plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''skin resurfacing devices, punctile resurfacing systems, radio-frequency microneedling systems, and components of each'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

InMode Ltd., Tavor Building Shaar Yokneam, P.O. Box 533, Yokneam 2069206, Israel

Invasix Inc. d/b/a InMode, 20996 Bake Parkway, Suite 106, Lake Forest, CA 92630

(b) The respondents are the following entities alleged to be in violation of section 337, and the parties upon which the complaint is to be served:

ILOODA Co., Ltd., 120 Jangan-ro 458beon-gil, Jangan-gu Suwon, 16200, Republic of Korea

Cutera, Inc., 3240 Bayshore Boulevard, Brisbane, CA 94005

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations is not a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 15, 2021.

Lisa Barton

Secretary to the Commission.

[FR Doc. 2021–08159 Filed 4–20–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–823]

Bulk Manufacturer of Controlled Substances Application: Research Triangle Institute

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of application.

SUMMARY: Research Triangle Institute, 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 June 21, 2021. Such persons may also file a written request for a hearing on the application on or before June 21, 2021.

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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 18, 2021, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Building, Room 106, Research Triangle Park, North Carolina 27709, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substance synthetically only for distribution to its customers for research and analytical reference standards. No other activity for this drug code is authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–08165 Filed 4–20–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–11]

Mark A. Wimbley, M.D.; Decision and Order

I. Procedural History

On October 20, 2016, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Mark A. Wimbley, M.D. (hereinafter, Respondent), of Costa Mesa, California. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC proposed the revocation of and denial of any pending application to modify or renew Respondent's Certificate of Registration No. BW5359004 pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that ''[his] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

The OSC alleged that Respondent issued prescriptions for controlled substances to four [1] individuals outside the usual course of the professional practice in violation of 21 CFR 1306.04(a) and in violation of California law and the minimum standards of medical practice in California. *Id.* at 2–8. Specifically, the OSC alleged that Respondent ''issued these orders for controlled substances without meeting the minimal medical standards required under California law, including those listed in the 'Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,' Medical Board of California, 7th Ed. 2013.'' *Id.* at 7. Additionally, the OSC alleged that for the four listed patients, Respondent failed to do one or more of the following:

perform a physical examination; take appropriate medical history; assess pain, physical and psychological function; make an assessment of any underlying or coexisting diseases or conditions; confirm the patient was taking previously prescribed

[1] The Government withdrew allegations related to one of the patients in its Supplemental Prehearing Statement, so this matter is limited to three patients. ALJX 7, 7–8.

controlled substance medications by checking California's Controlled Substance Utilization and Review System (''CURES'') or performing a urine drug test; order or perform any diagnostic testing; adequately discuss the risks and benefits of the use of controlled substances and other treatment modalities; periodically review the course of pain treatment or gather new information, if any, about the etiology of these patients or their state of health; or refer the patients to seek medical care to treat underlying conditions, such as pain management, orthopedics, behavioral therapy, physical therapy, and the like . . . . in violat[ion] of CA HLTH & S §§ 11150,[2] 11153(a), and 11154(a).

Id. at 7–8.

The OSC further alleged that Respondent ''continued the unlawful practices . . . even after [he] was arrested on December 15, 2015, and charged by the State of California with 12 felony counts of prescribing controlled substances without a legitimate medical purpose.'' *Id.* at 8. Finally, the OSC alleged other violations of California State law, including Cal. Bus. & Prof. Code §§ 2242(a), 2234, 725(a) and Cal. Health & Safety Code § 11190(a). *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 9–10 (citing 21 CFR 1301.43).

By letter dated November 11, 2016, Respondent timely requested a hearing. ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney II (hereinafter, the Chief ALJ). On November 15, 2016, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1–2. After requesting and being granted an extension of time, the Government filed its Prehearing Statement on December 7, 2016, and Respondent filed its Prehearing Statement on December 28, 2016. ALJX 6 (hereinafter, Govt Prehearing) and ALJX 8 (hereinafter, Resp Prehearing). On January 4, 2017, the Chief ALJ issued his Prehearing Ruling that, among other things, set out eight Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements, which were filed by both the Respondent and the Government on December 28, 2016, and January 25, 2017, respectively. ALJX 11 (Prehearing Ruling), at 1–6; ALJX 9 (hereinafter, Resp Supp Prehearing); ALJX 7 (hereinafter, Govt Supp Prehearing). On January 27, 2017, the Government filed a Motion *In Limine* to limit the testimony of Respondent's proposed expert witness to which Respondent filed an Opposition to Complainant's Motion *In Limine* and Request for Additional Time on January 27, 2017. ALJX 13 (hereinafter, Gov Mot *In Limine*); ALJX 14 (hereinafter, Resp Opposition). The Chief ALJ granted Respondent's request for more time to supplement his prehearing disclosures and denied the Government's Motion to exclude testimony and denied Respondent's motion for ''an indefinite amount of 'more time' to bring motions relating to issues raised in Government's supplemental prehearing statement.'' ALJX 16, at 7–8 (Order Regarding the Parties' Motions). Respondent filed a Second Supplemental Prehearing Statement on February 1, 2017. ALJX 10 (hereinafter, Resp Second Supp Prehearing). The parties filed additional Joint Stipulations [3] of Facts on February 6, 2017, and February 7, 2017. ALJX 17a and 17b; RD, at 3–4. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

