has been compensated for his professional work as an expert, including by DEA in this case. Tr. 83.

⁷Tr. 80.

⁸Tr. 76.

(Patient AA);¹¹ *^D Tr. 407–08 (Patient BB); Tr. 384–89 (Patient JD); Tr. 477–79 (Patient DD); Tr. 329–31, 349–52 (Patient SM). Further, Dr. Munzing identified instances where the Respondent's patients were maintained on doses of medications that far exceeded the morphine milligram equivalent (MME)¹² recommended by the Centers for Disease Control and Prevention (CDC)¹³ guidance without documentation that the patient was afforded an informed consent that explained the risks inherent in such treatment. Tr. 120; Gov't Exs. 2–8, 10–13; Tr. 132–37, 139, 141–43, 145, 148–49, 156–57, 164–65, 169, 179–84, 191–92, 204–05, 224–25, 231–32, 271, 306–07 (Patient AA); Tr. 401–02, 406–07, 409–15, 417–22 (Patient BB); Tr. 384–89, 393–400 (Patient JD); Tr. 477–79, 481–84, 488, 490–95 (Patient DD); Tr. 314–17, 321–23, 328–32, 350–51, 353–56, 360–62, 365, 370–72, 377–82 (Patient SM); *^E Tr. 424–29, 431–35,

¹¹ Although the chart maintained by the Respondent's practice on Patient AA reflected a diagnosis of hypereosinophilic syndrome (HES), it is Dr. Munzing's judgment that references in the record that conflate this treatment with cancer are not accurate. Tr. 194. Further, Dr. Munzing testified that the Respondent's progress notes indicate that the pain medication prescribed for this patient by the Respondent were to treat a lower back ailment, not HES. *Id.* at 194–95. As discussed, *supra*, the San Diego Medical Examiner reached a similar conclusion. Gov't Ex. 31 at 5.

*^D Dr. Munzing testified that there must be some exam even for an established patient, because "this patient is at much higher risk. We don't know whether anyone is checking the patient's heart, lung exam, vital signs, despite these levels. Because of that, you're monitoring the patient to try to keep them as safe as possible." Tr. 166. When asked if he could point to a source for this statement, Dr. Munzing credibly stated, "Do I know anywhere where it says you must do exactly this? No, but I do know that one needs to monitor and try to keep the patient as safe as possible. That's part of trying to keep the patient as safe as possible." *Id.* at 168. I credit Dr. Munzing's testimony.

¹² Dr. Munzing testified that the MME is a protocol by which medications can be compared by using an equivalent dosage of morphine as a common denominator. Tr. 121–22. In California (and in the present record), the term morphine equivalent dosage (MED) is used interchangeably with MME. *Id.* at 22, 121–23. The record contains MME conversion tables published by the Center for Medicare and Medicaid Services (CMMS) and the Centers for Disease Control and Prevention (CDC). Gov't Exs. 26, 27; Tr. 124–31.

¹³ The witness testified that the CDC set 90 MME as a high dose. Tr. 131–L; *see also* Gov't Ex. 23 at 24–25. [However, Dr. Munzing stated that there is no maximum MME because "some patients need a higher amount, and so there's—there's no written absolute amount, but there's certainly—one certainly needs to look at the risk to the patients, the potential benefits, and attempt to mitigate the risks." Tr. 131–B.]

*^E For example, Dr. Munzing testified that on October 31, 2016, Respondent prescribed SM, Soma, diazepam, fentanyl patch, oxycodone, and Norco, and the combined MME of the three opioids is 960 and included the trinity cocktail (*see* n.14). Tr. 353–551; *see also*, e.g., Tr. 389 (1,234 MME to JD); Tr. 407 (1,920 MME to BB).

437–38, 440–47, 450 (Patient ET). Likewise, controlled substances were prescribed in high-risk combinations¹⁴ that significantly elevated the risk of such things as central nervous system (CNS)/respiratory depression, overdose, and death¹⁵ without documented informed consent. Gov't Exs. 2–8, 10–13; Tr. 157–58, 164–65, 167, 191–92, 224–26, 231–32, 276–78, 302–03 (Patient AA); Tr. 409–14, 418–22 (Patient BB); Tr. 387, 393–400 (Patient JD); Tr. 477–81, 483–84, 488, 490–94 (Patient DD); Tr. 321–23, 329–32, 351–56, 360–62, 365, 370–72, 377–82 (Patient SM); Tr. 424–29, 431–35, 437–38, 440–47, 450 (Patient ET). Dr. Munzing also identified instances in the Respondent's patient charts where clear flags of potential diversion were present but not resolved prior to controlled substance prescribing. For example, the witness pointed to places in the medical records where anomalous urine drug screens (UDSs) were recorded, yet seemingly ignored,¹⁶ without documented patient counseling or medication modification. Gov't Exs. 3, 11, 13; Tr. 149–55, 180–82, 196, 198, 206–09, 224–26, 228–31, 271–75, 279–82, 289–302 (Patient AA);¹⁷ Tr. 362–64, 371–72 (Patient SM); Tr. 438–440 (Patient ET). Another category where the Government's expert found prescribing that, in his view, was below

¹⁴ Dr. Munzing testified that a particularly high-risk combination includes an opioid, benzodiazepine, and muscle relaxer. Tr. 324–26. This combination, colloquially known as "the trinity," creates increased euphoria, which increases the risk of substance use disorder, and elevates the risk for respiratory depression. *Id.* at 323–26. [Respondent prescribed the trinity to Patient S.M. Tr. 323, e.g. GX 11 at 11 and 281. Dr. Munzing further opined that the trinity prescription was a "red flag" of abuse or diversion. Tr. 324. He testified that it was not always outside the standard of care to prescribe the trinity in 2016, but "you are adding to the risk for the patient, both the risk of addiction, the risk of overdose, and the risk of death. And when you are increasing the risk, one needs to really identify it, notify the patient, and divulge to the patient that they are at increased risk." Tr. 395–96.]

¹⁵ Tr. 167.

¹⁶ In some instances, in the face of obviously anomalous UDS results, the chart incorrectly reflected that the results were consistent with the patient's treating program. Tr. 198–200, 209, 216; Gov't Ex. 2 at 75 (Patient AA); [*see also* e.g., Tr. 364 (Gov't Ex. 10 at 517 (UDS negative for opioids SM was prescribed and the note says UDS is "consistent with the medication program.")]

¹⁷ According to Dr. Munzing, chart notes that indicate that some of the medication was prescribed to be taken "PRN" (as needed) do not resolve the conflict because the dosage level was sufficiently high that declining to take the medication for the three days or so it would take to produce a clean urine catch would result in profound withdrawal symptoms. Tr. 151–53, 281–87. Additionally, if the patient was taking the medication sporadically, the refills would not have been as consistent as the records indicate they were. *Id.* at 151–55, 209, 281–89.

the applicable standard was in the area of early refill prescribing. According to Dr. Munzing, the charts he reviewed showed many instances where the Respondent wrote prescriptions refilling controlled substance prescriptions before the prior medications should have been expended.¹⁸ Gov't Exs. 2–5, 8, 10, 11; Tr. 158–59, 169–72, 177–78, 180–81, 184–89, 224–26, 271 (Patient AA); Tr. 409–17 (Patient BB); Tr. 486–89 (Patient DD); Tr. 338–47, 349–50 (Patient SM). *^F Dr. Munzing testified that regarding Patients AA,¹⁹ BB,²⁰ JD,²¹ DD,²² SM,²³ and ET,²⁴ over 150 controlled substance prescriptions were issued below the applicable standard in California, and were thus not issued in the usual course of professional practice by the Respondent.

One of the Six Patients merits additional discussion. On November 11, 2017, Patient AA died in his apartment

¹⁸ Dr. Munzing acknowledged that on a very occasional basis, to accommodate life contingencies such as weekends and vacations, the standard of care can absorb one or two days of flexibility regarding refill timing. Tr. 158. However, where the early prescribing forms a pattern resulting in a significant potential reservoir of extra medication, as is the case with the Respondent's patients, the controlled substance prescribing falls below the standard of care. *Id.* at 158–63. The standard of care requires that early prescription fills have an annotated "do not fill before" note on the prescription. *Id.* at 162–63. Dr. Munzing's view is that irrespective of the date the medication is ultimately dispensed to the patient (a date which can be procured by a query to the CURES system), it is the early prescribing of the drug that renders a prescribing event below the applicable standard of care. *Id.* at 175–76. ["When you repeatedly write it early then it's providing opportunity for the patient to get more than what you're prescribing." Tr. 176]. Additionally, the Government's expert testified that the early refill phenomenon was confirmed by consultation with CURES [demonstrating that the individuals had in fact filled the prescriptions early on the dates that they were prescribed]. Tr. 217–21; Gov't Ex. 2 at 14–15.

*^F Dr. Munzing testified that, for example, for Patient SM, prescriptions were issued two days early for a year. Tr. 347 (e.g. Gov't 11 at 45–46 (prescriptions for Valium, fentanyl patches, oxycodone and Norco)). He stated that for SM there are "over a dozen times in a row where every time you're approximately two days early or average two days early. Over time, you've ended up getting a lot of extra medication. And either that medication is going and used by the patient in addition to what was felt necessary by the doctor. Or they may end up diverted in some other way." Tr. 348. He concluded that although this might happen a few times and not cause concern, "after three or four times it arose, then it becomes a pattern and becomes a problem that you are falling below the standard of care." *Id.* at 348. Another example of early fills occurred to Patient DD, who was prescribed high dosages of opioids between 1–6 days early over sequential months. Tr. 486–491; Gov't Ex. 9 at 189–198.

¹⁹ Tr. 164, 192–93, 195, 203–04, 210–12, 225, 232, 271–73, 275–76, 278–79, 292, 295, 300–01, 303–06.

²⁰ Tr. 407–08, 415–16, 418, 421–22.

²¹ Tr. 388–89, 393–97, 400–01.

²² Tr. 486, 487–96.

²³ Tr. 332, 352, 365, 369, 371.

²⁴ Tr. 429–32, 435, 437–38, 442, 446, 450.

due to a drug overdose. Gov't Ex. 31 at 5. The San Diego Chief Deputy Medical Examiner (ME) ruled the cause of death as "fentanyl, clonazepam, alprazolam, ketamine, hydrocodone, and morphine toxicity," and determined that the overdose was accidental. *Id.* Interestingly, although the Medical Examiner's report (ME Report), like much of the Respondent's progress notes, noted that Patient AA's "medical history was significant for 'terminal blood and bone marrow cancer,'" the examination revealed that "[n]o terminal malignancy was identified." *Id.* Thus, the Medical Examiner's conclusions in this regard are consistent with Dr. Munzing's view that the HES that Patient AA was afflicted with was not cancerous.*^G and that the Respondent's pain protocols were directed at the patient's lower back ailments. Tr. 194–95. Dr. Munzing testified that among the drugs listed in the ME Report as toxicity causes of death, the Respondent's practice was prescribing hydrocodone and morphine, and that the charts demonstrated awareness that Patient AA was also taking a benzodiazepine.²⁵ Tr. 310. [Dr. Munzing testified that these two prescriptions, "were felt to be contributors to the death, the hydrocodone and the morphine," and that it was not just one of the controlled substances that caused death, but a "multitude, it's toxicity, a multitude of drugs including a couple [Respondent] prescribed." *Id.*]

Overall, Dr. Munzing's testimony was authoritative, reasonable, and supported by the admitted evidence of record. The witness presented as a qualified, knowledgeable, and dispassionate expert evaluator of the Respondent's controlled substance prescribing practices. Although, unlike the Respondent and Dr. Polston, Dr. Munzing does not practice pain medicine exclusively and does not hold a Board subspecialty in pain

*^GI note that Respondent took Exception to the fact that the Chief ALJ "seems to insinuate that because no malignancy was found during post mortem examination, that AA's HES was not cancerous." Resp't Exceptions at 17 (citing RD at 9). It is not relevant to this case whether AA's malignancy ultimately was cancerous. It would only be relevant if I were to credit Dr. Polston's testimony that there is a different standard of care for cancer patients. I agree with the Chief ALJ and do not credit that testimony. See *infra* n.87.

²⁵ According to Dr. Munzing, alprazolam, a specific causal medication cited in the ME Report, was one of the three benzodiazepines that the Respondent was prescribing. Tr. 310–11. Dr. Munzing also noted that the ME Report found evidence of oxycodone in Patient AA's system (Gov't Ex. 31 at 11), but apparently did not find the drug in a sufficient quantity that it was included among the toxicity causes of death. Tr. 311–12.

management, his testimony was supportive, objective, and convincing. Dr. Munzing's testimony was unburdened by the keen interest that the Respondent has in the outcome of the case. Indeed, as discussed elsewhere in this Recommended Decision, Dr. Munzing's presentation was sufficiently persuasive that on several occasions the Respondent accepted Dr. Munzing's conclusions and changed his practices *^H as a result of what he heard at the hearing. As discussed, *infra*, when confronted by the Respondent's agreement with Dr. Munzing's testimony, Dr. Polston actually altered his view to conform with the Respondent's version. This willingness to support the Respondent's opinions based merely on being advised of them undermined the weight that could be attached to Dr. Polston's presentation. Accordingly, in this Recommended Decision, Dr. Munzing's opinions will be afforded controlling weight.

The Respondent's Case

The Respondent

The Respondent presented his own testimony at the hearing. He testified that since his graduation from the University of Minnesota in 1985, and the completion of his residency at the University of California, Irvine, he has been practicing medicine for over thirty-one years, all in Escondido, California. Tr. 895–97. The Respondent's CV ²⁶ reflects that he is Board Certified in Physical Medicine and Rehabilitation and holds subspecialty certifications in

*^H Respondent argued in his Exceptions that he only changed one practice as a result of the hearing. Resp't Exceptions at 18. However, Respondent does argue that he changed other of his practices *before* the hearing. *Id.* I take note of this discrepancy, and to the extent Respondent finds it important, agree that the record only demonstrates that he only changed one of his practices as a result of the hearing. Respondent continues to adhere to his position that the new practice regarding refills that he instituted as a result of the hearing is not mandated by the standard of care, in spite of his own actions and the Chief ALJ's finding herein that the substantial evidence in the record demonstrates that it is. *Id.* ("Physicians in the San Diego area prescribe in this fashion, and Dr. Polston testified it is not below the standard of care to refill medications two days early. [] Notwithstanding this, Respondent took notice of what Dr. Munzing stated and immediately changed his practice to remedy this issue.") The Government points out that in spite of similar arguments from Respondent in the MBC case, the MBC found that it was a violation for Respondent to prescribe greater than a 30 day supply, and yet, Respondent did not change this practice until August of 2020. Gov't Response at 30 (citing Gov't Ex. 30 at 134). Although Respondent changed this practice at the hearing, I cannot be sure that he will continue to implement this change in the future given his delay in recognizing the failure and his continued arguments that the practice is not required.

²⁶ The Respondent's CV was received into the record. Resp't Ex. G; Tr. 898.

Pain Medicine and Neuromuscular and Electrodiagnostic Medicine. Resp't Ex. G; see also Tr. 899. The Respondent reckons that he has treated over 20,000 patients in the course of his professional life, and that his current patient base consists of adults between the ages of 18 and 97, each of whom has "a pain condition that causes some sort of functional deficit." Tr. 900–01. According to the Respondent, the patients carry "diagnoses from orthopedic, to neurology, to stroke, to debilitating rheumatologic diseases." *Id.* The Respondent testified that as a pain specialist, he routinely handles patients with high-impact pain conditions,²⁷ that 100% of his patient base is referrals, and that at the outset of patient establishment he vets the patients for doctor shopping, early refills, indicators of abuse and/or diversion, and on some occasions has referred prospective patients to addictionologists. Tr. 949–50. By his own account, he has never been sued for malpractice, never settled any malpractice litigation, and other than his recent entanglements with the California Board, his state medical license has never been subjected to sanction or limitation. *Id.* at 901.

During his testimony, the Respondent narrated those of the Government's allegations which he accepts, elaborated on some areas where he took issue, and in other areas he assumed a hybrid, more nuanced stance.

Regarding the Government's allegation that ten ²⁸ aberrant UDS results related to Patient AA were not adequately addressed and documented by patient queries and resolution,²⁹ the Respondent simply confessed error without particular equivocation. Tr. 934. Regarding his custom of simply marking aberrant UDS results with the letters PRN (*i.e.*, that the medication was written to be taken as needed), the Respondent agreed that he "needed to do more questioning of the patient, more documentation of that questioning, and then more reaction in terms of the patient reactions." *Id.*; see also *id.* at 1071.

²⁷ The Respondent testified that he employs the Stanford definition of high-impact pain conditions, which he explained as "somebody that's had pain greater than six months, with significant functional deficits." Tr. 951. The Respondent further explained that high-impact pain patients are a subset of chronic pain patients, with the latter comprising 20% of all national pain patients and the former representing 8%, with some "affect [on] function in some form, [that is,] standing, walking, sitting, driving, sleeping, [and] self-care." *Id.* at 952.

²⁸ This allegation was modified from 12 to 10 instances on the unopposed motion from the Government. ALJ Ex. 25.

²⁹ ALJ Ex. 1 ¶ 14.d.

Similarly, the Respondent confessed error regarding the manner in which he timed his prescriptions which, as the Government alleged,³⁰ resulted in the potential for significant reservoirs of excess medicine for Patient AA. Tr. 935–39. While commending himself for his practice of seeing Patient AA every twenty-eight days, the Respondent testified that he has now implemented corrections to his prescribing practice which circumscribes future controlled substance prescriptions to twenty-eight days.³¹ Tr. 936–39, 1071.

The Respondent also conceded that to the extent the Government alleges³² that he failed to adequately document the basis for the extremely high opioid dosage he prescribed to Patient AA, that is true. Tr. 928–29. The Respondent refined his position in this way:

I see in retrospect the documentation could be better, and I respect [the Government expert's] criticism when he was saying that the documents should show the next doctor what's going on. And I did not feel that I was able to do that.

Id. at 929. While conceding the inadequacy of the documentation, the Respondent did provide some explanatory details about the course of his treatment of Patient AA's pain symptoms with controlled substances. The Respondent explained that upon assuming his pain management care, Patient AA "had been a lobster fisherman in Boston, had gotten in car wrecks, had a finger rotting, and also had had [sic] the onset of [HES, and h]e was in quite a bit of hurt." *Id.* at 930. According to the Respondent, he held his level of pain medication steady, notwithstanding the patient's requests to the contrary, and reemphasized his contention that he was treating this patient during the evolution of professional pain management guidance. *Id.* at 930, 1068.

The Respondent took issue with the Government's contention that chart entries regarding Patient AA "indicate that [he] never discussed the risks of opioids with" the patient.³³ Tr. 931. He testified that, in his view, these risks were discussed with Patient AA, and while agreeing that he has beefed up the quality of his documentation based on the Government expert's testimony, his opinion is that the level of the discussion that occurred in the pain contract executed with the patient did

meet the required standard, and the Government's allegation to the contrary is not supported. *Id.* at 931–32. As an example, the Respondent pushed back on the opinion of the Government's expert that the failure to mention the risk of death is problematic. *Id.* According to the Respondent, while true that the pain contract did not precisely detail the risk of death, "it did discuss respiratory depression, which is usually the antecedence of that." *Id.* at 932.

Still, while not conceding fault in this regard, the Respondent testified that "[it should be better" and] he has developed an opioid informed consent document that "plug[s] that hole." *Id.* The Respondent ultimately allowed that specific mention of death is "important to mention to the patient, and . . . is something [that he] want[s] to do better and need[s] to do." *Id.*

The Government specifically alleges that the Respondent's concurrent prescribing of opioids and benzodiazepines to Patient AA was a "red flag of abuse or diversion" and "represented a dangerous combination, and constituted an extreme departure from the standard of care for the practice of medicine." ALJ Ex. 1 ¶ 14.c. In his testimony, the Respondent sidestepped the principal issues of this allegation somewhat, by countering that, notwithstanding the absence of documentation in this regard, the risks of benzodiazepines were discussed with the patient and his standards for documenting such discussions has been enhanced. Tr. 933. No mention was made about the opinion of the Government's expert regarding whether the prescribing combination fell below the standard, only that the issue of benzodiazepine risks were discussed, if not pristinely documented. *Id.*

The Respondent was unequivocal in his view that, contrary to the Government's allegation,³⁴ the Government's expert,³⁵ and the ME Report,³⁶ his prescribing was not a contributing factor in Patient AA's untimely demise. Tr. 943. The way the Respondent sees it, Patient AA would not have died had he not taken fentanyl and drank alcohol, both of which the Respondent feels were covered in the patient advisals set forth in the pain agreement and executed by the patient.

³⁴ ALJ Ex. 1 ¶ 14.f.

³⁵ Tr. 310–12.

³⁶ Gov't Ex. 31 at 5. The ME Report, in pertinent part, renders the following ultimate conclusion: "Based on the [report's integral] findings and the history and circumstances of [Patient AA's] death as currently known, the cause of death is best listed as 'fentanyl, clonazepam, alprazolam, ketamine, hydrocodone, and morphine toxicity' and the manner of death as 'accident.'" *Id.*

Id. at 943–45. When pressed on the issue, the Respondent provided the following elucidation on his own self-exoneration:

[Patient AA] had been on a combination of medications for a long time with no issues, and I feel badly that this event happened, but I honestly saw no issue where what we were providing was a significant component to someone who had so much additional medication in his system.

Id. at 943. The Respondent testified that he had no sense, indication, or warning that addiction or other substances were issues with Patient AA, based upon the following observations: "I never had him come early for his appointments, [he] never asked for additional medication, no exhibited behaviors, never was there alcohol." *Id.* at 944–45. Absent from his consideration in this regard was the ever-growing reservoir of extra medications the patient was receiving from refills that preceded the anticipated medication exhaustion dates³⁷ or the aberrant UDS results that were never addressed and documented.³⁸

The Respondent detailed his experience with the balance of the Six Patients, much of it following the same pattern, notwithstanding a nuance or two. He agreed that the Government was right with respect to the potential reservoir of medication created by his temporally-truncated prescribing practices.³⁹ Tr. 960–62. By the Respondent's account, the patients established with his office with painful medical issues and high-dosage MMEs, and he either maintained the patients at the pain medication levels they arrived at, notwithstanding their protestations to the contrary, or in some cases, according to the Respondent, he was able to effect some reductions.

The Respondent testified that such was the case with Patient BB. *Id.* at 946–49, 953–55, 957–58. The Respondent testified that Patient BB resisted his attempts to taper her pain medication,⁴⁰ and ultimately left his practice as a

³⁷ Tr. 158–59, 169–72, 177–78, 180–81, 184–89, 224–26, 271.

³⁸ Tr. 149–55, 180–82, 196, 198, 206–09, 224–26, 228–31, 271–75, 279–82, 289–302. [Further, the Government highlighted that Respondent did not test for Ketamine or fentanyl in the UDS on September 19, 2017. Tr. 1098 (citing Gov't Ex. 2 at 535).]

³⁹ ALJ Ex. 1 ¶ 18.d.

⁴⁰ The Respondent testified that the patient resisted his attempts to set her up with a behavioral health evaluation and detoxification process, and that he made numerous (ultimately fruitless) attempts to sort things out with her insurance provider and her (concurrently prescribing) primary care physician. Tr. 969–75.

³⁰ ALJ Ex. 1 ¶ 14.e.

³¹ The Respondent later explained that he realized the validity of this aspect of his prescribing while listening to Dr. Munzing's testimony, and started to implement corrective actions during the course of this hearing. Tr. 1311–12.

³² ALJ Ex. 1 ¶ 14.a.

³³ ALJ Ex. 1 ¶ 14.b.

response to her frustrations.⁴¹ Tr. 947, 969–70. He took issue with the Government’s allegation that the MME level he prescribed for this patient was “extraordinarily high,”⁴² opining that it was an appropriate dose under the circumstances, and conceding only that he “was not happy with [his] documentation at that point in time and [that he] fixed it.” Tr. 956; *see also id.* at 1068. In describing what he thought could be improved with his level of documentation, the Respondent allowed, in retrospect, that his documentation was “basic” and “wasn’t descriptive enough.” *Id.* at 956. The Respondent also resisted the Government’s allegation that his medical records were deficient in that they contained no discussion of the risks and benefits of opioid therapy.⁴³ The Respondent adhered to the view that the pain contract that he executed with this patient was sufficient to satisfy the requirement that the risks were discussed and true informed consent was obtained. Tr. 957–58.⁴⁴ The Respondent likewise declined to budge from his position that although his standard pain contract at the time made no mention of death, language which included the risk of respiratory depression was sufficient, contrary to the Government’s allegation and the position of its expert. *Id.* at 958–59.

⁴¹ The Respondent testified that other than the late Patient AA and Patient BB, the other four of the Six Patients are still under his care. Tr. 962.

⁴² ALJ Ex. 1 ¶ 18.a.

⁴³ ALJ Ex. 1 ¶ 18.b.

⁴⁴ Respondent seemingly contradicted his previous testimony that he always had the conversations with his patients on cross-examination, when he stated: “The—the informed consent document is better than it was before. It’s actually an informed consent document. But, as you know, informed consent is more than just a document. It’s the discussions surrounding it, and I think that’s what we’re doing much better with.” Tr. 1070. This statement undermines his previous testimony that true informed consent was obtained, but just not documented. He also appeared to change his position regarding whether his previous pain agreements met the minimum standard of care with respect to informed consent—answering that they did not. *Id.* Regardless, as explained herein, it is unnecessary to conclude whether or to what extent he had these discussions, because the documentary evidence does not demonstrate that he did. Further, even if he had, he waived on acknowledging whether discussing the risk of death associated with the medications, even if they are taken as prescribed, was essential to the standard of care. So even if he did have conversations about the risks, it is still unclear whether the content of those conversations met the standard of care as Dr. Munzing described it. Finally, I credit Dr. Munzing’s testimony that the issue of discussing risk is universal in medicine, because a lay person is not expected to know what the consequence of respiratory depression is. *See also infra* n.*S for further discussion of Respondent’s testimony regarding informed consent in the context of his purported acceptance of responsibility.

Consistent with much of his presentation, the Respondent was unwilling to agree with the Government’s allegation that prescribing the combination of opioids and benzodiazepines constituted an extreme departure from the standard of care,⁴⁴ but [] acknowledged that he was unhappy with Patient BB’s chart because it was “not as acceptable as [he would] like it to be with specific benzodiazepine interactions.” Tr. 960. The Respondent asserted that his standard paperwork has now been improved to include such interactions. He also testified that he has changed his practice to conform with certain views expressed by the Government’s expert witness. *Id.* at 957.

The same testimonial pattern was present regarding Patient JD. The patient came to the Respondent’s practice on a referral with a dramatic and acute set of pain etiologies⁴⁵ and on a high dosage of medication.⁴⁶ In the Respondent’s estimation, continuation of this patient’s high controlled substance dosing was not “an extreme departure from the standard of care for the practice of medicine,”⁴⁷ based on what he perceived as the best professional guidance available at the time and the existing medication level the patient was at when referred to his practice. Tr. 982–83, 1068. The Respondent explained that in his view, the available guidance regarding the pain management of patients has been the subject of considerable evolution over the past fourteen years. *Id.* at 901–02; *see also id.* at 930. The Respondent’s handling of the issue contained a high level of nuance.

At that time, we’re *just coming off* of the decade of maybe 2000, 2010. Pain is a fifth vital sign. *There’s no limits to dosing.* You dose to function, you don’t dose to milligram quantity. And that, I believe that’s how he got up to that level before he came to me. So at that point, it was *not an unheard-of dosage.* *Id.* at 982 (emphasis supplied). Unpacking this analysis is somewhat instructive. Even accepting the Respondent’s view that pain medication guidance was evolving, it is difficult to assess the significance that should be placed on his estimation of “just coming off of the decade of maybe 2000,

⁴⁴ ALJ Ex. 1 ¶ 18.c.

⁴⁵ According to the Respondent, Patient JD was status post a catastrophic vehicular/pedestrian strike, and had avascular necrosis involving one shoulder and both hips, cervical radiculopathy with osteophytes, ankylosing spondylitis affecting the lower spine, Lyme disease, multiple lower extremity fractures, and complex regional pain syndrome (RSD). Tr. 977–81.

⁴⁶ Tr. 976, 986–87.

⁴⁷ ALJ Ex. 1 ¶ 21.a.

2010”⁴⁸ of a divergent approach. To the extent that the decade the Respondent was referring to took place [] ended (as he says) in 2000, Patient JD established with the Respondent’s practice ten years later, in 2010. There is no indication in the record or any available source that expert guidance inexorably changed by the decade or how long it would take to “come off” such a decade, even if there were some logic to this statement. Likewise, the notation that any decade had “no limits to dosing”⁴⁹ dangerous controlled substances strikes as inconsistent with the limits of human endurance and common sense; and to justify the level at which he was medicating this patient by saying “it was not an unheard-of dosage”⁵⁰ is far from a persuasive endorsement of his controlled substance prescribing practices. Even taking the Respondent’s testimony in the most indulgent light possible, “not unheard-of” cannot be a meter that his actions are measured by to gauge whether he complied with the applicable controlled substance prescribing standard in California. When asked for clarification as to whether he agreed with the Government’s allegation regarding his dosing, the Respondent supplied the following *non sequitur*:

I don’t. As I stated, I received him at the higher dose. That’s why it’s coming to me, and I’m supposed to be the one who will contain it, control it, and reduce it over time while trying to increase function.

Tr. 983. The only self-criticism the Respondent offered was that his “documentation should have been better at that point in time . . . and [that he] wish[es he] had done a better job of documenting.” *Id.*

Again, the Respondent clung to his view that the Government’s allegation that his records fail to indicate sufficient opioid risks discussions with the patient⁵¹ is unfounded because his standard pain contract language at the time (although improved since) was sufficient to do the job. Tr. 984–85. While again confessing error⁵² regarding the 28-day visit vs. the 30-day early prescription issuance,⁵³ with respect to the Government’s allegation that prescribing a combination of opioids and benzodiazepines to Patient JD fell below the standard of care,⁵⁴ the

⁴⁸ Tr. 982.

⁴⁹ Tr. 982.

⁵⁰ *Id.*

⁵¹ ALJ Ex. 1 ¶ 21.b.

⁵² The Respondent testified, “That was a very easy one to fix with literally no fuss at all.” Tr. 986; *see also id.* at 1071.

⁵³ ALJ Ex. 1 ¶ 21.d.

⁵⁴ ALJ Ex. 1 ¶ 21.c.

Respondent offered only that he engaged the patient with an ultimately successful protocol to eventually wean him off the benzodiazepine. Tr. 985–86. In fact, the Respondent testified that during the course of his treatment of Patient JD, he successfully weaned him off multiple benzodiazepines and significantly reduced the overall MME of the medications he was taking. *Id.* at 988–89.

The pattern repeated itself with respect to Patient DD. The Respondent owned up to the early refill allegation.⁵⁵ Tr. 998–99, 1071. The Respondent testified that upon intake this patient had complicated orthopedic problems⁵⁶ that had been treated by another pain doctor prior to the referral. Tr. 990. Consistent with his description of the other Six Patients, the Respondent testified that Patient DD arrived on a high MME level of controlled medications, which was ultimately reduced through the Respondent's efforts. *Id.* at 991–95, 1001. The Respondent disputed the Government's allegation that the MME levels of the medications he prescribed to Patient DD "constituted an extreme departure from the standard of care for the practice of medicine,"⁵⁷ claiming that the medication levels were appropriate because (in his view, at that time) level of function (not the dosage) was the touchstone, and also because a review of prior medical records gave the Respondent no indication of the patient requesting early refills.⁵⁸ Tr. 995, 1068. The only culpability the Respondent would assume in this regard came from the quality of the templates in his electronic medical record software. *Id.* at 995–96. Once again, as he did in addressing the other Six Patients, the Respondent eschewed any responsibility for documenting deficiencies related to explaining the risks and benefits of opioid use by pointing to the language employed by the standard pain contract he was using at the time. *Id.* at 996.

The analysis presented in the Respondent's testimony about Patient SM did not differ substantially from the manner in which he described his treatment of the other members of the Six Patients group. According to the

⁵⁵ ALJ Ex. 1 ¶ 23.c (as amended, *see* ALJ Ex. 25 at 2, ¶ 7).

⁵⁶ According to the Respondent, Patient DD had a catastrophic lumbar spinal collapse, had endured multiple surgeries and an infected pain pump, as well as an unsuccessful go at a dorsal cord stimulator, and was presenting with surgically-placed titanium spinal rods that had snapped. Tr. 991.

⁵⁷ ALJ Ex. 1 ¶ 23.a.

⁵⁸ [Omitted.]

Respondent, at the time of her referral to his practice, Patient SM presented with pain from complex and serious etiologies,⁵⁹ and was being maintained on high-MME levels of pain medication combined with benzodiazepines. Tr. 1003–05. The Respondent testified that he worked to reduce the MME levels⁶⁰ and eliminate the benzodiazepines⁶¹ from the treatment equation. Tr. 1005. The Respondent accepted error regarding his early refill practices,⁶² but again defended his dosing levels against the Government's allegation that the levels were sufficiently high that they constituted "an extreme departure from the standard of care for the practice of medicine."⁶³ Tr. 1005–06, 1068. His answer was once again that the only conceivable hiccup in the prescribing⁶⁴ was his level of documentation. Tr. 1006. The Respondent explained it this way: "Looking at it now, with the lens that I have, I can see that the documentation should have been better." *Id.* However, the documentation deficits the Respondent owned up to regarding this patient, like the others, did not extend to the Government's allegation regarding the failure to adequately document risk warnings associated with opioid use,⁶⁵ as he again explained that, in his opinion, his standard pain contract covered this area sufficiently.⁶⁶ Tr. 1006–07. Similarly, the Respondent was resistant to the concept that dual prescribing benzodiazepines with opioids fell below the applicable standard as charged by the Government,⁶⁷ but offered instead that he "should have done a better job of documenting the risks of benzodiazepines." Tr. 1007–08.

⁵⁹ According to the Respondent, Patient SM suffered from cervical and lumbar issues, underwent multiple surgeries and other procedures, and ultimately lost the ability to swallow. Tr. 1003–04.

⁶⁰ Tr. 1010–12.

⁶¹ The Respondent testified that he ultimately discontinued the trinity combination of medications for this patient. Tr. 1008.

⁶² Tr. 1008 ("I see that as a processing error, as we talked about before. It's a very simple thing to correct, and it's already been implemented."); *see also id.* at 1071.

⁶³ ALJ Ex. 1 ¶ 26.a.

⁶⁴ According to the Respondent, "The dosing was appropriate, considering her medical condition, the fact that that's what she was on previously. And, again, that's where we start, and then we move down from there." Tr. 1006.

⁶⁵ ALJ Ex. 1 ¶ 26.b.

⁶⁶ Regarding this patient, and throughout the proceedings, the Respondent suggests that his forms had room for some improvement, but does not agree that utilization of this form to satisfy informed consent regarding the risks of opioid therapy falls below the standard. Tr. 1007 ("I am always in a state of continuous quality improvement, and I recognize that as an issue. We have corrected it.').

⁶⁷ ALJ Ex. 1 ¶ 26.c.

The Respondent adhered to a like pattern in his testimony regarding Patient ET. This referred patient arrived at his practice with high MME levels and sobering etiologies⁶⁸ behind his symptoms. Tr. 1012–13. The Respondent again confessed error on his unintended early refills issue,⁶⁹ and allowed that his documentation was inadequate,⁷⁰ but testified that, based on the science at the time and the medications she was on when she came into his care, he stood behind his dosing decisions,⁷¹ and that he reduced this patient's MME dosing. Tr. 1015–22. The Respondent referenced a report⁷² (PMC Report) prepared regarding Patient ET at the Respondent's request by the University of California San Diego Pain Management Clinic (PMC). Tr. 1015.*¹ The Respondent's testimonial assessment of the PMC Report's conclusion is that:

[PMC] said there was nothing more to offer from their perspective, in terms of intervention. And they recommended we continue the path, and that we continue to wean the patient.