The hearing in this matter spanned four days.[4] On May 22, 2017, the Government filed its Proposed Findings of Fact and Conclusions of Law and Respondent filed his Closing Brief. ALJX 30 (hereinafter, Govt Posthearing); ALJX 31 (hereinafter, Resp Posthearing). The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereafter, RD) is dated June 1, 2017. The Government filed exceptions to the RD (hereinafter, Govt Exceptions) on June 21, 2017. ALJ Transmittal Letter, at 1. On June 27, 2017, the Chief ALJ transmitted his RD, along with the certified record, to me. *Id.*

Having considered this matter in the entirety, I find that Respondent issued prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in California, in violation of federal law, and that Respondent also committed violations of state law.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

II. Findings of Fact

A. Respondent's DEA Registration

Respondent is registered with the DEA as a practitioner-DW/30 in schedules II, IIN, III, IIIN, IV, and V under DEA Certificate of Registration No. BW5359004 at the registered address of 2900 Bristol, A 106, Costa Mesa, CA 92626. Government Exhibit (hereinafter, GX) 1 (Respondent's Certificate of Registration). This registration expired on May 31, 2018.*Id.*[5]

B. The Government's Case

The Government's documentary evidence consisted primarily of medical records and pharmacy records and CURES reports related to three individuals treated by Respondent between October 2014 and July 2016. The Government called three witnesses: A DEA Diversion Investigator (hereinafter, the DI), who participated in the investigation of Respondent; a California State Investigator (hereinafter, the SI); and an expert witness, Dr. Timothy Munzing. RD, at 5–35.

The Government first presented the testimony of the DI, Tr. 15–140, who testified that she took over as the lead diversion investigator on the case during the execution of a search warrant on the Respondent's house in November 2015 on Respondent's residence, office and vehicles. *Id.* at 21–22. She testified that DEA seized some of the medical records in the Respondent's garage, two or three computers, and from one of the cars, ''a few vials of controlled drugs in the center console which were later identified to be hydrocodone'' and another controlled substance that was not labeled. *Id.* at 24–25. The DI testified that Respondent's clinic ''was somewhat in disarray. The boxes of documents were just like random patient documents that were in no order at all.'' *Id.* at 25. The DI stated that ''the

[2] Although the OSC alleged Cal. Health & Safety Code § 11150, I did not see any further mention of this provision in this proceeding, so I am not evaluating it. Further, I agree with the RD that this statute is inapplicable as an independent violation. *See* RD, at 69–70 n.165.

[3] In particular, the Government and Respondent stipulated as to the Respondent's criminal charges, the Respondent's agreement with the District Attorney's Office regarding prescribing and Respondent's state medical license suspension. They further stipulated that the combination hydrocodone products Lortab, Vicodin and Norco, oxycodone (brand names ''Oxycontin'' and ''Roxicodone'') were Schedule II controlled substances; carisoprodol (brand name ''Soma''), diazepam (brand name ''Valium), and alprazolam (brand name ''Xanax'') were Schedule IV controlled substances.'' RD, at 4. I incorporate the stipulated facts herein.

[4] Hearings were held in Los Angeles, California on March 28–31, 2017.

[5] The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474 (2019).

records were boxed up and brought back to the office. [She] then organized them according to patient, scanned them into the computer, and then placed them into evidence.'' *Id.* at 27.

The DI also testified to her presence at a second state warrant on Respondent's Clinic and vehicles, which was executed on August 30, 2016. Tr. 33, 45; RD, at 9; GX 19 (State Search Warrant and Receipts). She stated that the office was ''less organized'' and there was ''less stuff'' than during the first warrant, and the medical records seized were ''brought back to the DEA office.'' Tr. 46. The DI further testified that the investigators ''went through all the boxes page by page to identify the patients that we were searching for.'' Tr. 58; RD, at 9. She stated that the J.M. and C.B. files in the Government Exhibits include records obtained from both warrants and the R.D. file contains records only obtained as a result of the second warrant, and further that Respondent did not notify her until recently that there were any additional documents for these patients. Tr. 50–56, 58; RD, at 10. The Government's evidence includes three patient files obtained through those search warrants. GX 4, 6, 10–12. The DI also testified to the accuracy of the prescription records that she obtained from pharmacies. Tr. 61–86; GX 3, 5, 7–9, 11, 13. Finally, the DI testified to the methodology she undertook in obtaining the CURES report of the patients and Respondent. Tr. 89–90; GX 20–23.[6]

I agree with the Chief ALJ that the DI's testimony was ''plausible, detailed, consistent, and without any obvious motive to fabricate.'' RD, at 11. Therefore, I agree with the Chief ALJ that her ''testimony is accorded full credibility.'' *Id.*

The Government also presented the testimony of the SI, who is an investigator with the Department of Healthcare Services in California. Tr. 142–185; RD, at 5–8. The SI testified that she was the lead investigator for the State of California and began an investigation when, ''in November 2015, [her] department received a complaint from a Medi-Cal Beneficiary stating that his information was being used to fill prescription drugs, and on those prescriptions the prescriber was [Respondent].'' Tr. 146. The SI stated that she went to the location on the prescriptions and found it empty and had obtained a state search warrant for a new office address, which was executed on August 30, 2016. *Id.* at 149–151. During the search warrant, the SI stated that she had interviewed Respondent in the parking lot and he had stated that the three patients, J.M., R.D. and C.B., were his patients but had been discharged. *Id.* at 162–64; RD, at 6. She also stated that she asked Respondent specifically where all of his ''medical charts'' were and he stated that ''all of them are at this location.'' Tr. 165. The SI further stated that she indicated that the investigators searching Respondent's office ''stated that everything was thoroughly checked twice.'' *Id.* at 158; RD, at 6.