Id. The PMC Report does indeed recommend continuation of physical therapy and does state that it declines to recommend interventions, but it also recommends the addition of conservative therapies such as osteopathic manipulative medicine (OMM), acupuncture, and alternative medicine modalities, and states: "Continue medications per [the Respondent], recommend weaning if possible." ⁷³ Gov't Ex. 12 at 992.

The Respondent, consistent with the view he espoused in his Corrective Action Plan (CAP),⁷⁴ initially maintained his uniform position that the standard pain management contract he was employing at the time satisfied the applicable standard of care regarding his obligation to inform Patient ET about the risks associated with prescribing opioids,⁷⁵ but then, in

⁶⁸ The Respondent testified that Patient ET carried diagnoses of hemiplegic migraine, was status post cervical surgery, and had cervical radiculopathy. Tr. 1012–13.

⁶⁹ Tr. 1027–28.

⁷⁰ Tr. 1024.

⁷¹ Tr. 1022–24, 1068.

⁷² Gov't Ex. 12 at 987.

*¹ Respondent admitted that for this patient there was "a component of opiate use disorder" and that she was weaned off all of the pain medication and now, years later, being prescribed Suboxone, which "does have some pain implications and can reduce the craving for patients who need to cut back with their medication." Tr. 1020, 1021.

⁷³ An undated, handwritten note in the margin of the PMC Report reads: "Noted wean attempt in progress." Gov't Ex. 12 at 992; Tr. 1016.

⁷⁴ Resp't Ex. M at 5, ¶ 4.

⁷⁵ Tr. 1024–26.

something of a departure from his prior assessments, testified that “[o]n the issue of informed consent, the documents were not adequate.” Tr. 1026. The Respondent explained his unexpected change in perspective this way:

I needed to talk more about the actual conversations I had with the patient, the potential risks, including death, which was not mentioned specifically. And I see that as a deficit in my reading, documentation and my discussion with the patient.

Id.; see also *id.* at 1070. Oddly, this change of heart only apparently applied to his treatment of Patient ET, but the Respondent also testified that he has since introduced a specific opioid consent contract. *Id.* at 1039–40. While the Respondent maintained that his pain agreement was sufficient in all cases (other than Patient ET), he testified that the opioid consent document “was created specifically to plug some of the gaps that the pain agreement was not fully compliant [sic].” *Id.* at 1040. The Respondent further testified that he “felt like [he] needed to expand [his] offerings in terms of informed consent, to be fully compliant.” *Id.* at 1041. Thus, the Respondent testified (consistent with the position he took in his CAP)⁷⁶ that the pain contracts did meet the standard, then in the case of Patient ET that they did not meet the standard, then he testified to his creation of a separate opioid consent document “to plug some of the gaps” in the aforementioned pain agreements that were “not fully compliant.”⁷⁷ See Tr. 1040–41. It would not be hyperbolic to suggest that the Respondent’s view on this issue in his testimony was all over the place and did not enhance his credibility.

The Respondent resisted the Government’s allegation that he failed to appropriately respond to one of Patient ET’s UDS results based on his view that the result was not aberrant. *Id.* at 1028. Specifically, the Respondent testified that although Patient ET supplied a urine sample that tested positive for temazepam (a medication she was not prescribed), temazepam, according to the Respondent, is a metabolizer of diazepam (a medication that the Respondent had prescribed). *Id.* The Respondent followed up by offering that he has enhanced his internal office mechanisms for responding to UDS

results that appear inconsistent. *Id.* at 1028–29.

The Respondent described numerous improvements he has effected in his electronic medical records software⁷⁸ so that an increased level of detail and analysis would be reflected in the future.⁷⁹ Tr. 1029–34, 1038–39, 1044, 1047–52; Resp’t Ex. M at 4–7. When pressed as to why a multitude of prior notes showed that no one in his office had been taking weight measurements or other vital signs, the Respondent conceded that he “should have been doing it.” Tr. 1034. The Respondent explained some improvements he incorporated into his practice, and explained that he now sees one less patient per hour under his new protocol. *Id.* at 1041–43, 1053. He also testified that his staff now takes blood pressure readings from his patients. *Id.* at 1039. The Respondent explained that all his office notes correspond to his new, more detailed protocols, and offered that:

I’m much happier. The patients are better informed. And I feel as though each of these notes, when I finish, we have all the facts, whoever goes to the primary physician and anybody else in the circle of care. And I just feel like I’m doing a much better job of inter-operability and cooperation with the other physicians.

Id. at 1052. He also added that he “always want[s] to improve”⁸⁰ and that he has “never stepped down from a challenge.” *Id.* at 1062.

The Respondent made clear in his testimony that he only accepted responsibility for the deficiencies he was willing to acknowledge at the hearing. *Id.* In addition to his electronic recordkeeping enhancements, the Respondent testified that he no longer prescribes the trinity combination of medications,⁸¹ and has eliminated carisoprodol from the medicines he prescribes. Tr. 1065. Throughout the

⁷⁸ The Respondent testified that his medical records have been electronically maintained since 2005. Tr. 924.

⁷⁹ The Respondent testified that these enhancements were not the result of the DEA investigation, but rather, his experience with the Administrative Law Judge handling the state licensing proceedings. Tr. 1052.

⁸⁰ The Respondent testified to completing two continuing medical education (CME) courses in 2017 through the UCSD School of Medicine. Tr. at 1057–59. The Respondent personally attended a two-day course on physician prescribing and a two-day course on medical record keeping. *Id.*; see Resp’t M at 47, 49.

⁸¹ The Respondent did not admit that his combination prescribing fell below the standard of care, and pointed out that the CDC qualified its admonition against combining opioids and benzodiazepines as to be avoided “whenever possible.” Tr. 1072. The Respondent maintains that the relative merits of prescribing the trinity combination in the past “was not clear.” *Id.* at 1073.

hearing, the Respondent adhered to his position that his prescribing did not fall below the applicable standard of care, due to the available knowledge at the time, the high MME levels the patients carried upon his first encounter with them, and his eventual efforts to wean them down.⁸² Tr. 1068–69, 1073. By his reckoning, his only potential prescribing missteps in this regard were the unintentional early refills and the quality of his documentation, both of which he argues have since been remedied.

Surprisingly, although, as discussed, *supra*, the findings of the California Board set forth in the Board Order are entitled to preclusive effect in these proceedings,⁸³ the Respondent devoted no portion of his testimony to any of those issues. Thus, although the Board Order established much of the Government’s overall case, the Respondent’s testimony offered neither an acceptance of responsibility nor a plan of remedial action concerning those issues.

As is always the case in these proceedings, among the witnesses who testified at this hearing, the Respondent unarguably possesses the greatest interest in the outcome, and hence, the greatest motivation to enhance, modify, or even fabricate his testimony. However, even apart from the risk of implicit bias, the Respondent’s testimony presented a robust array of other reasons to eschew accepting his version of events without a significant level of skepticism. The Respondent initially testified, as he argued in his CAP, that his standard pain medication contracts satisfied the applicable standard of care relative to the required appraisal of the risks of opioid use and combined prescribing to his patients. However, when the identical issue arose regarding one of his patients, Patient ET, the Respondent suddenly changed course and claimed that his standard pain medication contracts did not meet the standard, and even cited this as a reason that he changed his practice and

⁸² The Government assisted the witness in highlighting the fact that, notwithstanding progress notes expressing an intention to wean, not all of his opioid medication titrations have pointed downward. Tr. 1074–96. [For just one example, Respondent’s notes for SM stated that attempts at reducing the medication were met with decreased function, but there were no substantial attempts to reduce in the actual prescribing as demonstrated in the records from March 2014 until April 2018. Tr. 1080, 1084; Gov’t Ex. 10 at 149.] The Respondent offered that he encouraged some of his patients to reduce their medications below the amounts he was prescribing, but unpersuasively conceded that such a recommendation would not be documented in his charting. *Id.* at 1103–04.

⁸³ See *Robert L. Dougherty, M.D.*, 76 FR 16823, 16834 (2011).

⁷⁶ Resp’t Ex. M at 5, ¶ 4.

⁷⁷ In his CAP, the Respondent highlighted language he added to his standard pain medication agreement, implicitly arguing that the agreement, as modified, satisfies the standard without a separate opioid consent agreement. Resp’t Ex. M at 33, ¶ 15; Tr. 1061.

introduced specific opioid consent documents and implemented changes to his standard pain medication contracts. Additionally, although the Respondent consistently defended his high-MME prescribing based on his practice of titrating the medications down, a review of his progress notes reflects that although this was a consistently-documented intention that would presumably be understood by anyone reviewing his charting, the reality was that in many instances weaning was not effected, and later notes, instead of reflecting the failure to taper, just continued to express the purported aspiration. The potential inescapable inference here is that inexorably repeated comments supposedly seeking to taper and failing to document no progress in that regard was intentional window dressing to create a variety of plausible deniability. Another aspect of the Respondent's presentation that was unhelpful to his credibility was the manner in which he addressed his perception that medical literature on the issue of opioid prescribing presented an evolving landscape. As discussed, *supra*, the Respondent depicted his prescribing decision point as "just coming off of the decade of maybe 2000, 2010], where plain is a fifth vital sign[and t]here's no limits to dosing." Tr. 982. To be sure, scientific guidance is rarely fixed in any field, much less medicine, and controlled substance prescribing in the medical field has seen its fair share of fluctuation. But even assuming the accuracy of this broad reality, defending the prescribing of dangerous and powerful controlled substances to his patients based on something as vague as what "decade" *k he was "coming off" does not reflect a

*k Respondent took exception to the Chief ALJ's comment that Respondent was vague as to the exact decade. Resp't Exceptions at 23 n.6 ("[Respondent] states clearly the time is 2010. This means the decade of pain occurred approximately between 2000–2010."). Even if the Respondent was clear in this statement, what remains unclear is the issue that the Chief ALJ highlighted—how long after the decade can Respondent still claim ignorance as to the dangers of prescribing high levels of opioids? The prescribing activity in the OSC allegations falls between 2014 and 2019, so if Respondent is claiming that this "decade of pain" ended around 2010, it is not credible that the decade would still be affecting the standard of care four to nine years (almost an another entire decade) after it ended. Respondent notably stretches the decade to around 2012 in his Exceptions using Dr. Polston's declaration, but even taking this expanded timeframe into account, he cannot cover the activity in question. Resp't Exceptions at 24 (citing Ex. L). In fact, the Government points out that the evidence demonstrates that Respondent's prescribing behavior did not begin to change until around the same time that the California Medical Board was preparing to file an action against Respondent, which was "ultimately filed on October 5, 2017." Gov't Response at 33 (citing Gov't Ex. 30 at 4).

serious analysis of the issue or any level of reflective circumspection. Medical science does not adjust itself based on the inexorable flipping of the calendar decades, and it would be impossible to even define when a prescriber was "coming off" one decade and jumping into another, even if this were a realistic concept—which it is not. Is a month after a decade "coming off"? Is three or five years? Suffice it to say that this sort of glib dismissal of the proper standard to be applied to controlled substance prescribing at the moment he was writing prescription after prescription did not enhance the level of credibility and reliability that can be reasonably assigned to the Respondent's testimony.

That is not to say that the Respondent is entirely incredible or that his professional opinions are to be easily dispatched. The Respondent is an experienced, knowledgeable, well-credentialed physician with a considerable level of subject-matter expertise. There were aspects of his biographical information, the progress of his career, and even some aspects of his testimony regarding treatment that were reliable and believable and should be relied upon and believed, but where the Respondent's testimony conflicts with the testimony of other witnesses and evidence of record (which is substantial), it must be viewed with a heightened level of scrutiny.

Dr. Gregory Polston, M.D.

The Respondent presented the expert testimony of Dr. Gregory Polston.⁸⁴ Dr. Polston's CV reflects that he has been Board Certified in Anesthesiology for over twenty years, has held a subspecialty certification in Pain Medicine for nearly twenty years,⁸⁵ and completed a pain fellowship at the University of California, San Diego (UCSD). Tr. 1140, 1142–43, 1146–47; Resp't Ex. K. The witness testified that he is currently the Assistant Director of the Center for Pain Management at UCSD, the Sector Chief for the Pain Service at the Veteran's Affairs Medical Center in San Diego, and his current medical practice is exclusively devoted to patients with acute or chronic pain. Tr. 1141–42, 1148; Resp't Ex. K. Dr. Polston was tendered⁸⁶ and accepted⁸⁷

⁸⁴ Dr. Polston testified that he has been compensated by the Respondent for his professional work as an expert in this case. Tr. 1285.

⁸⁵ Dr. Polston testified that there is no pain management board certification available, and that the added pain management qualification awarded by the American Board of Anesthesiologists is the closest that a physician can get to a board certification in pain management. Tr. 1146–47.

⁸⁶ Tr. 1148–49.

⁸⁷ During *voir dire*, Dr. Polston stated that his expert opinion was influenced by statements the

as an expert witness in controlled substance prescribing in California, including controlled substance prescribing for intractable pain. Tr. 1153–54.

The Respondent's expert testified that he reviewed patient files for the Six Patients from the Respondent's practice and (at least initially) testified that the Respondent's controlled substance prescribing did meet the standard of care in California. *Id.* at 1193, 1224–26, 1229–30, 1284. Specifically, the witness opined that the amount of medication the Respondent prescribed for each of the Six Patients was within the standard the care. *Id.* at 1167, 1192–93, 1199, 1204, 1211, 1217–18, 1224–26. To support his reasoning, Dr. Polston identified patient records that stated the patients had a diagnosis that could be painful and/or the patients' history contained evidence of multiple pain, indicating the patients were candidates for opiate therapy.⁸⁸ Gov't Exs. 2–4, 6, 8, 10, 12; Tr. 1155–56, 1166–67 (Patient AA); Tr. 1186–88, 1190–93 (Patient BB); Tr. 1196–99, 1203 (Patient JD); Tr. 1206–10 (Patient DD); Tr. 1214–15 (Patient SM); Tr. 1222–24 (Patient ET). He also explained that, in determining whether to prescribe controlled substances, a physician should consider subjective input from patients and increased functionality, and then pointed to instances in the record where subjective input and functionality were identified. Tr. 1167, 1184 (Patient AA); Tr. 1191–92 (Patient BB); Tr. 1201, 1203–04 (Patient JD); Gov't Ex. 8; Tr. 1210–11 (Patient DD); Gov't Ex. 10; Tr. 1215–17 (Patient SM). The Respondent's expert explained his view of functionality analysis this way:

Initially physicians would consider the functional report of pain or reduction in pain as being more important. As time evolved we felt that function was more important and it's a balancing act. There are some patients who

Respondent made during preparation sessions with the Respondent's counsel. Tr. 1151–52. The tribunal recognized Dr. Polston as an expert but directed the witness to inform the tribunal at any point during his testimony if his opinion was influenced by an explanation or elaboration that the Respondent gave during a preparation session. *Id.* at 1153–54.

⁸⁸ Dr. Polston explained that Patient AA's primary diagnosis was HES, which he classifies as a form of cancer. Tr. 1155–56. In Dr. Polston's opinion, it was important that Patient AA had a cancer diagnosis because "the guidelines are much different for chronic benign pain versus cancer pain." *Id.* at 1156. Remarkably, the witness explained that, in his view, a cancer diagnosis "really strips away nearly all guidelines" for prescribing controlled substances. *Id.* at 1157. It was clear from Dr. Polston's testimony that his perception that the Respondent was treating this patient for cancer essentially dissolved other constraints that might otherwise be placed on his pain medication prescribing.

report less function as you reduce medicines because they say they have more pain, they reduce their activity, and have more anxiety and more difficulty. There are some patients that go the other way and find more function as the medicines go down and that is something that, you know, that you are always trying to use both of those markers as a way to judge whether the therapy is appropriate.

Tr. 1202–03.

Dr. Polston also testified that the Respondent reduced the MME levels for Patients JD,⁸⁹ DD,⁹⁰ SM,⁹¹ and ET,⁹² and that the Respondent met the standard of care by virtue of the reductions he made in these patients' MME levels. Tr. 1200, 1213, 1221, 1228–29. However, according to Dr. Polston, reducing MMEs is not always necessary to meet the standard of care,⁹³ and the Respondent met the standard of care when he did not reduce Patient AA's opioid dosage. Tr. 1284. After being directed to the autopsy report for Patient AA, Dr. Polston opined that the Respondent's prescriptions were not a contributing factor to Patient AA's overdose death. *Id.* at 1182; *see also* Gov't Ex. 31. According to Dr. Polston, “[t]his patient, if he would not have taken the fentanyl, added in the alcohol and the ketamine, . . . would be still alive.” Tr. 1182. [Dr. Polston later clarified his testimony on cross-examination that the fentanyl, alcohol and ketamine “are contributing to his death,” but that “to say that those are precise cause of death, no, I cannot go that far.” Tr. 1280.]

Dr. Polston also testified that after reviewing all patient records presented to him, it was his opinion that the Respondent met the standard of care with respect to informed consent. *Id.* at 1229–30. However, when asked if it would change his opinion if he learned that the Respondent believed his care of the patients fell below the standard of care in regards to informed consent, Dr. Polston answered affirmatively; that is, learning that the Respondent's view that he failed to meet the standard would change Dr. Polston's mind on the issue. *Id.* at 1231–32. The witness explained his change in opinion this way: “[I]f he's reviewing his records and says that he did not meet the standard of care then I would agree with that.” *Id.* at 1232.

The witness initially testified that there was no evidence of early refills in

this case, and that the Respondent's practice of writing prescriptions of thirty day dosages every twenty-eight days was within the standard of care in California. *Id.* at 1232–33, 1236–38.^{*L} However, when Dr. Polston was asked if it would change his opinion if he learned that the Respondent believed his prescribing every twenty-eight days fell below the standard of care, he answered affirmatively. *Id.* at 1239. The witness altered his expert opinion based on the Respondent's alleged testimony, explaining that “he alone will know precisely what was going on at that appointment when he's writing it, and if he . . . feels that he was below the standard of care then I would say that, that would be below the standard of care.” *Id.*

Dr. Polston also testified regarding medical records presented by the Government that bore indicia of anomalous UDS results regarding Patient AA. Tr. 1243–44, 1250–53. Dr. Polston identified Patient AA's UDSs as inconsistent (not aberrant),^{*M} testifying that there was no indication in the records that he reviewed of aberrant behavior by Patient AA, and opining that the purported inconsistency could have resulted from the patient being a rapid metabolizer.⁹⁴ Tr. 1244–45, 1281–82. In his opinion, the Respondent's handling of the inconsistent UDS results

^{*L}I also found Dr. Polston's testimony about whether early fills are outside the standard of care to be evasive. “I don't think that's good care. I'm not sure, you know, the—your argument over time is concerning to me, but I can say that I know that that occurs. The standard of care is what reasonable physicians in the community would approve, and I have seen that in the community at multiple different levels.” When the Chief ALJ pressed him to clarify, he said, “I would say best practices is not to do that, but I see reasonable physicians in the community doing that.” Tr. 1237–38.

^{*M}I did not find Dr. Polston's argument about the difference between aberrant and inconsistent urine screens to be credible. He seemed to want to justify his stance that these drug screens did not rise to what he deemed “aberrant” no matter what the circumstance. Respondent's counsel asked if “there [was] any indication in any of the drug results or any of the records that [he] reviewed that this patient was having aberrant behavior and not just inconsistent?” Dr. Polston answered, “Yes. These appeared to me inconsistent and that those results were the same. I am concerned that there was multiple times. But in some ways, multiple times also means that there was something unusual about that.” Tr. 1282. He first references a concern that could make these UDS results “aberrant,” but then decides that that very concern is, in actuality, a reason not to be concerned. This logic is circular and evasive. Regardless of which term is used, the heart of the matter here is whether or not there needed to be documentation of the resolution of the aberrant or inconsistent UDS. Dr. Polston seemingly attempted to evade and confuse this issue.

⁹⁴Neither the Patient AA charts nor the balance of this record (including the Respondent's testimony) bore any indication that this patient was a rapid metabolizer, or that the Respondent believed he might be a rapid metabolizer.

in the charts was rendered within the standard of care by the act of the Respondent writing the letters PRN on some of the screens and by seeing the patient on a regular basis. *Id.* at 1263–65. However, when Dr. Polston was informed that the Respondent testified that even he believed that he fell below the standard of care when he dealt with the inconsistent UDSs, the witness again deserted the opinion he had previously offered with conviction and (with equal conviction) testified that it had become his (new) opinion that the Respondent did in fact not meet the standard of care in this category. *Id.* at 1265–66.

Overall, Dr. Polston's unabashed willingness to forsake his purported expert opinions at the first sign that the Respondent offered testimony that conflicted with those opinions obviously created internal inconsistencies that undermined the weight that can be attached to his presentation. While there is no question that the witness's credentials were impressive, Dr. Polston presented an overall impression that he was present to support the Respondent's position, even where the Respondent's position evolved. It was unhelpful that Dr. Polston initially testified that the Respondent's controlled substance prescribing did meet the standard of care in California, but when confronted by the Respondent's agreement with Dr. Munzing's testimony regarding informed consent, early refills, and anomalous UDSs, Dr. Polston unhesitatingly changed his view to conform with the Respondent's version. It was almost as if to say that his expert opinion was whatever the Respondent may have said before, now, or later, even if the Respondent's position toggled back and forth. To offer “whatever he said” as an expert opinion is not a feature that enhances the reliability that can be attached to the views expressed by a purported expert. Suffice it to say that Dr. Polston's amenability to instantly change course and support the Respondent's fluid opinions, based merely on being advised of them, undermines the weight that can be attached to his testimony. Additionally, at one point in his testimony, the Respondent's expert testified that “the guidelines are much different for chronic benign pain versus cancer pain.” Tr. 1156. According to Dr. Polston, a cancer diagnosis “really strips away nearly all guidelines” for prescribing controlled substances.⁹⁵ Tr.

⁹⁵Even setting aside the relative merits of this view, [it is unclear from the Medical examiner's report whether AA, in fact, had cancer, and given that he died of an overdose, it certainly is not a

⁸⁹Tr. 1200.

⁹⁰Tr. 1211–13; *see* Resp't Exs. D at 1051–55, L at 8–9, ¶ 27.

⁹¹Tr. 1214, 1219–20; *see* Resp't Exs. E at 1494, L at 10, ¶ 29.

⁹²Tr. 1226–28; *see* Resp't Ex. L at 10–11, ¶ 32.

⁹³Tr. 1273–76, 1284.

1157. The unique concept that a particular diagnosis would obliterate any controlled substance prescribing standard was offered here without any supporting sources and challenges common sense. Under a mild extrapolation of this logic, a near-lethal, or even lethal dose of controlled pain medication would not be excluded from Dr. Polston's view of acceptable prescribing.

That is not to say that Dr. Polston is entirely unreliable. Like the Respondent, this is an extremely experienced and well-credentialed professional. There were certainly aspects of his biographical information, the progress of his career, and even some testimony regarding treatment and prescribing that presented as sensible and consistent with the record, and those opinions and information should be relied upon. However, it is where Dr. Polston's testimony conflicts with the testimony of other expert testimony and evidence of record that reliance becomes problematic. Specifically, where Dr. Polston's expert testimony conflicts with the testimony of Dr. Munzing, it is Dr. Munzing's view that must control.

Other facts necessary for a disposition of this case are set forth in the balance of this Recommended Decision.

The Analysis

Public Interest Determination: The Standard

Under 21 U.S.C. 824(a)(4), the Agency may revoke the COR of a registrant if the registrant "has committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4). Congress has circumscribed the definition of public interest in this context by directing consideration of the following factors:

- (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).

stretch to question whether he had other motivations for seeking medication. Gov't Ex. 31 at 5; Tr. 194–95. However, I find that whether or not AA had cancer is not relevant to my overall finding that Respondent prescriptions to AA were issued beneath the applicable standard of care and outside the usual course of professional practice.]

"These factors are to be 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 COR should be revoked. *Id.*; see *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Moreover, the Agency is "not required to make findings as to all of the factors," *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall*, 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail, *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). 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).

In adjudicating a revocation of a DEA COR, the Government has the burden of proving that the requirements for the revocation it seeks are satisfied. 21 CFR 1301.44(e). Where the Government has met this burden by making a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough*, 73 FR 364, 387 (2008). Further, "to rebut the Government's *prima facie* case, a[] registrant is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 FR 8194, 8236 (2010); *accord Krishna-Iyer*, 74 FR 464 n.8. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.*, 78 FR 38363, 38364, 38385 (2013).

Normal hardships to the registrant, and even to the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. See *Linda Sue Cheek, M.D.*, 76 FR 66972, 66972–73 (2011); *Gregory D. Owens, D.D.S.*, 74 FR 36751, 36757 (2009). Further, the Agency's conclusion that "past performance is the best predictor of future performance" has been sustained on review in the courts, *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct, *Hoxie*, 419 F.3d at 483.⁹⁶

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, see *Steadman v. SEC*, 450 U.S. 91, 100–03 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by "substantial evidence," *Hoxie*, 419 F.3d at 482. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz v. U.S. Dep't of Justice*, 873 F.2d 1089, 1092 (8th Cir. 1989) (internal citation omitted), all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered, *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007); see *Humphreys v. DEA*, 96 F.3d 658, 663 (3d Cir. 1996). The ultimate disposition of the case "must be 'in accordance with' the weight of the evidence, not simply supported by enough evidence 'to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.'" *Steadman*, 450 U.S. at 99 (quoting *Consolo v. FMC*, 303 U.S. 607, 620 (1966)).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall*, 412 F.3d at 183, but mere unevenness in

⁹⁶ The Agency has repeatedly upheld this policy. See *Ronald Lynch, M.D.*, 75 FR 78745, 78754 (2010) (holding that the respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.*, 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.*, 74 FR 17529, 17543 (2009); *Krishna-Iyer*, 74 FR 463; *Steven M. Abbadessa, D.O.*, 74 FR 10077, 10078 (2009); *Med. Shoppe-Jonesborough*, 73 FR 387.

application does not, standing alone, render a particular discretionary action unwarranted. *Chein v. DEA*, 533 F.3d 828, 835 (D.C. Cir. 2008), *cert. denied*, 555 U.S. 1139 (2009); *cf. Dep't of Homeland Security v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (holding that an agency must carefully justify significant departures from prior policy where reliance interests are implicated). It is well settled that, because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Agency's final decision, *see Morall*, 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. *See* 5 U.S.C. 557(b); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

[Factor One

In this case, it is undisputed that Respondent holds a valid state medical license in California. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.*, 76 FR 20011, 20018 (2011). It is well established that a "state license is a necessary, but not a sufficient condition for registration." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chien, M.D.*, 72 FR 6580, 6590 (2007), *aff'd Chien v. DEA*, 533 F.3d 828 (D.C. Cir. 2008).

In determining the public interest, the "recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered." 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is

the basis for the DEA OSC. *John O. Dimowo, M.D.*, 85 FR 15800, 15810 (2020); *see also Vincent J. Scolaro, D.O.*, 67 FR 42060, 42065 (2002).

In this case, neither the MBC nor any other state entity has made a direct recommendation to DEA regarding whether the Respondent's controlled substances registration should be suspended or revoked. There is evidence on the record that on October 29, 2019, the MBC found that the Respondent violated state law by prescribing dangerous controlled substances to the Board Patients. Gov't Ex. 30 at 147, 157–61, 196–199. The MBC found in favor of revocation, but stayed the revocation pending completion of probation. *Id.* at 168.

The evidence before me is different than the evidence that was before the MBC. It demonstrates that Respondent engaged in additional violations of state and federal law with respect to his prescribing practices. The fact that the MBC chose to stay the revocation of Respondent's state medical license carries minimal weight under Factor One, because there is no evidence that the MBC would have made the same decision in the face of the additional misconduct found herein involving different patients.*^N Further, it is noted that, in spite of the decision's stay, the Board actually found in favor of revocation, which does not indicate a substantial amount of trust in Respondent. For all of these reasons, the terms of the MBC Order have been considered, but I find that they have little impact on the public interest inquiry in this case. *See Jeanne E. Germeil*, 85 FR 73786, 73799 (2020); *see also John O. Dimowo, M.D.*, 85 FR 15810. It ultimately is the Administrator who makes a determination of whether maintaining a COR is in the public interest as defined by the CSA, and the Administrator's purview is focused on entrusting Respondent with a controlled substances registration, which is a much more narrow inquiry than a medical

*^NIn *Dimowo*, the Acting Administrator found that "[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state;" however, *Dimowo* also limited the "recommendations" DEA would consider to the "actions of an appropriate state entity on the same matters, particularly where it rendered an opinion regarding the practitioner's medical practice in the state due to the same facts alleged in the DEA OSC." *John O. Dimowo*, 85 FR 15810. Although the same "matters" may include similar types of violations, in this case, I have no indication that the MBC would have made a similar decision in the face of these additional violations and misconduct.

license generally. *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5490 (2019).

In sum, while the terms of the MBC are not dispositive of the public interest inquiry in this case and are minimized due to the differences in the evidence in the MBC Order, the record evidence before me and the severity of the sanctions ordered by the MBC, I consider the stay of the MBC's revocation of Respondent's California medical license and give it minimal weight in Respondent's favor, because the charges could have immediately resulted in the revocation of his medical license, instead of a stayed revocation. *See Jennifer St. Croix*, 86 FR 19010, 19022 (2021). Even with this minimal weight in his favor, I do not find Respondent's continued registration to be within the public interest as explained below.]

Factors Two and Four: The Respondent's Experience Dispensing Controlled Substances and Compliance With Federal, State, and Local Law

The Government has founded its theory for sanction exclusively on Public Interest Factors Two (the Respondent's experience conducting regulated activity) and Four (the Respondent's compliance with state and federal laws related to controlled substances), and it is under those two factors that the lion's share of the evidence of record relates.⁹⁷ In this case, the gravamen of the allegations in the OSC as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that

⁹⁷ [Omitted the Chief ALJ's discussion of Factor One and added it into the text above]. [T]here is no record evidence of a conviction record relating to regulated activity (Factor Three). Even apart from the fact that the plain language of this factor does not appear to emphasize the absence of such a conviction record, myriad considerations are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities which lessen the logical impact of the absence of such a record. *See Dougherty*, 76 FR 16833 n.13; *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010) ("[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry."). *aff'd, MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.*, 74 FR 6056, 6057 n.2 (2009). Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. Since the Government's allegations and evidence fit squarely within the parameters of Factors Two and Four and do not raise "other conduct which may threaten the public health and safety," 21 U.S.C. 823(f)(5), Factor Five considerations are inapplicable and militate neither for nor against the sanction sought by the Government in this case.

part of his practice relative to prescribing controlled substances and acts allegedly committed in connection with that practice. Thus, it is analytically logical to consider Public Interest Factors Two and Four together. That being said, Factors Two and Four involve analysis of both common and distinct considerations.

Regarding Factor Two, it is beyond argument that the Respondent is a well-credentialed, experienced medical practitioner who has been treating many patients for many years. Resp't Ex. G; Tr. 898. There is likewise no evidence of record that, prior to his present difficulties, that the Respondent has been the subject of discipline by state or federal authorities relative to his controlled substance prescribing. [Omitted for brevity.] The Respondent's experience as a registrant is lengthy, and there is no evidence to contradict his contention that he has treated many, many patients, but the Agency has long held that benign experience cannot overcome intentional misconduct, and that the misconduct established by record evidence is considered under both Factors Two and Four. *See Roberto Zayas, M.D.*, 82 FR 21410, 21422 n.27 (2017) (announcing that "misconduct is misconduct whether it is relevant under Factor Two, Factor Four, or Factor Five, or multiple factors"). Thus, the balance of the evidence related to Factor Two, per the Agency's interpretation, will be considered below together with Factor Four.

As discussed, *supra*, Factor Four compels consideration of the Respondent's compliance with state and federal laws related to controlled substances. The DEA regulations provide that to be effective, a prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). The Supreme Court has opined that, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). Further, the Agency's authority to revoke a registration is not limited to instances where a practitioner has intentionally diverted controlled substances. *Bienvenido Tan*, 76 FR 1763, 17689 (2011); *see Dewey C. MacKay, M.D.*, 75 FR 49956, 49974 n.35 (2010) (noting that revocation is not precluded merely because the conduct was "unintentional, innocent, or devoid of improper motive") (citation omitted).

To effectuate the dual goals of conquering drug abuse and controlling

both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Controlled Substance Act (CSA)]." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a); *see* 21 U.S.C. 829. Furthermore, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR 1306.04(a).

The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *George C. Aycock, M.D.*, 74 FR 17529, 17541 (2009) (citing *Gonzales*, 546 U.S. at 274); *see also United States v. Moore*, 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Gonzales*, 546 U.S. at 274. A registered practitioner is authorized to dispense, which the CSA defines as "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis*, 72 FR 4035, 4040 (2007). The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States v. Alerre*, 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied*, 574 U.S. 1113 (2006); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986).

"Under the CSA, it is fundamental that a practitioner must establish and maintain a [bona fide] doctor-patient relationship in order to act in the usual course of . . . professional practice and to issue a prescription for a legitimate medical purpose." *Mackay*, 75 FR 49973 (citation omitted); *Patrick W. Stodola, M.D.*, 74 FR 20727, 20731 (2009); *Ladapo O. Shyngle, M.D.*, 74 FR 6056, 6057–58 (2009). The CSA generally looks to state law to determine whether a bona fide doctor-patient relationship was established and maintained. *Stodola*, 74 FR 20731; *Kamir Garcés-Mejias, M.D.*, 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.*, 72 FR 50397, 50407 (2007).

While true that the CSA authorizes the "regulat[ion of] medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales*, 546 U.S. at 909–10, and the agency also evaluates state standards. *Joseph Audio, M.D.*, 74 FR 10083, 10090 (2009); *Garcés-Mejias*, 72 FR 54935; *United Prescription Servs.*, 72 FR 50407. In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from engaging in unlawful prescribing. *Aycock*, 74 FR 17541.*^o

Here, the relevant state law provisions largely mirror the CSA where they do not go beyond it. *Compare* Cal. Health & Safety Code § 11153(a) with 21 CFR 1304.06(a). California Health and Safety Code § 1153(a), like its CSA counterpart,⁹⁸ provides 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." California law further provides that "[r]epeated acts of clearly excessive prescribing" constitutes unprofessional conduct for a physician. Cal. Bus. & Prof. Code § 725(a). Additionally, gross negligence, incompetence, and repeated negligent acts can subject a physician to sanction by the state medical board. Cal. Bus. & Prof. Code § 2234.

California has specifically classified two categories of controlled substance prescriptions as *per se* illegal:

(1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled

*^oOmitted for clarity.

⁹⁸ 21 U.S.C. 802(21), 823(f).

substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

Cal. Health & Safety Code § 11153(a). A practitioner in California who knowingly issues such an illegal prescription faces criminal exposure. Cal. Health & Safety Code § 11153(b).

During the course of his testimony, the Government's expert, Dr. Munzing, outlined six elements that compose the standard of care for prescribing controlled substances in the usual course of professional treatment in California. Dr. Munzing explained that a physician must acquire a patient history, conduct a physical examination of the patient, determine whether additional data is necessary, produce an assessment of the patient that includes risk stratification, create an individualized treatment plan and obtain informed consent, and have proper documentation throughout each step. Tr. 94–111. These elements laid out by Dr. Munzing are consistent with instructions provided by the California Board in its publication, *Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons* (the MBC Guide). See Gov't Ex. 21 at 57–61. The MBC Guide also lays out six basic components to assist practitioners in meeting the standard of care in managing pain patients: History/physical examination; treatment plan, objectives; informed consent; periodic review; consultation; and records. *Id.* at 59–61. The California Board supplies the following explanation for acquiring a patient history and conducting a physical examination:

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

Id. at 59. The California Board explains producing an assessment of the patient, or the creation of a treatment plan, as follows:

The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a

rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Id. In clarifying informed consent, the California Board states that physicians “should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver, or guardian.” *Id.* at 60.

The California Board also suggests that a physician “should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health.” *Id.* In addressing consultation, the California Board advises that “physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.” *Id.* Dr. Munzing emphasized the importance of the documentation requirement to ensuring patient safety. Tr. 105–07. Dr. Munzing's explanation of the documentation requirements mirrored the California Board's guidelines.