I agree with the Chief ALJ and find that the SI ''had no obvious motivation to be anything but objective, and presented testimony that was sufficiently plausible, detailed, and internally consistent to be accorded full credibility in this recommended decision.'' RD, at 7–8.

The Government's expert witness, Dr. Timothy Munzing, has been employed by Kaiser-Permanente for over thirty-one years, twenty-eight of which he has served as the family medicine program director. GX 16 (Curriculum Vitae of Dr. Munzing); *see also* RD, at 11; Tr. 186–563. The Chief ALJ accepted Dr. Munzing without objection as ''an expert in family medicine, pain management, and the prescribing of controlled substances in California.'' Tr. 211–12. The matters about which Dr. Munzing testified included the general standard of care in California and his review and standard-of-care analysis of the medical records in the Government's Exhibits belonging to three of Respondent's patients.

The Chief ALJ found, and I agree, that Dr. Munzing ''presented testimony that was generally authoritative, consistent, well-supported, objective, and persuasive.'' RD, at 35.

C. The Respondent's Case

Respondent presented the testimony of two witnesses at the hearing, including his own. He also presented [7] supplemental medical records (hereinafter, Respondent's Supplemental Records) that were not included in the Government's Exhibits for the three patients at issue in the case and written reports from his expert. Respondent Exhibit (hereinafter, RX) 3–5, 10, 17. The first witness, Dr. Umer Malik, was offered by Respondent and accepted (without objection) as an expert on the prescribing of controlled substances in the state of California, including required documentation for such prescribing. RD, at 38; Tr. 579–608; 735–851. Dr. Malik graduated from medical school in Pakistan in 2005 and became a board certified physician in internal medicine in the United States in 2010. RD, at 38–39; Tr. 579–80. Dr. Malik has practiced in in-patient and out-patient settings and he ''estimated that he has seen 40 to 50 patients over an extended period of time who were on chronic opioid medications'' and that he has treated 600 to 800 patients in California who were on opiates for chronic pain. RD, at 39 (citing Tr. 583). Dr. Malik also was an ''internal expert reviewer'' for the quality control department when he was at Stanford University and continues to provide external expert review there and also for the Medical Board of California. Tr. 583–84; RD, at 39; *see also* RX 11 (Curriculum Vitae of Dr. Malik).

Dr. Malik testified as to his familiarity with the term ''prescription drug cocktail'' and that he has prescribed opioid medications to over 500 patients. Tr. 588; *see also infra* II.E. He testified regarding the standard of care in California and in the end opined that the prescriptions that he reviewed in Respondent's Supplemental Records were issued within the applicable standard of care in California. Tr. at 743–44. He stated that in preparing his export report, he reviewed RX 3–5. *Id.* at 764–65; Tr. 806. Although he did receive the Government's Exhibits, he did not include them in his reports. *Id.* at 799.

I agree with the Chief ALJ that ''[a]lthough Dr. Malik presented as generally knowledgeable, certain aspects of his testimony undermined the confidence that could otherwise be afforded his opinions.'' RD, at 54. For example, the Chief ALJ noted that Dr. Malik testified that he had no idea that a pharmacy could refuse to fill a prescription presented by a patient, which is ''basic knowledge related to the regulation of controlled substance.'' *Id.* at 54–55 (citing Tr. 798). He further noted that Dr. Malik testified contrary to the DEA regulatory requirement regarding Schedule II controlled substances in 21 CFR 1306.12(a), that '' 'there are physicians who call in for the refills of the benzodiazepines and for the refills of opiates if they have a chronic relationship with the patients.' '' *Id.* at 55 (quoting Tr. 843). Further, the Chief ALJ pointed out that there were inconsistencies with Dr. Malik's written report, including referenced pictures and blank progress notes that did not exist in Respondent's Supplemental Records and inconsistencies regarding how long

[6] I agree with the reasoning of the Chief ALJ in admitting the CURES data in GX 20–22 over the Respondent's objection as to its authenticity. Tr. 93–96.

[7] Respondent included a declaration from Dr. Elliot Felman, who monitored Respondent's compliance with his California Ex Parte Interim Suspension Order. *See* RX 8. I agree with the Chief ALJ that ''because the records that Dr. Felman reviewed post-dated the conduct charged in the [OSC] and does not concern the patients at issue in this matter, any factual representations or opinions expressed in his declaration should be deemed irrelevant.'' RD, at 21 n.3.

Respondent had been seeing a patient. RD, at 55–56 (citing RX 17, at 1; RX 5; Tr. 801–02, 809; RX 10). Ultimately, the Chief ALJ found, and I agree, that with regard to Dr. Malik's testimony, RD, at 56–57.

His knowledge deficits in rudimentary aspects of the CSA and its regulations, his lack of specificity regarding where he located the key aspects of the Supplemental Files upon which he based his opinions and his willingness to reach into the future to essentially bootstrap prescribing decisions made in the past, were all factors that eroded the weight that can be afforded to his expert onions here, and make those opinions less persuasive than the opinions by the Government's expert, Dr. Munzing.

Respondent testified on his own behalf. Tr. 610–734; 860–912. He testified that he attended medical school at the University of California at Los Angeles and trained to become a surgeon, but was in a car accident and ''couldn't really operate.'' Tr. 864; RX 1, at 1–2 (Respondent's Curriculum Vitae). Respondent testified about the courses that he had taken ''primarily on pain management'' and future courses he planned on taking. Tr. 864–65; RX 1, at 3–18; RD, at 35. He also testified about a Medical Board of California disciplinary action, after which he was allowed to prescribe only Schedule V controlled substances. Tr. 871–72; RX 16 (Interim Suspension Order).[8] He testified that he has treated ''more than 500 [patients] probably I think in 10 years'' as a pain management practitioner. Tr. 873–74.

Regarding his medical records, Respondent testified that he ''tried to be extremely well documented,'' but that he ''didn't have a specific system for them. I had the patients, their packets and notes, and they weren't necessarily all together. They might have been. Some might have been somewhere together.'' Tr. 632, 683.

Respondent testified as to the legitimacy of the files for C.B., J.M. and R.D. in RX 3, 4, and 5 (Respondent's Supplemental Records). *Id.* at 610. Respondent testified that on August 30, 2016, a state investigator came to his residence. *Id.* The SI showed Respondent a list of patients and he told her that several of the patients ''and then several other individuals on that list that are not my patients.'' *Id.* at 613. He also stated that the SI told him that ''she [was] investigating Medi-Cal fraud'' and he does not ''treat Medi-Cal patients now.'' *Id.* at 616–17. Respondent explained that he drove to the office to open it for the investigators to execute the search warrant and ''they searched the vehicle several times.'' *Id.* at 619–20. Respondent confirmed that the patient records were not in a file cabinet and that ''there were some by desk'' and he ''had different stacks of paper, different—[he] was trying to organize things for [his] attorney, some things have been taken to the attorney for different parts of this case or another case,'' and the other files ''were in different stacks in different locations in [his] office.'' *Id.* at 621–23. He stated that ''[s]ome of the files like for R.D. were in the car.'' [9] *Id.* at 622. When asked if the SI asked him where the records were for the patients, he answered that ''the main focus of the conversations that I recall was Medi-Cal fraud, a list of people that were not my patients.'' *Id.* at 626. When asked if the files were with his criminal attorneys, he stated, ''I had some things being reviewed because I was changing counsel.'' *Id.* Respondent stated that he found the RX 3, 4, and 5 ''rapidly'' and that ''they came on August 30th'' to conduct the search warrant and ''either that day or in a couple days they were in [his attorney's] office, probably before the 3rd or 4th of September.'' *Id.* at 631.[10]

When asked about whether Respondent had told the DI that all of the medical records should be in his office, Respondent first answered, ''I may have.'' *Id.* at 656. Then when asked again, he stated, ''I mean, it's kind of obvious, isn't it?'' *Id.* Finally, he stated, ''The only particular request she made was the Patient M.C., and I told her exactly where to find the chart.'' *Id.* at 658.

Respondent agreed that medical records should contain exam notes, progress notes, referrals, diagnostic testing, and medications prescribed, red flags, diversion review, and steps to resolve red flags, and that in California Schedule II prescriptions require certain information. *Id.* at 636–37. However, Respondent maintained that the prescriptions at issue in this case were issued within the applicable standard of care in the State of California. *Id.* at 878–86.

During the hearing, in evaluating whether to admit Respondent's Supplemental Records, the Chief ALJ stated that Respondent's credibility is a ''mixed bag. I think he was frequently lacking in detail. He lost patience then answered questions that were not asked of him. Frequently, he would be responsive to his own counsel but almost intentionally unresponsive to Government's counsel.'' Tr. 731–32. Further, in the RD, the Chief ALJ stated that, ''he presented as a defensive, frequently non-responsive, vague [11] witness.'' RD, at 38. Therefore, the Chief ALJ found, and I agree, that ''where the Respondent's testimony conflicts with other credible testimony and evidence, it cannot be afforded full credibility.'' *Id.*

D. Admission of Supplemental Patient Records

During the hearing, over the Government's objections,[12] the Chief ALJ admitted Respondent's Exhibits 3, 4, and 5 (Respondent's Supplemental Records), which consisted of patient records offered by the Respondent that supplemented the patient records found by the Government during the two

[8] As discussed further under *supra* III.A.1, the California Office of Administrative Hearings entered an Interim Suspension Order on December 17, 2016, stating that ''Respondent shall not prescribe any Schedule II, III, or IV controlled substances.'' RX 16, at 7.

[9] Respondent stated that the R.D. records were ''like in a container for files'' in his vehicle ''in the back seat area'' and that the DI did not take those records. *Id.* at 659. Respondent's counsel had stated that the R.D. files were in the ''trunk'' of his car. Tr. 625.