The physician and surgeon should keep accurate and complete records according to [the five other controlled substance prescribing components], including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

Gov't Ex. 21 at 61.

The applicable California Code provisions are consistent with the standards outlined by the Government's expert, Dr. Munzing. Further, the Respondent (and ultimately his expert) conceded that his controlled substance prescribing fell below the applicable standard of care in California in regard to prescribing early refills, addressing inconsistent UDSs, and (at least with respect to Patient ET) acquiring adequate informed consent. Accordingly, on these issues, the testimony of the Government's expert stands uncontroverted on the present record. When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross v. Gardner*, 365 F.2d 554 (6th Cir. 1966). There is no shortage of reliable expert knowledge in the present record, at least regarding these issues, it is uncontroverted, and it is not favorable to the Respondent.

At issue in this case is the Respondent's controlled substance prescribing to ten patients: The four Board Patients that were the subject of findings by MBC, and the Six Patients that were evaluated by Dr. Munzing. While the evidence of record is generally discernible, the same cannot entirely be said of the allegations propounded by the Government in its OSC relating to the Six Patients. While it is likely that the Government's intention was to contend that the Respondent issued prescriptions to the Six Patients for controlled substances outside the usual course of professional practice, that is not entirely reflected in the plain language of the Government's charging document.

As discussed, *supra*, the CSA authorizes the Agency to impose a sanction upon a finding that a registrant “has committed such acts as would render his registration under [21 U.S.C. 823] inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). Thus, for the Government to satisfy its *prima facie* burden, it must allege facts that, if sustained, would actually demonstrate that the registrant committed such acts as would render his registration inconsistent with the public interest. See *id.* Here, in a subset of allegations relating to the Six Patients (the He-Opined Allegations), the Government does not allege actions, conduct, or omissions attributable to the Respondent, but rather conclusions or observations made by its own medical expert. ALJ Ex. 1 ¶¶ 14.a, c, d, e, f; ¶¶ 18.a, c, d; ¶¶ 21.a, c, d; ¶¶ 23.a, c; ¶¶ 26.a, c, d; ¶¶ 30.a, c, d. The plain language of each of the He-Opined Allegations points not to conduct or omissions made by the Respondent, but merely to the fact that (at some unspecified point in time) the Government's expert concluded that certain matters were true.⁹⁹ [Omitted for brevity.]

In pursuing a sanction under the Administrative Procedure Act (APA) the Government is obligated to provide timely notice to a respondent, *inter alia*, of “the matters of law and fact asserted.” 5 U.S.C. 554(b)(3); see also 21 CFR 1301.37(c). The Agency is required to provide a respondent with notice of those acts which the Agency intends to rely upon in seeking a sanction so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *CBS Wholesale Distribs.*, 74 FR 36746, 36749 (2009). An administrative charging document is not subject to the same level of formality as

⁹⁹ [Omitted for relevance.]

required in a criminal indictment or a pleading filed in a civil case, *Clair L. Pettinger, M.D.*, 78 FR 61591, 61596 (2013); *Roy E. Berkowitz, M.D.*, 74 FR 36758, 36759–60 (2009), but neither is the requirement meaningless or illusory. The notice must be adequate, but the allegation as written, must also establish culpability if proved. [Omitted for brevity.]

However, [] the Agency has embraced the concept of litigation by consent. *Grider Drug #1 and Grider Drug #2*, 77 FR 36746, 44070 n.23 (2012). Where, as here, a respondent has been provided with adequate notice of an allegation, was afforded a full and fair opportunity to litigate the issue, and did fully litigate the issue without objection, the Agency has applied the well-established principle of litigation by consent to adjudicate that which was intentionally tried by the parties. However, the analysis of litigation by consent is fact specific and the Agency may not base its decision on an issue that was inadvertently tried by the parties. *See Farmacia Yani*, 80 FR 29053, 29059 (2015). “Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.” *Id.* (internal citations omitted).

It is beyond argument that the He-Opined Allegations are unartfully pleaded, but it is likewise irrefutable that the parties mutually understood that they were litigating the issue of whether the controlled-substance prescribing issues set forth in a subset of those allegations depicted conduct that fell below the applicable standard. In fact, the Respondent, through his counsel, frequently tracked along with the OSC allegations and phrased many of his queries on whether the Government-expert’s criticisms raised by the He-Opined Allegations were valid. *See, e.g.*, Tr. 535, 643, 929, 932–33, 962, 981, 983, 1005, 1182. Additionally, this issue was not raised by the Respondent in his closing brief. *See* ALJ Ex. 37. This case raises no realistic notice issues, and the language related to the opinions of the Government’s expert will be treated here as surplusage that does not impact the validity of the charges or the findings. Accordingly, based on the conduct of the parties at the hearing, as well as their post-hearing briefs, the He-Opined Allegations will be considered as if the underlying actions are alleged, not as if the conclusions of the Government’s expert (at some

unspecified time) are the single issue (that is: as they were drafted and served on the Respondent and this tribunal).¹⁰⁰ *P

During the course of this case, Dr. Munzing delivered his expert opinion that the Respondent’s charts did not reflect that he adequately discussed the risks attendant upon the opiate course of treatment he was employing on the Six Patients. While the Respondent and Dr. Polston held differing views of this perspective, Dr. Munzing’s views on this issue (and all the issues upon which he opined in this case) are afforded controlling weight. Accordingly, OSC Allegations 14.b, 18.b, 21.b, 23.b, 26.b, and 30.b are *sustained*.

Similarly, Dr. Munzing’s expert opinion, supported by the findings of the San Diego Medical Examiner’s Office in its ME Report¹⁰¹ (although in conflict with the views of the Respondent and Dr. Polston), that controlled substances prescribed by the Respondent were among the contributing factors to Patient AA’s death,¹⁰² is likewise afforded controlling weight. Accordingly, OSC Allegations 12 and 14.f are *sustained*.

The Respondent’s practice of refilling 30-day controlled substance prescriptions every 28 days for the Six Patients, causing a reservoir of extra medication, is an area where the Respondent, during the course of his testimony, was able to agree with the expert opinion of Dr. Munzing. Accordingly, as amended,¹⁰³ OSC Allegations 14.e, 18.d, 21.d, 23.c, 26.d, and 30.c are *sustained*.

Although the Respondent remained convinced about the validity of the controlled medications and dosages he prescribed to the Six Patients, as well as

the combinations of medicines in the context of the time and the ailments he was treating, in general he did not resist the Government’s view, supported by the expert opinion of Dr. Munzing, that the documentation generated in the Respondent’s charting of the Six Patients was inadequate to a point where it fell below the applicable standard of care. Dr. Munzing’s expert opinion has been afforded controlling weight. Accordingly, OSC Allegations 14.a, 14.c,*Q 18.a, 18.c, 21.a, 21.c, 23.a, 26.a, 26.c, and 30.a are *sustained*.

The OSC contains allegations regarding controlled substances with doses and amounts specific to each of the Six Patients. The record contains sufficient evidence to preponderantly sustain the amounts alleged for Patients

*Q In his Exceptions, Respondent claims that the Chief ALJ recommended sustaining allegations 14c and 18c that Respondent’s concurrent prescribing of opioids and benzodiazepines was beneath the standard of care “without discussing the reasons why.” Resp’t Exceptions at 10. Respondent claims, as he did many times in this case, that the CDC Guidelines “do not prohibit this combination.” *Id.* Dr. Munzing testified that “the fact that you prescribe a benzodiazepine to [sic] an opioid, the risk of overdose goes up ten-fold. That’s a significant increase.” Tr. 448. He stated that “the FDA and the CDC both came out with—one was a black box warning by the FDA; the other is the CDC guidelines, but it was known before that time. It was in literature by 2015, potentially earlier than that.” Tr. 449. Dr. Munzing further testified that because “the patient is being put at significantly increased risk,” the standard of care requires that “[i]t certainly needs to be recognized, addressed, and if the patient has conditions that the potential benefit is outweighed by the potential risk, which it would be hard to show that in this case. Doctors need to well document that and show that alternatives are really not an option.” Tr. 449. Therefore, Respondent’s testimony that he had discussions with these patients regarding the risks, but simply did not document those discussions “as well as [he] should have,” Tr. 933, does not address the other issues that Dr. Munzing raised, such as documenting that alternatives are not an option. The testimony Respondent cites to in its Exceptions clearly only addresses documenting the discussion of the risks with the patient, not alternative treatments or the risks of the combination generally. Resp’t Exceptions at 11. Further, even if I found, in accordance with Respondent and Dr. Polston, that “in the year 2014, prescribing opioids and benzodiazepines was not outside the standard of care,” the Government’s allegations would still include several years of prescribing to AA and BB, during which Respondent’s documentation did not address the concerns that the co-prescribing of these substances raised. Resp’t Exceptions at 11 (citing Ex. L at 10). Dr. Polston notably did not testify about this combination and the only reference to it is in his report as the Respondent cited, which is given limited weight given my inability to assess the credibility of these statements. Ultimately, I find that the record evidence clearly supports the Government allegations related to the concurrent prescribing, and I do not find Respondent’s Exception to be meaningful in my overall assessment that Respondent issued prescriptions beneath the standard of care and outside the usual course of professional practice to AA and BB, particularly given the multitude of other reasons why these prescriptions fell beneath the standard.

¹⁰⁰ [Footnote omitted for clarity.]

*P I agree with the Chief ALJ that the OSC’s drafting was imprecise. I note that the OSC did include overarching acts or omissions in addition to the more-specific expert opinions. The OSC stated that Respondent “violated federal and California law by issuing prescriptions for controlled substances outside the usual course of profession practice and not for a legitimate medical purpose, to more than six patients.” *See, e.g.*, OSC at 3; *see also id.* at 2 (“a prescription for a controlled substance is legitimate only if ‘issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.’” (citing 21 CFR 1306.04(a))). Therefore, although I agree with the Chief ALJ that the drafting could be improved, I also agree with him that Respondent was adequately noticed of the allegations against it in this case.

¹⁰¹ Gov’t Ex. 31 at 5.

¹⁰² The Government did not allege, nor is it necessary for this Recommended Decision to find, that the Respondent’s prescribing was the sole or even principal factor [or a “significant component,” Tr. 943] in Patient AA’s overdose death.

¹⁰³ ALJ Ex. 25.

AA,¹⁰⁴ BB,¹⁰⁵ JD,¹⁰⁶ and ET¹⁰⁷ as charged. Accordingly OSC Allegations 8, 15, 19, and 27 are *sustained*. However, the amounts specified regarding Patients DD¹⁰⁸ and SM¹⁰⁹ are more problematic, and it is at least possible that a greater investment on the part of the Government in this regard could have been more helpful.¹¹⁰ Although subsection (1) of the Patient DD OSC dosage/amount allegation references “patches,” only lozenges were raised by the evidence, and there is no evidence to support the subsection (4) reference to eight fills of temazepam. Accordingly, OSC Allegation 22 is *sustained in part* to the extent that subsection (1) alleges “a quantity of fentanyl citrate,” subsections (2) and (3) are *sustained* as charged, and subsection (4) is *not sustained*. Similarly, the dosage/amount allegation pertaining to Patient SM contains insufficient quantitative evidence to support the amounts specified in subsections (3), (4), and (5).¹¹¹ Accordingly, OSC Allegation 24 is *sustained in part* to the extent that subsection (3) alleges “a quantity of diazepam,” subsection (4) alleges “a quantity of fentanyl,” and subsection (5) alleges “a quantity of oxycodone.” Subsections (1) and (2) are

¹⁰⁴ ALJ Ex. 1 ¶ 8.

¹⁰⁵ ALJ Ex. 1 ¶ 15.

¹⁰⁶ ALJ Ex. 1 ¶ 19.

¹⁰⁷ ALJ Ex. 1 ¶ 27.

¹⁰⁸ ALJ Ex. 1 ¶ 22.

¹⁰⁹ ALJ Ex. 1 ¶ 24.

¹¹⁰ See *Gregg & Son Distributors*, 74 FR 17517, 17517 n.1 (2009) (clarifying that “it is the Government’s obligation as part of its burden of proof and not the ALJ’s responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding”). In addressing the specifically-alleged amounts of medications prescribed to the Six Patients, the Government’s closing brief avers that the Respondent issued “numerous prescriptions” of a particular controlled substance to a patient and then provides a general reference to a contemporaneously-filed attachment. ALJ Ex. 35 at 5–9. Not to put too fine a point on the matter, but this methodology is less helpful than it could have been in this case because the attachment is regrettably hobbled by numerous entries that appear to be less than entirely accurate. For instance, the chart attachment for Patient DD contains no reference to patches of fentanyl citrate, modafinil, or temazepam (although OSC Allegation 22 alleges specific amounts of each), it lists only 58 prescription dates (while OSC Allegation 22 alleges 93 separate fills of fentanyl patches and 60 separate fills of OxyContin), and it appears that it may even be missing a third page. See *id.* at 41–42. The chart attachment for Patient BB includes at least one prescription issued by the Respondent outside of the timeframe alleged in OSC Allegation 15. See *id.* at 33–35. Further, multiple prescriptions listed in the Patient SM chart attachment contain inaccurate dosages and medications. See *id.* at 43–46.

¹¹¹ See *Gregg & Son Distributors*, 74 FR 17517 n.1 (noting that “it is the Government’s obligation as part of its burden of proof . . . to sift through the records and highlight that information which is probative of the issues in the proceeding”).

sustained as charged.*R^{112 113 114 115 116 117 118}

The Government alleges that the Respondent examined CURES reports eight times regarding Patient BB, but presented no evidence that this occurred (or why it would be relevant to the extent he had done so).¹¹⁹ Accordingly, OSC Allegation 17 is *not sustained*.

The Government alleges that on multiple occasions where the Respondent encountered anomalous urine drug screen results relative to two of the Six Patients,¹²⁰ his medical charting failed to reflect actions that would have been required to stay within the standard of care. Dr. Munzing’s expert opinion has been afforded controlling weight, and although the Respondent pushed back regarding Patient SM,¹²¹ in general, he accepted that his documentation in this regard was lacking. Accordingly, OSC Allegations 9, 10, 14.d, 28, and 30.d are *sustained*.

The Government introduced an October 29, 2019 order (Board Order)

*R The Government allegations also included references to “letters of concern” from insurance companies that identified the high level of MMEs that Respondent was prescribing. ALJ Ex. 1 ¶ 13, 16, 35, 29, 20; See *e.g.*, Gov’t Ex. 2 at 522–23, 542–44, 596–98, 672–74. The Chief ALJ sustained some of the allegations related to the letters of concern, and in doing so, noted issues with the Government’s evidence. RD at 39. I am declining to consider these letters as separate violations—they appear to more support the overall notion that Respondent’s prescribing was in violation 21 CFR 1306.04; however, there is little explanation on the record supporting the direct relevance of the letters, and there is ample evidence on the record to support finding a violation of 21 CFR 1306.04 without such letters. As such, I have omitted this section of the RD.

¹¹² Omitted. See n.*R *supra*.

¹¹³ Omitted. See n.*R *supra*.

¹¹⁴ Omitted. See n.*R *supra*.

¹¹⁵ Omitted. See n.*R *supra*.

¹¹⁶ Omitted. See n.*R *supra*.

¹¹⁷ Omitted. See n.*R *supra*.

¹¹⁸ Omitted. See n.*R *supra*.

¹¹⁹ Again, see *Gregg & Son Distributors*, 74 FR 17517 n.1 (clarifying that “it is the Government’s obligation as part of its burden of proof and not the ALJ’s responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding”).

¹²⁰ ALJ Ex. 1 ¶¶ 9, 10, 14.d (Patient AA); ¶¶ 28, 30.d (Patient ET).

¹²¹ The Respondent testified that he did not feel that Patient ET’s positive drug screen result for temazepam was truly aberrant because, in his view, that result was consistent with a medication (diazepam) that he had prescribed. Tr. 1028. Although the Government did not present evidence to refute the Respondent’s proposition in this regard, Dr. Munzing’s opinion has been afforded controlling weight.

¹²² Gov’t Ex. 30 at 5.

¹²³ Stips 1, 2.

¹²⁴ See 21 CFR 1301.44(e).

¹²⁵ See *Dougherty*, 76 FR 16830; *Johnson*, 75 FR

issued by the California Board regarding disciplinary action taken by MBC against the Respondent. Gov’t Ex. 30. In DEA administrative proceedings, factual findings and legal conclusions based on state law reached by state administrative tribunals are given preclusive effect. *Robert L. Dougherty, M.D.*, 76 FR 16823, 16830 (2011); *Gilbert Eugene Johnson, M.D.*, 75 FR 65663, 65666 (2010); see also *James William Eisenberg, M.D.*, 77 FR 45663, 45663–64 (2012) (holding that official notice taken of findings in a state medical board censure order gives those findings preclusive effect). State medical boards are presumed to be the expert agency with the authority to determine whether one of its practitioners has engaged in unprofessional conduct or provided incompetent medical care, and “[w]here . . . a state medical board has determined that a practitioner’s conduct violated the standard of care, its findings of fact and conclusions of law are not subject to relitigation before the Agency.” *Ruben*, 78 FR 38369. The key inquiry is not whether a full evidentiary hearing was conducted in the prior proceedings, but whether the parties had a full and fair opportunity to litigate the issues prior to the Agency’s decision. *Jose G. Zavaleta, M.D.*, 78 FR 27431, 27434 (2013).

The Board Order introduced by the Government includes the following findings related to MBC’s decision that the Respondent violated state and/or federal law and engaged in unprofessional conduct by prescribing dangerous controlled substances to the Board Patients. Gov’t Ex. 30 at 147, 157–61. MBC’s findings regarding the Board Patients are herein discussed *in seriatim*.

With respect to Board Patient A, MBC found that the Respondent prescribed opioids to Patient A, between December 2011 and early 2013, in an amount that exceeded 300 MEDs. *Id.* at 129–30. While prescribed these large quantities of controlled substances, Patient A “reported lack of analgesia and continued chronic pain, and decreased function, and [] displayed aberrant behaviors.” *Id.* at 129. MBC found that the Respondent “committed gross negligence in his care and treatment of Patient A” by continuing to prescribe high dose opioids even though her chronic pain was not effectively treated with the prescribed medications and she displayed aberrant behaviors. *Id.* at 128–29, 157. Accordingly, inasmuch as the California Board’s findings are *res judicata* in these proceedings, OSC Allegation 31.a, which pertains to Patient A, must be and is *sustained*. See

Dougherty, 76 FR 16830; *Johnson*, 75 FR 65666.

Regarding Board Patient B, the California Board found that the Respondent committed gross negligence when he failed to discuss the attendant risks and benefits of controlled substances and failed to enter into a pain management agreement with Patient B. Gov't Ex. 30 at 130, 146, 158. The Respondent additionally prescribed greater than 30-day supplies of controlled substances to Patient B on multiple occasions during 2013, which the Board found to constitute gross negligence. *Id.* at 131, 144, 158. Accordingly, inasmuch as the California Board's findings are *res judicata* in these proceedings, OSC Allegations 31.b and 31.c, which pertain to Patient B, must be and are *sustained*. See *Dougherty*, 76 FR 16830; *Johnson*, 75 FR 65666.

MBC found that the Respondent's treatment of Board Patient D was grossly negligent in that he continued to prescribe her controlled substances despite aberrant behaviors, possible addiction, and noncompliance with her pain management agreement. Gov't Ex. 30 at 135, 158. In finding that the Respondent failed to adequately monitor his treatment of Patient D, the Board identified that the Respondent could have employed, but did not, UDSs and random pill counts as monitoring methods. *Id.* at 136. Notably, the California Board found that, for at least one prescription, the Respondent's conduct with respect to Patient D was an "extreme departure" from the standard of care for medical professionals in California. *Id.* at 98, 136–37. Accordingly, inasmuch as the California Board's findings are *res judicata* in these proceedings, OSC Allegation 31.d, which pertains to Patient D, must be and is *sustained*. See *Dougherty*, 76 FR 16830; *Johnson*, 75 FR 65666.

With respect to Board Patient E, the California Board found the Respondent's conduct to similarly be grossly negligent. Gov't Ex. 30 at 137, 158. MBC found that the Respondent prescribed controlled substances to Patient E without "taking a systematic and thorough history including vitals, without periodically reviewing and documenting efficacy of treatment, without regularly assessing for possible diversion, and without discussing the risks, benefits, and alternatives of pharmacological treatment." *Id.* at 137; see also *id.* at 158. Moreover, MBC found that the Respondent further departed from the standard of care in prescribing methadone to Patient E, a known alcoholic, when methadone and

alcohol are known to be contraindicated. *Id.* at 139–40, 148, 158, 161. Inasmuch as the California Board's findings are *res judicata* in these proceedings, OSC Allegations 31.e and 31.f, which pertain to Patient E, must be and are *sustained*. See *Dougherty*, 76 FR 16830; *Johnson*, 75 FR 65666.

All subsections of OSC Allegation 31 (the Board Patient Allegations) are *sustained*, and any one of these subsections, standing in isolation is (and all, when considered collectively are) sufficient to satisfy the Government's *prima facie* burden in this case.

OSC Allegations 1 and 2 (COR and state licensure status) are *sustained* based on the evidence¹²² and stipulations¹²³ of record.

Accordingly, even in the face of the Respondent's lengthy experience as a practitioner and registrant, a balancing of Factors Two and Four militate strongly and powerfully in favor of the imposition of the revocation sanction sought by the Government.

Recommendation

The evidence of record preponderantly establishes that the Respondent has committed acts which render his continued registration inconsistent with the public interest. See 21 U.S.C. 824(a)(4). Since the Government has met its burden¹²⁴ in demonstrating that the revocation it seeks is authorized, to avoid sanction the Respondent must show that, given the totality of the facts and circumstances, the revocation sought by the Government is not warranted. See *Med. Shoppe-Jonesborough*, 73 FR 387. In order to rebut the Government's *prima facie* case, the Respondent must demonstrate not only an unequivocal acceptance of responsibility but also a demonstrable plan of action to avoid similar conduct in the future. See *Hassman*, 75 FR 8236. On the present record he has accomplished neither objective.

Agency precedent is clear that a respondent must unequivocally admit fault as opposed to a "generalized acceptance of responsibility." *The Medicine Shoppe*, 79 FR 59504, 59510 (2014); see also *Lon F. Alexander, M.D.*, 82 FR 49704, 49728 (2017). To satisfy this burden, the respondent must show "true remorse" or an "acknowledgment of wrongdoing." *Michael S. Moore, M.D.*, 76 FR 45867, 45877 (2011). The Agency has made it clear that an unequivocal acceptance of

responsibility is an unwaivable condition precedent for avoiding a sanction. *Dougherty*, 76 FR 16834 (citing *Krishna-Iyer*, 74 FR 464). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 830–31 (11th Cir. 2018); *MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011); *Hoxie*, 419 F.3d at 483.

As discussed, *supra*, the findings of the California Board, which are afforded preclusive effect here,¹²⁵ preponderantly and conclusively establish the Board Patient Allegations, and are sufficient standing alone to satisfy the Government's *prima facie* case for revocation. Yet beyond noting that MBC declined to impose greater sanctions than it could have,¹²⁶ the Respondent did not address those charges in his testimony or accept responsibility for any of the misconduct established therein. In his closing brief, the Respondent addressed the Board Order only insofar that he argued that it did not impact Public Interest Factor One (recommendation from an authorized state licensing authority) to his detriment. ALJ Ex. 37 at 3–4.^{127 128} The Agency has consistently held that without record evidence of both prongs (acceptance of responsibility and remedial steps aimed at avoiding recurrence), neither is relevant. *Ajay S. Ahuja, M.D.*, 84 FR 5498 n.33; *Jones Total Health Care, LLC*, 81 FR 79188, 79202–03 (2016); *Hassman*, 75 FR 8236. Thus, as the record stands, the Government has established OSC Allegations 31.a–31.f, which collectively and separately make out the Government's *prima facie* case for revocation, and the Respondent has offered no acceptance of responsibility. Hence, on this posture, based exclusively on the Board Patient Allegations and irrespective of the remainder of the analysis, it would be impossible under the Agency's interpretation of the CSA for the Respondent to avoid sanction.

The Respondent's defense fares no better regarding the balance of the Government's case related to the Six Patients. During his testimony, the Respondent accepted responsibility for a standard office practice that yielded each of the Six Patients a bounty of extra medicine, but not much else. In

¹²⁵ See *Dougherty*, 76 FR 16830; *Johnson*, 75 FR 65666.

¹²⁶ Tr. 1064–65.

¹²⁷ [omitted for relevance.]

¹²⁸ [omitted for relevance.]

¹²² Gov't Ex. 30 at 5.

¹²³ Stips 1,2.

¹²⁴ See 21 CFR 1301.44(e).

fact, the Respondent was careful to limit his acceptance to the deficiencies he was willing to acknowledge at the hearing.¹²⁹ Tr. 1062. He agreed that most¹³⁰ of the anomalous UDS results merited additional patient queries and documentation in his charts, and, in general, that the level of his medical record documentation could bear some level of improvement in the future. But the Respondent stridently adhered to the medical correctness of his controlled substance choices and dosing, based primarily on the only mostly accurate premise that he received the patient at a high dose, the somewhat accurate premise that he was engaged in a taper,¹³¹ and the untenable premise that the practice of pain management was “just coming off of the decade” where there was “no limits to dosing.” Tr. 982. At one point in his testimony, he described a high dosage to one of the Six Patients as “not an unheard-of dosage.” *Id.* The meaning (or timing) of “coming off of the decade”¹³² was never clear, and the concept that there was ever a point in time where there

¹²⁹ Even in his closing brief, the Respondent’s purported acceptance of responsibility, which is limited to the Six Patients allegations, reads this way: “By way of mitigation/remediation, [the Respondent] acknowledged and accepted responsibility for deficiencies contained in the OSC.” ALJ Ex. 37 at 32, ¶ 209 (record citation omitted). The Respondent’s carefully-worded closing-brief assertions that he has “unequivocally accepted responsibility for his deficiencies, as stated herein,” *id.* at 38 (emphasis added), and that he “admitted and took responsibility for numerous deficiencies that happened in the past,” *id.* at 39 (emphasis added), strike as a trifle too layered to satisfy the Agency’s requirement of an unequivocal acceptance of responsibility. Indeed, the Respondent’s closing brief represents that “he unequivocally accepted responsibility with respect to most of the allegations levied against him,” *id.* at 41 (emphasis supplied), and lists five areas where he reckons he got the acceptance job done, *id.* at 41–42. No effort is made on any level to accept any responsibility regarding the Board Patient Allegations.

¹³⁰ Regarding a UDS for Patient ET that reflected a positive result for temazepam, the Respondent testified that he does not feel that this was anomalous because the patient had been prescribed diazepam, which according to the Respondent, would metabolize into yielding a positive temazepam result. Tr. 1028–29; *see also* ALJ Ex. 37 at 31.

¹³¹ Although the Respondent’s progress notes frequently referenced his intention to wean down medications, the record evidence demonstrated that for extended periods of time these notes were limited to aspirations, and the medication was not reduced. The Respondent’s post-hearing-brief argument that he was, in essence, resisting the urge to “abruptly taper” or suddenly discontinue opioid therapy, ALJ Ex. 37 at 8, ¶¶ 49–50, is unpersuasive here, as the Government has not ascribed fault to the failure to engage in recklessly fast weaning of his patients’ medications. No weaning whatsoever took place regarding Patient AA, and no weaning for extended periods was evident regarding the balance of the Six Patients.

¹³² Tr. 982.

were “no limits to dosing”¹³³ is unsupported in this record and dubious at best.

Furthermore, during the hearing, the Respondent sporadically persisted in his position that the standard pain management contracts executed by each of the Six Patients constituted an adequate risks/benefits discussion to support informed consent. Admittedly, he seemed to acknowledge at some points that the opioid risks discussion would have benefitted by adding more detail (*e.g.*, such as the risk of death¹³⁴), but it would not be at all fair to say that this record paints a picture that demonstrates that he understands that the standard pain medication contract he employed did not meet the standard. It is clear from the plain language of the pain management contracts that these instruments were designed to advise patients of the consequences associated with medication-related non-compliance, not to supply adequate informed consent. Although the Respondent agreed that the pain management contracts did not advise the patients, *inter alia*, that death is a risk associated with the high dosage levels he was employing (or continuing), the Respondent maintained that the contracts did the job.¹³⁵ By the Respondent’s reckoning, the fact that the pain management contract mentioned the potential for respiratory depression was sufficient, because respiratory depression “is usually the antecedence of [death].” Tr. 932. This tack was particularly puzzling in light of the revelation that the Respondent ultimately did generate an opioid informed consent document that “plug[s] that hole.” *Id.* The Respondent’s inconsistent approach to this issue seemed dependent upon who was asking the questions and how the questions were framed. At one point during his testimony, when pressed on the issue, the Respondent seemed to offer a limited acknowledgement:

I needed to talk more about the actual conversations I had with the patient, the potential risks, including death, which was not mentioned specifically. And I see that as a deficit in my reading, documentation and my discussion with the patient.

Id. at 1026. [Omitted. The Chief ALJ noted, and I agree, that Respondent waived on whether he had the level of detailed conversations about risk that Dr. Munzing credibly testified were required by the standard of care, to

include the risk of death, with his patients.]^{*S}¹³⁶ On the present record it is far more plausible that such detailed conversations with the Six Patients never occurred, and that glossing over the issue by saying he wished he documented it better is unhelpful to the credibility of his position. The Respondent at once seemed to express understanding, even detailing a remedial step to improve documentation, but simultaneously declined to accept responsibility for the focus of the remedial step he implemented. The Respondent took essentially the same approach regarding his prescribing of dangerous combinations of drugs; *to wit*, that it was only the depth of his documentation that was lacking. More fundamentally, the Government’s position is that the Respondent’s high level of opioid prescribing created a sufficient danger to his patients such that he was required under the applicable standard of care in California to provide a specific warning

^{*S} Respondent argues in his Exceptions that Respondent “unambiguously testified his pain agreement was not an adequate document and it needed to be improved.” Resp’t Exceptions at 25. Respondent did testify at times that he had conversations with his patients about the risks and he did admit that his pain management agreement “should be, and has been improved.” Tr. 25. I also agree with the Chief ALJ that Respondent pushed back at one point about whether he needed to include death, RD at 11–12 (citing Tr. 932). Contrary to Respondent’s contention, it is not clear from the record whether he specifically discussed the risk of death with his patients, which Dr. Munzing testified was necessary under the standard of care. Regarding having “words such as death,” Respondent stated, “I think it’s important to mention to the patient, and that is something I want to do better and need to do.” Tr. 932. Nowhere did Respondent clearly testify that he discussed the risks, including the risk of death with his patients. *See also* n.136 and n.*I *supra*. Considering the fact that Respondent and the Chief ALJ and myself had to pull strands of the record to try to eke out an understanding of Respondent’s position on whether he had detailed discussions with his patients, including about the risk of death, and whether he believed he needed to have these detailed discussions to meet the standard of care, there is not enough on the record to find that Respondent accepted responsibility unequivocally, which necessarily includes a clear acknowledgement of the wrongdoing.

¹³⁶ The Respondent testified that he had an opioid risk discussion with Patient AA, but only “in the context of his original pain agreement” and supplied a vague reference to “subsequent discussions.” Tr. 931. In his closing brief, the Respondent avers that the evidence evinces “multiple discussions with [Patient AA] regarding the pain treatment agreement and the patient’s medication program.” ALJ Ex. 37 at 11, ¶ 74. Regrettably, the record citations supplied by the Respondent in his closing brief do not support the proposition that the risks associated with a high opioid protocol were discussed with the patients. *See, e.g.*, ALJ Ex. 37 at 17, ¶ 109; 21, ¶ 132; 25, ¶ 156. Even the few potential exceptions do not address high-dosage opioids, but rather “[t]he risks and benefits of the medical program.” *See, e.g.*, Gov’t Ex. 6 at 376, 390 (cited at ALJ Ex. 37 at 21, ¶ 132).

¹³³ *Id.*

¹³⁴ Tr. 932, 1026.

¹³⁵ The Respondent took a like position in the CAP he filed with the Agency. Resp’t Ex. M at 4–5.

to those patients about the risks associated with such high levels of pain killers. The Government's expert reliably testified to that standard of informed consent, and the Respondent never [clearly and unequivocally] accepted responsibility for the absence of such a [detailed] warning; whether documented in his charts or not.

The Respondent likewise declined to take any responsibility for any role that his prescribed medications [or any of his misconduct] played in the unfortunate death of Patient AA. Although this patient died from an overdose of multiple medications, some of which were prescribed by the Respondent, because Patient AA did not appear early for refills or ask for additional medications,¹³⁷ the Respondent, even in his closing brief,¹³⁸ adheres to the position that his prescribing played no role in Patient AA's overdose death, notwithstanding the contrary views held by the Government's expert¹³⁹ and the San Diego Medical Examiner.¹⁴⁰

[Respondent notes in his Exceptions, that he believes that the Chief ALJ did not adequately credit him for what he contends was unequivocal acceptance of responsibility for failing to take vital signs for his patients until 2018. Resp't Exceptions at 13 (citing Tr. 1034 "When I consult with my orthopedist and surgeons and so on, whom I was in the department with, and we'd look at their notes, they didn't contain that. And quite honestly, looking back on it, it was really a defect on my part that I wasn't collecting it, and I should have been doing it."*T). Respondent is correct to point out that this statement is much closer to accepting responsibility for found misconduct; however, he is incorrect in characterizing this statement as unequivocal. He begins his statement with a minimizing excuse—that no one else in his Department was doing it, and he uses the pronoun "we" to make clear that he was acting with

consensus of others of some kind.*U but most importantly, this statement is lacking in an understanding of the gravity of his misconduct. Dr. Munzing testified that vital signs are monitored "to try to keep [the patients] as safe as possible" due the high risk of the high dosages being prescribed to them. Tr. 166. I find Respondent's statement here, and elsewhere, where he claims to accept responsibility, to be lacking in a complete understanding and acknowledgment of these risks and the potential consequences of his misconduct. "[T]he degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator." *Stein*, 84 FR 46973. Respondent's statement acknowledges the mistake, but it lacks remorse, and it lacks recognition or even acknowledgement of the impact. I agree with the Chief ALJ that Respondent handled these issues with the gravity that someone would apply to nitpicks—that he is now checking boxes, as opposed to really changing his viewpoint. For all of these reasons, although I credit Respondent for admitting some fault on the vital signs violation, I cannot find that Respondent has unequivocally accepted responsibility, even for something that was clearly found in this case and in the MBC case against him.]

Although the Respondent testified that he has improved the detail level of his electronic charting, [takes vital signs from his patients to ensure their safety,] no longer prescribes dangerous combinations of controlled substances, now eschews the prescribing of carisoprodol, and has taken various courses to address controlled substance prescribing and documenting, in light of his refusal to enter an unequivocal acceptance of responsibility, his expressed, commendable plans further his case not at all.

To be sure, the transgressions alleged and proved here are serious and

numerous, but it is at least arguable that a true, unequivocal acceptance of responsibility, coupled with a thoughtful plan of remedial action could have gone a long way to supporting a creditable case for at least some level of sanction lenity. Indeed, while true that Agency precedent holds that the lack of an unambiguous acceptance of responsibility and remedial action plan are a cold bar to the avoidance of a sanction,¹⁴¹ the wisdom of the Agency's policy is vindicated in this case by the reality that the Respondent still believes that the gravamen of his transgressions amount to little more than documentation deficiencies and a numerical prescribing practice error. He feels his dosing and medicine combinations were appropriate,¹⁴² that the Six Patients received adequate informed consent about the high opioid levels through their pain contracts, and that although Patient AA died as a result of an overdose where his drugs were irrefutably *among* the medications that precipitated the fatality, that it was simply not his fault. The Respondent's message is essentially that the Government is nitpicking a knowledgeable practitioner, and to make the regulators happy he will clean up his documentation and drop dangerous combinations of medications from his treatment repertoire. And regarding the Board Patient Allegations, he has offered no responsibility acceptance whatsoever [on the record of this hearing.] It is not necessary or wise to conjecture whether an unequivocal acceptance of responsibility would have yielded a different result here. The fact is that it was not a part of the record.