[10] Respondent testified that in 2016, at his Newport Beach office, a toilet had overflowed and some of his records ''got wet,'' but he did not know whether they contained records for these patients. *Id.* at 641. However, Respondent's counsel objected to questioning about Respondent's Supplemental Records, because they were dated ''all after these water incidences'' from November 2015 to April 2016. *Id.* at 645. After the objection, Respondent stated, ''I'm not sure that I made a mistake. What I said is it happened before I moved. It was in 2015.'' He further stated that his house flooded in 2012 and his rental property in 2014 and that he may have lost documents in those floods, but he did not know whether they involved the patients at issue. Tr. 649–52. The SI testified that she saw no evidence of flood damage at his Newport Beach office and she stated that the property manager said he ''was evicted based on complaints and late rent.'' Tr. 172. Ultimately, I do not find any reliable evidence on the record, even from Respondent's own testimony, that Respondent possessed relevant records that were destroyed in these alleged water incidents, and therefore, I do not find these alleged water incidents relevant to these proceedings.

[11] In particular, I found Respondent's testimony regarding the presence of two separate records for the same patient on the same date to be vague and not credible. GX 10, at 67 is a form filled out at the top by R.D. and filled out on the bottom portion by Respondent, dated April 13, 2016. RX 5, at 25 is dated from the same visit; however, it provides a much more detailed account of the visit and is filled out entirely by Respondent. First, Respondent testified that the Respondent's Exhibit notes were written while the patient was sitting there and that the Government Exhibit notes were written ''probably right after he—right after he left.'' Tr. 694. When confronted with the notion that it does not make logical sense that he wrote the detailed notes while the patient was sitting there and then wrote more cursory notes on the form that the Respondent filled out after the patient left, he changed his testimony and stated that he ''wrote the more detailed one [the Respondent's Exhibit] later . . . after the patient left.'' *Id.* He stated, ''I'm writing on another piece of paper. At the same time later, I might finish whatever I need to do in another packet, or I might not. It's not that different.'' *Id.* at 693.

[12] The Government objected to the admission of these records into evidence based on authenticity during and prior to the hearing. *See* ALJX 24 (Notice of Objection on the Basis of Authenticity (March 21, 2017)); Tr. 601.

search warrants. In admitting the records, the Chief ALJ stated that ''the proponent of any exhibit bears the burden of proof to establish that the document is what it purports to be.'' Tr. 731. He further stated, ''Because all of the documents weren't seized, and some of them bore things that I cannot fathom where they came from or how they would be generated later. Because that is true, what I'm going to do is admit the documents and allow you to use them to procure the expert opinion.'' *Id.* at 731–32. The Chief ALJ caveated that he did not ''have a high level of confidence in them'' and that he did not know ''why [Respondent] didn't comply with the [warrant.]'' *Id.* at 732.

In the RD, the Chief ALJ explained that:

> While true that in administrative enforcement proceedings the subsequent discovery of additional medical files can (and often does) raise the potential specter of evidence manufactured to support deficient records, the records offered by the Respondent contained some pages that would have been difficult to manufacture after-the-fact, including test results originating from other offices stamped with facsimile transmittal information and forms that were apparently completed by the patients themselves which are dated before the last search took place.

RD, at 37–38.

I agree with the RD that Respondent's exhibits contained records that could not have been easily manufactured and appear to be legitimate.[13] Furthermore, as the Chief ALJ noted, multiple witnesses testified during the hearing that Respondent's paperwork was in ''complete disarray'' with patient records in piles all over his office, exam rooms and even inside his vehicle. RD, at 36 (citing Tr. 715, 718–19); *see also* Tr. 622–23; Tr. 169. The RD summarized that ''[Respondent] had no filing system, kept no payment or billing receipts, and was paid in cash on those occasions when his patients brought money to him.'' RD, at 36 (citing Tr. 683, 717–19). On the whole the evidence demonstrates that records were a mess and that some of the Respondent's Supplemental Records appeared legitimate. *See* RD, at 38 n.104.[14] Therefore, in spite of the dubious authenticity and origin [15] of some of Respondent's records, I ultimately will agree with the Chief ALJ's decision to admit them into evidence.

E. The Applicable Standard of Care in California

Regarding the applicable standard of care in California, Dr. Munzing testified that on the first visit ''one must determine essentially whether or not this patient actually has a legitimate need for whatever treatment you're going to do.'' Tr. 213. ''[F]or controlled substances the first thing you need to do is take a history.'' *Id.* The history you need to assess includes: ''how long has one had the pain; specifically the area of pain,'' ''did it start gradually'' or ''was there an inciting incident'' and ''the pain level or how severe the pain is, but more importantly, is the—actually, the function.'' *Id.* Dr. Munzing stated that ''function's really more important because function is a little more objective than a number.'' *Id.* at 214. Further, as part of the medical history, ''[o]ne wants to know have you had imaging before, what kind of treatments have you had before, are you been on medicines before.'' *Id.* Also, Dr. Munzing testified that ''I want to know today or in the last couple of weeks, I want to know where things are: pain level, functional level'' and about ''mental health history.'' *Id.* at 214–15. ''Once you've taken a thorough history, then you want to do a thorough exam.'' *Id.* at 216. Dr. Munzing said the exam should be a ''general exam on heart, and lungs, and kidney'' and ''[t]hen hone in on the area of pain.'' *Id.* He stated that ''you want to actually observe it, palpate it, touch it. Is it tender? Look for range of motion.'' *Id.* Additionally, for chronic pain, he stated that you want ''relatively recent imaging.'' *Id.* at 217. Next, he stated that a practitioner would need ''to first of all look for red flags in [the patients'] story.'' *Id.* Dr. Munzing testified that he orders urine drug screens and checks CURES and the Prescription Drug Monitoring Program database (hereinafter, PDMP) ''to make sure that if they say that this is what I'm taking, I ensure that that's consistent.'' *Id.* at 218–19. Finally, Dr. Munzing stated, ''All this needs to be documented.'' In the documentation, he testified that there must be ''both pertinent positives, pertinent negatives, exams, documenting the information.'' *Id.* at 220.

The Government included in its evidence the Medical Board of California, Guide to the Laws Governing the Practice of Medicine (7th Ed. 2013) (hereinafter, the Guide) and the Medical Board of California, Guidelines for Prescribing Controlled Substances for Pain (November 2014). GX 17, 18. Dr. Munzing testified that the guidelines for prescribing controlled substances are meant to ''kind of say here's the things you need to do if you're actually going to prescribe controlled substances.'' Tr. 235. Dr. Munzing further stated that ''[y]ou don't have to do every single one of those, but if you're substantially complying with the standard of care—with the guidelines that would be the standard of care.'' Tr. 228. Regarding documentation, he testified that ''really, the medical record documentation, not only is it a law, is it a requirement, but I think it is that because it really is about patient safety . . . it's for my own recollection of on this date and time this is what was going on.'' *Id.* 239. He also stated that ''if someone else is going to see the patient that way it's an accurate reflection of what's happening at this

[13] RX 5, at 4 is a laboratory report for R.D. that was faxed on May 30, 2016. Tr. 721. RX 3, at 45 is a fax cover sheet for an Operative Report from Dr. Lee's office for C.B. *Id.* at 721–22. Respondent testified that RX 3, at 1 and RX 4, at 1, are filled out by the patient and RX 4, at 2 included the patient's signature. *Id.* at 706–08. RX 5, at 8 includes a ''fax form'' that ''was sent from Perris Family Care Center, and it's—where it refers to the lab results that are back here.'' *Id.* at 709. Respondent testified that he found and provided the records to his attorney ''probably before the 3rd or 4th of September.'' *Id.* at 631. Government counsel noted that RX 3, at 45 also includes a fax time stamp of December 20, 2016, which was after the September timeframe that Respondent claimed he gave the documents to his lawyer. *Id.* at 723.

[14] The DI testified that during the second search in August 2016, investigators found very few documents dated before the date of the first search in November 2015, which may not even be related to the patients in this case. Tr. 137–38. The Chief ALJ found that this strengthened Respondent's position that the Supplemental Records were legitimate. RD, at 38 n.104. However, it is unclear from the record where Respondent's records were at any given time. Respondent stated that he ''was trying to organize things for [his] attorney, some things have been taken to the attorney for different parts of this case or another case.'' Tr. 622. I credit the testimony of the DI and SI regarding their thorough search of Respondent's records. The fact that some of Respondent's Supplemental Records could not be fabricated, indicates that they may have been elsewhere during the searches. It is ultimately unimportant to the resolution of the case, because Respondent only produced Supplemental Records for a portion of the controlled substance prescriptions in this case.

[15] The Government asserts that there are multiple reasons why the records should be discredited. For example, the ''character of Respondent's versions of records removed by law enforcement'' was ''at best cursory, and in most cases blank,'' whereas Respondent's records were ''multipage and extensive,'' and this gave the appearance that they had been ''tailored to address many of the deficiencies alleged in the [OSC].'' Govt Posthearing, at 41 (*comparing, e.g.,* GX 4, at 17–20 with RX 4, at 21–27). ''Moreover, there is complete disparity between the two versions; there are no exam notes in records recovered by law enforcement that are in any way as extensive and complete as those in Respondent's versions, and similarly there are none in Respondent's that are as cursory or vacant as those recovered by law enforcement.'' *Id.* I agree with the Government regarding all of the suspicious circumstances surrounding these records; however, considering the breadth of evidence that the Government has submitted, which the Respondent has not rebutted, I find it unnecessary to make a finding that these records were not legitimate. As explained herein, the Government has more than met its burden in demonstrating that Respondent's registration is inconsistent the public interest, even if I take Respondent's records to be what they claim to be.

date and time. My thought process behind it . . . .'' *Id.* Dr. Munzing testified that the standard of care required documentation ''[i]n the progress note it's vital to see a diagnosis that has something to do with pain in it.'' *Id.* at 241.