The Agency is thus faced with a choice of imposing a registration sanction or imposing none and therein creating a fair likelihood that it will be instituting new proceedings, charging the same conduct against the same doctor, soon thereafter. To the extent the Respondent, after being present at this hearing, does not see that he was not acting as a reliable registrant, it is highly unlikely that he will see the light in a month, a week, or a day from an Agency action that affords him another chance.

In determining whether and to what extent imposing a sanction is appropriate, consideration must also be given to the Agency's interest in both specific and general deterrence and the

¹³⁷ Tr. 943–45.

¹³⁸ ALJ Ex. 37 at 13, ¶ 86.

¹³⁹ Tr. 310–12.

¹⁴⁰ Gov't Ex. 31 at 5. The ME Report, in pertinent part, renders the following ultimate conclusion: "Based on the [report's integral] findings and the history and circumstances of [Patient AA's] death as currently known, the cause of death is best listed as 'fentanyl, clonazepam, alprazolam, ketamine, hydrocodone, and morphine toxicity' and the manner of death as 'accident.'" *Id.*

*T Respondent also notes that "in response to criticism elsewhere, [he] started using the Vital Signs." Although he did not specifically reference it directly, in spite of arguing that he had accepted responsibility for the MBC's findings, I am assuming that he is referring to the California Medical Board complaint that was alleged against him around the time when he started taking vital signs. Tr. 1033.

*U See *Stein*, 84 FR 46972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility); see also *Ronald Lynch, M.D.*, 75 FR 78745, 78754 (2010) (Respondent did not accept responsibility noting that he "repeatedly attempted to minimize his [egregious] misconduct"); *Michael White, M.D.*, 79 FR 62957, 62967 (2014) (finding that Respondent's "acceptance of responsibility was tenuous at best" and that he "minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict.").

¹⁴¹ *Hassman*, 75 FR 8236.

¹⁴² Even in his closing brief, the Respondent highlights (with italics for emphasis) the concept that the CDC does not prohibit prescribing a combination of opioids and benzodiazepines. ALJ Ex. 37 at 12, 18.

egregiousness^{*V} of the offenses established by the Government's evidence. *Ruben*, 78 FR 38364, 38385. Considerations of specific and general deterrence in this case militate in favor of revocation. Specific deterrence is something of a mixed bag here. On one hand, the Respondent has credibly related that he has deployed a prescribing regimen that addresses the systemic early refill issue identified by the Government, he has taken CME classes that address helpful standards, and he credibly testified that he has cleaned up some of his documentation. However, as discussed, *supra*, the Respondent has not supplied any indication that, beyond picayune electronic documentation complaints, and understandable early refills,¹⁴³ that he has done anything worthy of a sanction. The Respondent did not present as a practitioner who intends to change the high level of his dosing, and there is no real way to track whether the Respondent genuinely intends to indefinitely limit the combination prescribing that he continues to feel was warranted. On the whole, [J]^{*W} the issue of specific deterrence supports a sanction. [The Chief ALJ found that specific deterrence supports a sanction, but that it was an "admittedly close case." ^{*X} Although I agree that

^{*V} The Administrator has noted that "there may be some instances in which the proven misconduct is not so egregious as to warrant revocation . . . and a respondent, while offering a less than unequivocal acceptance of responsibility[,] nonetheless offers sufficient evidence of adequate remedial measures to rebut the Government's proposed sanction." *Roberto Zayas, M.D.*, 82 FR 21410, 21429 (2017). This is not such an instance. Although I do give credit to Respondent's remedial measures, I do not find that I can ultimately trust him to continue implementing them without constant monitoring by this Agency, and as stated herein, he has not given me reason to extend him such a benefit. Furthermore, the violations herein are egregious and absolutely warrant revocation.

¹⁴³ In fact, notwithstanding his seeming acknowledgement of this below-standard activity, his closing brief reminds that his expert witness, Dr. Polston, testified that this practice "is NOT below the standard of care and it is something that reasonable physicians in the community have done." ALJ Ex. 37 at 13, ¶ 85 (emphasis in original).

^{*W} The Chief ALJ found that specific deterrence supports a sanction and I strongly agree. Although Respondent has made steps to improve his practice, I am not convinced by his limited and equivocal acceptance of responsibility that he will not repeat similar behavior once his probation period in California has ended. It is unclear to me that he understands the gravity of the misconduct alleged against him and that he has reacted appropriately and with the amount of contrition and acceptance that would convince me that he will not slip back into his old prescribing habits. Therefore, I find that the issue of specific deterrence weighs strongly in favor of revocation.

^{*X} Respondent takes this statement, which was evaluating one of the many aspects that I consider when deciding a sanction, out of context, arguing that "it is clear that Judge Mulrooney had a difficult

Respondent has made steps to improve his practice, I am not convinced by his limited and equivocal acceptance of responsibility that he will not repeat similar behavior once his probation period in California has ended. Therefore, I find that the issue of specific deterrence weighs in favor of revocation.]

As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben*, 78 FR 38385. This record contains such a high volume of errant prescribing and even an overdose death for which the Respondent eschews responsibility. To continue the Respondent's DEA registration privileges on the present record would send a message to the regulated community that it is acceptable to keep prescribing powerful drugs to multiple patients, in dangerous combinations, for years, even contributing to the death of a patient, until you get caught; and even then, it is not even required to admit your mistakes. The interests of general deterrence militate convincingly in favor of a sanction on this record.

Regarding the egregiousness of the Respondent's conduct, as discussed, *supra*, the Respondent prescribed inordinately high levels of medication to a host of patients, in dangerous combinations, with inadequate documentation and informed consent for many years, and one of his prescribed medications was a contributing factor in the death of one of those patients. These actions were not borne of an understandable misapprehension of his responsibilities, or an isolated misstep taken in the midst of a busy medical practice. The conduct preponderantly established on this record is extremely troubling, and warrants a substantial sanction.

A balancing of the statutory public interest factors, coupled with consideration of the Respondent's failure to unequivocally accept responsibility, and the Agency's interest in deterrence, supports the conclusion that the Respondent should not continue to be entrusted with a registration.

Accordingly, it is respectfully recommended that the Respondent's DEA COR should be *revoked*, and any pending applications for renewal should be *denied*.

time in deciding his recommendation." Resp't Exceptions at 34 (citing RD at 48). I disagree that the Chief ALJ had a difficult time deciding his recommendation. He stated clearly, and I agree, that "the conduct preponderantly established on this record is extremely troubling, and warrants a substantial sanction." RD at 49.

Dated: November 5, 2020.
John J. Mulrooney, II,
Chief Administrative Law Judge.

Respondent's Exceptions

On December 1, 2020, Respondent filed its Exceptions to the RD. I find that Respondent's Exceptions are either without merit or irrelevant to my Decision as explained below. Therefore, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's continued registration is inconsistent with the public interest, and that revocation is the appropriate sanction.

Exception 1

(I) Respondent first argues that Dr. Munzing should not have been accepted as an expert in controlled substance prescribing for pain management. Resp't Exceptions at 2. Respondent's argument is based on his concern that his attorney raised at the hearing that "the credibility and weight" given to the testimony of Dr. Munzing should be limited due to the fact that he does not generally treat patients on high dosages of opioids.^{*Y} Tr. 85. The Chief ALJ admitted Dr. Munzing as an expert in "the standard of care in prescribing controlled substances in the State of California including for the management of pain." Tr. 89.^{*Z} Dr. Munzing was not qualified as an expert in the practice of pain management, which Government counsel specifically made clear at the hearing, Tr. 84. For that matter, neither was Respondent's Expert, Dr. Polston, who was tendered and accepted as an expert witness in controlled substance prescribing in California, including controlled substance prescribing for

^{*Y} Given the evidence, which Respondent repeatedly highlighted, that he had successfully managed to reduce the MME of his patients and the fact that the witnesses were largely in agreement that reduction of the high dosages was important to the applicable standard of care, I find this argument to be confusing. *See, e.g.*, Tr. 1204 (Dr. Polston opining that Respondent's dosing was within the California standard of care, because "in total, the patient showed indications and the doses of opioids were being reduced as the care was ongoing"); *see also* Resp't Exceptions at 10 (touting that "[o]ver time, [Respondent] brought each one of them down drastically. Today, he does not accept any patients who are on daily MMEs over 90, and 93% of his current patients are at 90 MME or below." (emphasis in original)). It seems that Respondent is suggesting that the fact that Dr. Munzing has limited risk to his patients by prescribing at lower MME levels somehow makes him less of an expert. I cannot agree. It also seems a particularly odd argument given Respondent's assertions that he, himself, no longer prescribes at these levels to most of his patients.

^{*Z} Furthermore, it is noted that the Chief ALJ repeatedly ensured that the experts stayed within the scope of their expertise. *See, e.g.*, Tr. 100 ("We are only talking about the standard of care for controlled substance prescribing in California—the minimum standard of care").

intractable pain. Tr. 1153–54. In this Exception, Respondent reframes the primary issue in this case to be about the practice of pain management, when the underlying issue is actually whether Respondent’s prescribing of controlled substances was within the applicable standard of care and usual course of professional practice in California. Respondent also conveniently ignores the fact that the MBC found specifically that Respondent’s prescribing was beneath the standard of care with respect to some of the patients at issue in this case (the Board Patients). For the other patients (the Six Patients), Respondent mischaracterizes Dr. Munzing’s testimony. Dr. Munzing testified that identified instances where the Respondent’s patients were maintained on doses of medications that far exceeded the morphine milligram equivalent (MME) recommended by the Centers for Disease Control and Prevention (CDC) guidance without documentation that the patient was afforded an informed consent that explained the risks inherent in such treatment. Tr. 120; Gov’t Exs. 2–8, 10–13; Tr. 132–37, 139, 141–43, 145, 148–49, 156–57, 164–65, 169, 179–84, 191–92, 204–05, 224–25, 231–32, 271, 306–07 (Patient AA); Tr. 401–02, 406–07, 409–15, 417–22 (Patient BB); Tr. 384–89, 393–400 (Patient JD); Tr. 477–79, 481–84, 488, 490–95 (Patient DD); Tr. 314–17, 321–23, 328–32, 350–51, 353–56, 360–62, 365, 370–72, 377–82 (Patient SM); Tr. 424–29, 431–35, 437–38, 440–47, 450 (Patient ET). Respondent argues that Dr. Munzing testified that “he does not know the precise amount of MMEs a patient should be prescribed,” and concludes that “[i]t is appalling that credibility is given to an expert who does not know the proper dose of MMEs, yet opines the amounts Respondent prescribed are somehow incorrect.” Resp’t Exceptions at 3 (citing Tr. 704–06). A closer look at Dr. Munzing’s testimony demonstrates a much more measured and neutral picture. Tr. 131–B (explaining that there is no maximum amount of MME because “some patients need a higher amount, and so there’s—there’s no written absolute amount, but there’s certainly—one certainly needs to look at the risk to the patients, the potential benefits, and attempt to mitigate the risks”); Tr. 704–05 (responding to the question “[s]o what’s the exact dose that you should be receiving?” with “[w]ell, obviously, you know that one can’t say—I mean, you could have many people with the same symptoms and the dosage required would be very different. Again, as I said before, you balance the

benefit of the treatments including prescribed medications and other treatments with risk . . . and so you just can’t say here’s the number. But what I can say is that the risk is incredibly high. We don’t know whether or not medications at one-half or one-third this dosage may give the same level of benefit. Many times that is the case. And so that we don’t know because we haven’t actually tried that as far as what we can see here in the notes.”).

Contrary to Respondent’s argument, I find Dr. Munzing’s opinion to be rational and to permit much more flexibility in prescribing than Respondent would like to make it seem. The problem with Respondent’s prescribing of these high levels of MMEs is not the level itself—it is the risk associated with that level, which has been objectively established, and whether the Respondent adequately addressed that risk. The record demonstrates that he repeatedly did not address the risk for these patients over the course of many years, or at the very least did not meet many of the documentation requirements for addressing the risks.

I agree with the Chief ALJ that Dr. Munzing was qualified as an expert in the standard of care in prescribing controlled substances in the State of California including for the management of pain, and I reject Respondent’s Exception.

(II) Respondent next argues that Dr. Munzing’s testimony should not be given controlling weight over that of Dr. Polston for much of the same reasons that underlie his arguments that Dr. Munzing should not have been qualified as an expert. Respondent specifically picks apart the Chief ALJ’s rationale for finding Dr. Munzing more credible. In particular, he highlights that Respondent “only changed *one thing* in response to Dr. Munzing’s testimony, not many things.” Resp’t Exceptions, at 4 (highlighting that Respondent *only* changed his early prescribing practices as a result of Dr. Munzing’s testimony). Respondent also dedicates an entire Exception 6 to this issue, stating “[w]hile it is accurate that Respondent agreed with Dr. Munzing’s criticisms on other issues, he did not change his practices with respect to those issues after Dr. Munzing’s testimony. In fact, the bulk of the criticisms that Dr. Munzing had with Respondent’s care stemmed from care prior to April 2019.” Respondent then emphasizes that he is following the standard of care as described by Dr. Munzing now, and in fact, he argues that the record

demonstrates that he began to do so after April 2019.*^{AA}

I find Respondent’s argument about disqualifying Dr. Munzing’s expert testimony on the applicable standard of care to be incongruous with his argument that his practices now follow the standard of care as described by Dr. Munzing. If he only changed one thing as a direct result of Dr. Munzing’s testimony at the hearing, that is noted, but the record demonstrates, and Respondent actively argues, that he has changed *many* of his practices since the time period covered by the majority of the allegations in the OSC, and those practices clearly comport with the standard of care described by Dr. Munzing. I find that the standard of care as described by Dr. Munzing was supported by the record in this case, by California laws and guidance and even by the findings of the California Medical Board against the Respondent for the Board Patients. Further, I agree with the Chief ALJ that Dr. Polston’s version of the standard of care was less credible in that it shifted, was often vague and argumentative and that his testimony did not come across as neutral (regardless of the noted objective issues with neutrality for both paid experts).*^{BB} Therefore, I reject Respondent’s Exception.

*^{AA} In doing so, Respondent opines that it “is critical for the Administrator’s analysis because the Government’s own expert is testifying that as of April of 2019, Dr. Chesler had addressed the issues with which he was concerned and was practicing within the standard of care.” Resp’t Exceptions at 18 (citing Tr. 763–64 Dr. Munzing opining that *one* progress note for Patient BB at the end of the Government’s allegations in April 2019 was more in line with the standard of care as he had described it). The part of my analysis to which this finding might be “critical” is whether Respondent has accepted responsibility and instigated remedial measures such that I can entrust him with a registration. I credit Respondent for implementing practices that are more in line with meeting the standard of care in California and I hope that he continues to practice within the standard of care in the future, as I am sure does the Medical Board of California. Even assuming all of his current practices and all of his practices before and after the allegations are completely beyond criticism, which I do, the record still demonstrates that he prescribed beneath the applicable standard of care and outside the usual course of professional practice in California to many patients over the course of many years and in violation of federal and state law. Further, the record demonstrates that these violations were egregious and that, regardless of whether Respondent contributed to the cause, a patient died, and another patient had opiate use disorder (*Supra* n.*), and all of the Six Patients and Board Patients were at some amount of risk due to the high dosages they were prescribed.

*^{BB} Again, Respondent’s general medical decisionmaking is not the basis for the allegations in the OSC—the OSC allegations are focused on whether or not the identified prescriptions were issued in accordance with the applicable standard of care and in the usual course of professional practice and in accordance with state law. See

Exception 2

Respondent next takes Exception to the individual findings on the allegations as sustained by the Chief ALJ. I have addressed some of these in footnotes in the actual findings *supra*.

I note in particular here that Respondent took Exception to the finding that a physician “must avoid or carefully justify MMEs beyond 90 mg per day” and those related to the combination of controlled substances. Resp’t Exceptions at 8, 10, 11. In sustaining these allegations, the Chief ALJ stated the following:

Although the Respondent remained convinced about the validity of the controlled medications and dosages he prescribed to the Six Patients, as well as the combinations of medicines in the context of the time and the ailments he was treating, in general he did not resist the Government’s view, supported by the expert opinion of Dr. Munzing, that the documentation generated in the Respondent’s charting of the Six Patients was inadequate to a point where it fell below the applicable standard of care. RD at 38.

In taking Exception to these findings, Respondent once again tries to reframe the question regarding whether his prescribing was beneath the applicable standard of care and outside the usual course of professional practice by attempting to make this question into a determination about whether his patients “demonstrated an etiology consistent with a need for pain treatment.” Resp’t Exceptions at 9. He emphasizes that the “medical record shows a patient was receiving a functional benefit and pain relief based on the medications prescribed.” *Id.* In support of Respondent’s argument, I note that the MBC Guide does include objectives in the treatment plan, such as “pain relief and/or improved physical and psychosocial function.” MBC Guide at 59. However, I credit Dr. Munzing, who testified, “[W]ell, I mean, it’s good to get improved function. It’s good to get reduced pain. Nowhere is the issue that this person has extremely risky treatments. And so in no way do we know whether or not this patient might get the same benefits from having

generally, OSC. The expert testimony in this case is necessary, in conjunction with California law and guidelines, to understand the applicable standard of care. Dr. Munzing clearly demonstrated his expertise in how the standard of care applied to the facts in this case and furthermore, his testimony regarding his expertise was credible. In those places where Dr. Munzing’s and Dr. Polston’s testimony differed regarding the standard of care, California law and guidelines aligned more closely with Dr. Munzing’s testimony. Accordingly, I affirm the ALJ’s decision to qualify Dr. Munzing as an expert in this case and to credit his testimony over Dr. Polston’s.

medication that’s one-quarter or one-third, one tenth the amount. We just don’t know that.” Tr. 719. Again, the overarching issue with Respondent’s prescriptions is whether or not they were issued within the standard of care and usual course of professional practice. The record clearly indicates that Respondent’s prescribing at dosages with high MMEs and combination prescribing put his patients at risk, and his documentation clearly did not adequately address those risks either with adequate informed consent or adequate acknowledgements of the risks and formulation of a plan to reduce the MME levels for many of the years of the allegations. Regardless of whether the patients were transferred to Respondent at high levels of MMEs or on dangerous, highly abused combinations of controlled substances, and regardless of whether he eventually, after several years, managed to reduce their MME levels or wean them off of the combinations,^{*CC} the medical records do not demonstrate that he adequately addressed these risks when they existed. Therefore, I reject Respondent’s Exception and sustain the Chief ALJ’s finding that, particularly given the high levels of MME and the combination of controlled substances that Respondent was prescribing, “the documentation generated in the Respondent’s charting of the Six Patients was inadequate to a point where it fell below the applicable standard of care.” RD at 38.