The California Guide to the Practice of Medicine sets forth guidelines in managing pain patients, which Dr. Munzing described provides ''almost a outline of what I described a little bit ago. You need to do a history and a physical exam . . . then you come up with a treatment plan.'' Tr. 247 (citing to GX 17, at 59–61). He also stated that the Guide requires that the practitioner ''go over and discuss informed consent with the patient'' and ''periodic review.'' *Id.* at 248. Regarding the Guide's requirements for documentation, Dr. Munzing stated, ''I guess I can't emphasize enough they're incredibly important, again for patient safety and for knowing what happened at any particular time. They're also important, again, for any kind of transfer of care, whether it's temporary or, you know, permanent.'' *Id.* at 249 (citing GX 17, at 65). He further stated that ''you want very thorough documentation for any kind of chronic pain, controlled substance medications, and some of the other areas because they're just higher risk areas.'' *Id.* Dr. Munzing stated that the record retention requirement for Schedule II controlled substances is three years, but ''in reality, everyone I know keeps them indefinitely.'' *Id.* at 250. When asked to summarize what information should be kept in medical records under the standard of care in California, Dr. Munzing said, ''the history, which includes past medical history, the medications; the other medical problems; the vital signs . . . the exam; any additional imaging results, lab results . . . and then the assessment . . . and then what your management plan is going forward.'' Tr. 253–54.

Regarding ''red flags,'' Dr. Munzing testified that they are ''things that kind of are just potential factors for abuse, diversion, misuse'' and include ''doctor shopping, seeing multiple doctors getting controlled substance medications, pharmacy shopping, going to multiple pharmacies.'' Tr. 256–57. When a practitioner is presented with a red flag, he has to ''delve a little deeper'' and ''it depends on what the red flag is.'' *Id.* at 259. For example, if he sees on CURES, that a patient is ''getting what—the combination called the trinity or holy trinity, which is an Oxycodone with a Benzodiazepine with Carisprodol—Soma is the brand name—you put that together, that's a huge red flag because that's a popular combination in the drug culture.'' *Id.* at 260. Finally, he testified that the standard of care requires that ''one needs to document significant red flags.'' *Id.* at 261.

Dr. Munzing also testified that ''when an individual is either taking an opioid or a physician is prescribing it, it's vitally important to calculate the Morphine equivalent dosing (MME). What that does is it translates an opioid, whether it be Oxycodone, or Methadone, or whatever to a base number, which they use Morphine as the base number.'' *Id.* at 288. He further stated that ''[t]he reason it's important is that if you go above 50 milligrams per day of Morphine-equivalent dosing, the amount of overdose risk and death increases. Once you get to 100 milligrams per day—and the CDC is now recommending keep it under 90. If you go over 100, then you have an eightfold risk of overdose in a—per year . . . .'' *Id.* at 288–89.

Regarding the applicable standard of care in California for prescribing controlled substances, Respondent's expert, Dr. Malik, testified, ''If there is no physical examination documented, if there is no history documented, if the doctor's not making a diagnosis, just giving the pain medications, that is breaching the standard of care.'' *Id.* at 787. He further stated that even for minimal risk of opiate abuse patients, ''the recommendations are to do a CURES test, to do a urine toxicology, and to make quick follow up visits. So, yes, it is within the standard of care for a physician to do at least these three things even if the patient comes under the mild opiate risk tool.'' *Id.* at 787–88.

In general, Dr. Malik's and Dr. Munzing's expert opinions regarding the standard of care for prescribing opioids in California were often similar. They both used the Medical Board of California guidelines to formulate their opinions about whether Respondent had met the standard of care. *Id.* at 768; 235. Dr. Malik testified that a physician needed to be in compliance with most of the guidelines to be within the standard of care, whereas, Dr. Munzing described the guidelines as an ''outline'' of what a physician needs to do to meet the standard. *Compare id.* at 744 *with id.* at 247.

In a few areas, the experts diverged. Dr. Malik testified that it is not a breach of the standard of care to prescribe a trinity cocktail,[16] and that there are times when ''the patient has an intractable pain.'' *Id.* at 735–36. He affirmed Dr. Munzing's testimony that physicians do calculate the morphine equivalent of controlled substances and stated that the morphine equivalent ''was designed to have a new medical standard on the basis of which different opiates can be compared based on their potential efficacy in a human's body.'' *Id.* at 736. Dr. Malik testified that it is not a deviation in the standard of care to provide more than 100 milligrams of morphine equivalent dose and per day;'' however, ''a physician has to be more careful, obviously have to be keep [*sic*] an eye on all these side effects, which can happen on a higher dose of MME.'' *Id.* at 737–38. Dr. Malik opined that based on Respondent's exhibits, Respondent was complying with the standard of care in terms of having his patients return to his office on a frequent basis. *Id.* at 738.

Overall, Dr. Malik testified that ''[Respondent is] a very poor documenter'' and that ''[i]t really takes a lot of effort to gather all that information, and think that the documentation is poor on his side, but I also believe that he has followed if not all, most of the recommendations from the guidelines of the Medical Board of California.'' *Id.* at 743. He further stated that ''following a substantial number of those guidelines can bring you to the standard of care.'' *Id.* at 744.

As the Chief ALJ found, issues with Dr. Malik's credibility made his ''opinions less persuasive than the opinions by the Government's expert, Dr. Munzing.'' RD, at 57; *see also supra* II.C. Therefore, I generally apply the standard of care as testified to by Dr. Munzing to the prescriptions[17] at issue in this case.

F. Allegations of Issuing Prescriptions Outside of the Usual Course of the Professional Practice and Prescribing Below the Applicable Standard of Care in California and Violations of State Law

Having read and analyzed all of the record evidence, I agree with the RD's conclusion and find substantial record evidence that Respondent prescribed controlled substances outside of the usual course of the professional practice and below the applicable standard of care in California. RD, at 93–94 (listing sustained allegations). Overall, I find that the record contains substantial evidence that Respondent issued

[16] Dr. Malik testified that he had never heard of the trinity cocktail until two months before he reviewed the records for this case. Tr. 792; RD, at 41.