Exception 3

Respondent takes Exception to the Chief ALJ’s findings that he did not conduct physical examinations on patients other than AA. I have amended the RD where Respondent has asked for clarification *supra* and have addressed Respondent’s contention that he accepted responsibility in the Recommendations Section *supra*. Respondent also took Exception to the Chief ALJ’s finding that Respondent did not take vital signs from the patients, noting that “[w]hile this is true in the beginning of the time of review,

^{*CC} Respondent states that “the Administrator should find that Respondent’s mere prescribing of these medications was not below the standard of care.” Resp’t Exceptions at 11. I find nowhere in the RD that makes such a statement. Respondent seems again to be trying to reframe the violations. He seems intent on limiting his violations to what he partially accepted responsibility for—that “his documentation should have been better,” *id.*, but he does not seem to understand the serious implications of his failure to document—that he was putting his patients at risk without adequately addressing those risks in the medical records—without demonstrating his planning and the thinking behind his prescribing actions, which as found herein is required by the standard of care and state law.

Respondent made significant changes over time and began taking vital signs in 2018.” *Id.* Respondent states that he took vital signs for all patients from that period on, *id.*, however, unfortunately, AA died on November 11, 2017, so he did not receive the benefit of Respondent’s improved practices. I have made an addition to clarify the RD in accordance with Respondent’s Exceptions. The fact that Respondent *only* failed to take vital signs from his patients for approximately four out of the five years covered by the Government’s allegations, during which he was issuing controlled substance prescriptions at high levels of MMEs to his patients, who were at increased risk for respiratory depression, does not alter my finding that the prescriptions for controlled substances at issue in this case were issued outside the standard of care.

Exception 4

I have addressed Respondent’s Exception related to informed consent in *supra* n.*I and *S.

Exception 5

Respondent takes Exception to the finding that the prescriptions he issued to AA contributed to his death. Resp’t Exceptions at 16. The OSC alleged that Respondent’s “prescriptions to Patient AA were a contributing factor to Patient AA’s overdose death.” OSC at 14.f. The ME Report, in pertinent part, renders the following ultimate conclusion: “Based on the[report’s integral] findings and the history and circumstances of [Patient AA’s] death as currently known, the cause of death is best listed as ‘fentanyl, clonazepam, alprazolam, ketamine, hydrocodone, and morphine toxicity’ and the manner of death as ‘accident.’” *Id.* Dr. Munzing stated that based on this report, “[t]wo of the medications that were prescribed were felt to be contributors to the death, the hydrocodone and the morphine.” Tr. 312. “It’s a multitude, it’s toxicity, a multitude of drugs including a couple he prescribed.” *Id.* According to Dr. Polston, the controlled substances prescribed did not contribute to A.A.’s death. He stated, “[t]his patient, if he would not have taken the fentanyl, added in the alcohol and the ketamine, . . . would be still alive.” Tr. 1182. Dr. Polston later clarified his testimony on cross-examination that the fentanyl, alcohol and ketamine “are contributing to his death,” but that “to say that those are precise cause of death, no, I cannot go that far.” ^{*DD} Tr. 1280.

^{*DD} Based on Dr. Polston’s clarification, I cannot characterize Dr. Polston’s testimony regarding the

I find that the substantial evidence on the record as described above supports the Chief ALJ's finding that the controlled substances prescribed by Respondent to AA were *among* the contributing factors to his overdose. However, the overarching issue for Patient AA, and all of the patients, is whether the alleged prescriptions were issued beneath the applicable standard of care in California and outside the usual course of professional practice, and the evidence clearly demonstrates that Respondent did not issue the alleged prescriptions to AA within the standard of care. I am not surprised by Respondent's adherence to his position that his prescriptions did not contribute to AA's death, considering the cascading implications that such a finding could have on his liability, but I also find that his testimony on this issue did not compel me to believe that he had more than a passing regret regarding any of his prescribing decisions related to AA. Regardless of whether the hydrocodone and the morphine actually contributed to his death, the evidence demonstrates that AA was abusing controlled substances, Respondent had been prescribing controlled substances to AA for a considerable period of time and did not detect this, in spite of several negative UDS for one of his prescriptions, and importantly, Respondent's medical records for AA offer little-to-no ability for the Agency to find out what was occurring. Furthermore, the fact is that one of Respondent's patients died of an overdose. In light of such a drastic occurrence, I would expect some sort of acknowledgement of the wrongdoing surrounding this incident, even without taking fault for the actual death. Instead, Respondent stated, "[AA] had been on a combination of medications for a long time with no issues, and I feel badly that this event happened, but I honestly saw no issue where what we were providing was a significant [*EE] component to someone who had so much additional medication in his system." Tr. 943.*FF

cause of AA's death as "unequivocal," as Respondent would suggest. Resp't Exceptions at 16.

*EE It is noted that Respondent used the term "significant component," which seems to acknowledge that the controlled substances he prescribed were a component of the death and contradicts his Exception to the Chief ALJ's finding that these controlled substances were "*among* the contributing factors" to AA's death. RD at 38.

*FF Respondent also stated, "I feel badly because I know he was supposed to be and I'm still not sure what had him take this test." Tr. 945. It is unclear from the record what test he is referring to or what AA was supposed to be doing—possibly exhibiting signs of addiction? But again, the testimony that Respondent felt "badly" did not amount to any sort of acceptance of responsibility for the prescriptions

Respondent's sole statement of regret related to AA's death was that he "feels badly." This casual throw away statement does nothing to acknowledge the magnitude of the situation and furthermore focuses the entire attention of his remorse on himself and the way that he feels about the death, which is apparently "badly." See *Nicholas Roussis M.D.*, 86 FR 59190, 59194 (2021) (finding that "remorse and acceptance of responsibility are not the same thing and . . . Respondent's consistent focus on his own suffering does not suggest an unequivocal acceptance of responsibility, but rather, suggests regret for the negative consequences that he has personally faced."). Respondent provided no acknowledgement that any of the wrongdoing, even the conduct that he admitted to, related to his care of AA could have played a small part in the patient's overdose. Had Respondent documented informed consent that he had discussed the risk of death with AA, had he documented that he conducted a physical examination or vital signs, had he more completely addressed the negative UDS in the records, had he addressed the high levels of MMEs he was prescribing and shown that he was carefully assessing all of these risks, then I doubt that AA's death would be an issue in this case. The questions that are unanswered with respect to AA's death demonstrate the true value of a prescribing practitioner's documented rationale.

Additionally, I do not find that Respondent has adequately accepted responsibility for his misconduct related to this patient, even setting aside whether or not the two controlled substances he prescribed were *among* the contributing factors to his death. Furthermore, my finding that Respondent has not accepted responsibility for something so serious, has significant implications about whether I can entrust him with a controlled substances registration in the future.

Exception 6

I have addressed Exception 6 related to Respondent's change in his practices in *supra* n.*H.

Exception 7

Respondent also takes Exception "to the conclusion he did not accept responsibility for misconduct in the Medical Board of California case." Resp't Exceptions at 19–20. In support of his argument, he cites to several

he issued to this patient beneath the standard of care.

findings in the MBC case where "he admitted he committed repeated negligent acts." *Id.* (citing Gov't Ex. 30 at 150–51). Instead of diving into the MBC's opinion on this issue, I will review the evidence to which the Respondent points that he accepted responsibility in that proceeding. Respondent himself states that "the MBC ALJ specifically made mention of this [Respondent's acceptance of responsibility] with respect to Patients D and E and further ruled that Respondent believed the care provided to A, B and C was appropriate and that the fact that he did not admit to mistakes with those patients was not a factor in the outcome of the case." *Id.* at 20. Essentially, Respondent is admitting that he did not fully accept responsibility in the MBC case, but arguing that because the MBC did not consider his non-acceptance as essential to its decision, I should not either. However, what matters to me in carrying out my responsibility under the CSA is whether Respondent can be entrusted with a registration. "Respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not recur." *Stein*, 84 FR 46974.

Respondent did testify that he made changes to his medical practice "regarding the Medical Board situation, which you know about, was highlighting some of the same—these are the same cases, the same era. It was my reaction to that, to show them that I was making a good faith effort to repair this." Tr. 1052. It appears to me that this statement was very careful, stumbling almost, not to acknowledge that the MBC found many of the exact same type of violations of the standard of care as were at issue in this hearing. And in fact, even though Respondent brought it up in his testimony, he still did not take a moment to accept responsibility for the MBC findings on the record, but stated that his reasoning for the changes to his practice was to "show them"—the MBC—that he was now complying with the standard of care. *Id.* I do credit Respondent for stating that he is "happier" about these changes. *Id.* However, as further discussed below and herein, Respondent has not unequivocally accepted responsibility for the Board Patients or the Six Patients.

Furthermore, I find it relevant to whether Respondent accepted responsibility for the MBC findings that Respondent continued to argue that his prescribing practices were historically within reason, given what he described

as the end of a “decade of pain.” On October 29, 2019, the MBC had clearly stated:

[A]s commented on earlier in this decision, the evaluation of respondent’s treatment of all of these patients needs to be looked at in terms of the risks to these patients and respondent’s efforts to size up and manage these risks using the tools available to him. By November 2011, when the CDC declared prescription drug abuse to be a nationwide epidemic, respondent as a pain specialist was on notice that he needed to use the tools available to him, whether UDTs, cup screens, pill counts, and/or CURES, and he also need to critically assess patients and what they told him. Respondent was slow to respond to this change in the opioid pain management landscape and did not consistently use the tools available to him. Even when he did use these tools and was put on notice of potential problems, he did not take actions to protect his patients from their risky aberrant behaviors.

Gov’t Ex. 30 at 165.

Respondent states on the one hand that he has addressed and accepted responsibility the issues that the MBC found, while still re-hashing arguments that the MBC discredited—that his prescribing practices were explained given the historical period that had just ended. The MBC found that “Respondent was slow to respond to this change in the opioid pain management landscape and did not consistently use the tools available to him.” *Id.* Had Respondent really understood and accepted responsibility for the MBC findings, I find it doubtful that he would have attempted to excuse his behavior in his DEA hearing.

Exception 8

Respondent again argues that he has adequately responsibility. I have discussed some of these specific arguments in the Recommendation Section and throughout where relevant.

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

Respondent argues that he “accepted full responsibility for deficiencies for which he agreed with Dr. Munzing. There were other allegations for which he provided a defense, as stated herein. Dr. Chesler should not be made to accept responsibility for allegations for

which he does not believe are accurate. That would be disingenuous and not something he should do as an honorable and credible person.” Resp’t Exceptions at 28. I disagree, as explained in more detail *supra* that Respondent unequivocally and credibly accepted responsibility for the deficiencies for which he agreed with Dr. Munzing. With respect to his high dosing levels and combination prescribing, which seem to be primarily the focus of his continued disagreement with Dr. Munzing, I am confounded as to why he continues to argue these points, while also stating that he no longer prescribes these combinations or at these levels.

Additionally, although Respondent repeatedly admitted that his documentation “could be better,” see, e.g., Tr. 929, he gives little weight or understanding to these statements. Respondent’s cavalier assumptions about his documentation responsibilities and the fact that he did not undertake this responsibility with seriousness weigh against my ability to entrust him with a registration. See *Singh, M.D.*, 81 FR 8248 (“[U]ntil . . . [a] Respondent can convincingly show he accepts the authority of the law and those bodies charged with enforcing it and regulating his activities, granting [] a DEA registration will gravely endanger the public.”). The truth is that it is not possible to tell whether Respondent’s care was as appropriate as he claims because his recordkeeping did not support those claims. Nowhere is this more obvious than with Patient AA.

With respect to the dosing levels, Respondent argues that I should now trust him because he has corrected something that he does not believe was a mistake. He then states that if DEA wants to ensure that he does not prescribe at high levels, “a CURES monitoring program could easily be set up between him and the DEA to track prescriptions for all patients.” Resp’t Exceptions at 32. DEA is responsible for regulating more than just Respondent and Respondent has already violated my trust through the multiple, egregious proven allegations. Ensuring that a registrant is trustworthy to comply with all relevant aspects of the CSA without constant oversight is crucial to the Agency’s ability to complete its mission of preventing diversion within such a large regulated population.*^{GG} *Jeffrey Stein, M.D.*, 84 FR 46974. I do not see how I can believe that Respondent has

*^{GG} With a regulated community of nearly two million registrants, DEA must be able to rely on registrants to comply with the standard of care without constantly monitoring them. See DEA FY 2020 Budget Request available at <https://www.justice.gov/jmd/page/file/1142431/download>.

accepted responsibility for his actions and reformed, while arguing that the rationale underlying some of those reforms is superfluous. His acceptance of responsibility did not adequately convince me that he can be entrusted with a registration. Once his state probation ends and the scrutiny is off of him, I am not convinced that he will continue the practices that he put in place, when he does not believe that they are necessary in the first place or truly demonstrate a grasp of their gravity and importance.

Exception 9

Lastly, Respondent argues that “[d]isciplining Respondent based upon findings of the deficiencies in the Recommended Decision is inconsistent with, and has no nexus to, the DEA’s stated goals of avoiding diversion.”*^{HH} Resp’t Exceptions at 33. The Government, however, is not required to prove that diversion resulted from the unauthorized issuance of prescriptions. *Arvinder Singh, M.D.*, 81 FR 8247, 8249 (2016). Rather, when a practitioner violates the CSA’s prescription requirement, set forth in 21 CFR 1306.04(a), by issuing a prescription without a legitimate medical purpose and outside the course of professional practice, the DEA essentially considers the prescription to have been diverted. *George Mathew, M.D.*, 75 FR 66146. Furthermore, the Agency is not, as Respondent suggests, required to find intentional misconduct in order to support a sanction. Resp’t Exceptions at 33. DEA decisions have found that “just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or

*^{HH} It is noted that the CSA’s core purposes are not, as Respondent suggests, limited to diversion, but also include abuse of controlled substances. See *John O. Dimowo, M.D.*, 85 FR 15800, 15810 n.K, M (2020). Further, “it is axiomatic that another core purpose of the CSA is to protect patients from the drug-related deaths and injuries that may result from drug abuse and diversion.” *Salman Akbar M.D.*, 86 Fed Reg. 52181, n.*O (2021). In this case, there is evidence that Respondent’s prescribing put his patients at risk and that he did not document informed consent surrounding that risk. Further, there is evidence on the record that a patient died of an overdose, and regardless of whether the controlled substances Respondent prescribed contributed to that death, the overdose itself indicates abuse. Additionally, there is evidence that another one of Respondent’s patients had opiate use disorder by Respondent’s admission. *Supra* n.*J. And finally, there is evidence that AA was possibly not taking his oxycodone and that patients were repeatedly receiving extra controlled substances beyond their prescriptions—all of which have the potential to contribute to diversion. Therefore, even though, contrary to Respondent’s assertion, I am not required to find evidence of abuse and diversion in order to find in favor of a sanction, I disagree with Respondent’s bold assertion that “there is no evidence of addiction or medication abuse.” Resp’t Exceptions at 33.

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)). In fact, the Agency has found in favor of revocation in cases where registrants have failed to document their prescribing decisions—a violation which has been clearly established in this case. The Agency has repeatedly emphasized that “[c]onscientious documentation is . . . not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician’s prescribing practices are within the usual course of professional practice.” *Cynthia M. Cadet, M.D.*, 76 FR 19,450, 19,464 (2011) (internal citation and quotation omitted); *see also Kaniz F. Khan-Jaffery, M.D.*, 85 FR 45,667, 45,686 (2020) (“DEA’s ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.”).

The case at hand demonstrates prescribing beneath the applicable standard of care and outside the usual course of professional practice in California to multiple patients over the course of many years. I agree with the Chief ALJ that this conduct was egregious and I agree with his rationale for sanction. As stated above, for many reasons, I cannot find that I can entrust Respondent with a registration.

Accordingly, I reject Respondent’s Exceptions and affirm the RD’s conclusion that Respondent’s registration should be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. BC1317165 issued to Bradley H. Chesler, 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 pending application of Bradley H. Chesler, M.D., to renew or modify this registration, as well as any other pending application of Bradley H. Chesler, M.D. for registration

in California. This Order is effective March 2, 2022.

Anne Milgram,
Administrator.

[FR Doc. 2022–01838 Filed 1–28–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–947]

Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Siegfried USA, LLC. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 1, 2022 Such persons may also file a written request for a hearing on the application on or before April 1, 2022.

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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 8, 2021, Siegfried USA, LLC., 33 Industrial Park Road, Pennsville, New Jersey 08070–3244, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid ..	2010	I
Dihydromorphine	9145	I
Hydromorphanol	9301	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Oripavine	9330	II

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Opium tincture	9630	II
Oxymorphone	9652	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substance in bulk for development of a new active pharmaceutical ingredient (API) and validation for a Drug Master File submission to the Food and Drug Administration. No other activity for this drug code is authorized for this registration.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2022–01816 Filed 1–28–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–4]

Austin J. Kosier, M.D.; Decision and Order

On September 30, 2021, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Austin J. Kosier, M.D. (hereinafter, Respondent) of Zanesville, Ohio. OSC, at 1 and 3. The OSC proposed the revocation of Respondent’s Certificate of Registration No. FK6714504. It alleged that Respondent “[does] not have authority to dispense or prescribe controlled substances in the [s]tate of Ohio, the state in which [Respondent is] registered with DEA.” *Id.* at 1 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about May 12, 2021, the State Medical Board of Ohio issued an Order suspending Respondent’s state license to practice medicine and surgery. *Id.* at 2. The Order was effective immediately and ordered that Respondent “immediately cease the practice of medicine and surgery in Ohio.” *Id.*

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