[17] However, as further explained herein, Dr. Munzing did not opine about whether Respondent's Supplemental Records met the standard of care for prescribing controlled substances. *See infra* F.

numerous controlled substance prescriptions to J.M. and R.D. outside the usual course of the professional practice and beneath the applicable standard of care and in violation of several California laws and that Respondent issued controlled substance prescriptions to C.B. without complying with California law. The Chief ALJ found, and I agree that the record contains substantial evidence that Respondent issued sixteen controlled substance prescriptions to J.M., and eight controlled substance prescriptions to R.D. outside the usual course of the professional practice in violation of 21 CFR 1306.04 and Cal. Health & Safety Code § 11153(a) (Westlaw, Current with urgency legislation through Ch. 2 of 2021 Regular Session),[18] and without a medical examination or legitimate medical indication in violation of Cal. Bus. & Prof. Code § 2242(a) (West, 2016).[19] *Id.* Further, the Chief ALJ found, and I agree, that Respondent issued twelve Schedule II controlled substance prescriptions to J.M., eleven controlled substance prescriptions to R.D. and three controlled substance prescriptions to C.B. without making a record that comports with the requirements of Cal. Health & Safety Code § 11190(a) (Westlaw, Current with urgency legislation through Ch. 2 of 2021 Regular Session).[20] Additionally, the Chief ALJ found, and I agree that Respondent's prescribing on eight dates constituted ''excessive prescribing'' in violation of Cal. Bus. & Prof. Code § 725(a) (Westlaw, Current with urgency legislation through Ch. 2 of 2021 Regular Session).[21] I agree with the Chief ALJ's findings regarding these prescriptions and I further find, as explained below, an additional fourteen controlled substance prescriptions that Respondent issued to R.D. outside the usual course of the professional practice and beneath the applicable standard of care in violation of 21 CFR 1306.04 and Cal. Health & Safety Code § 11153(a).

1. J.M.

(a) J.M.'s Medical Records in Government Exhibits

Dr. Munzing testified in detail as to the contents of each record in the Government's Exhibits for J.M. He stated that the records included documentation of ''Past medical problems'' filled out by the patient, but with no date. Tr. 264–65 (citing GX 4, at 1–2). The records contained an opioid risk tool, which was never added up. *Id.* at 270 (citing GX 4, at 8). The patient filled out ''a depression scale.'' *Id.* at 270–71 (citing GX 4, at 10–11). The records reflected questions about whether an individual is receiving controlled substances or opioids, but ''it's not filled out.'' [22] *Id.* at 272 (citing GX 4, at 12). J.M.'s records included a ''patient assessment questionnaire,'' which ''would typically be a form presumably filled out by the patient when they came in prior to seeing [Respondent].'' *Id.* at 272–73 (citing GX 4, at 13). Dr. Munzing identified GX 4, at 14 as ''essentially the progress note form that would be completed by the physician or provider when they were seeing the patient,'' but that ''there are 10 words here,'' ''there is no information as far as the assessment'' of the tumor listed, ''there should be a management plan there, and that's completely blank.'' *Id.* at 273–74. Dr. Munzing testified that ''[t]his isn't even in the universe of what an appropriate documentation, and exam, and evaluation should be.'' *Id.* at 274. He concluded that if this chart supported a decision to prescribe a controlled substance it would be ''very far below'' the standard of care in California. *Id.* at 274–75. He stated that the documents ''[a]s I went through the standard of care earlier, [the documents] meet, actually, practically none of those.'' *Id.* at 280. On March 31, 2014, the Government's Exhibits include a pain assessment questionnaire and then a corresponding progress note with no writing, but ''a circle on the figure in the general area of the neck and one the general, or the low back,'' which ''transmits no useful information and so it still falls far below the standard of care as we talked before.'' *Id.* 282 (citing GX 4, at 23). On November 4, 2013, the note includes ''complains of right knee pain,'' but [t]here's no assessment and no treatment plan.'' Tr. 286 (citing GX 4, at 34). As such, Dr. Munzing testified that ''it falls completely short of the standard of care.'' *Id.* at 286.

Dr. Munzing also testified that if a patient is on ''Norco [23]'' on a regular basis, the medical files should contain blood work ''most likely at least every year, year and a half, two years'' to check for kidney [24] and liver function, which would not usually have clinical symptoms. Tr. 453–55, 458.[25]

(b) J.M.'s Prescriptions

The Government alleged that Respondent issued a total of thirty-two controlled substance prescriptions on seven dates to J.M. outside the usual course of professional practice and in violation of California law, on October 30, 2014, November 10, 2014, November 20, 2014, November 9, 19 and 29, 2015, April 9, 2016, and April 19, 2016. OSC, at 2–3; RD, at 68–70.

On October 30, 2014, J.M. received a prescription for: 30 milligram tablets of Roxicodone at 55 tablets to be taken one four times a day; 80 milligram tablets of Oxycontin at 46 tablets to be taken one four times a day; 350 milligram tablets of Soma at 40 tablets to be taken one three times a day; and 10 milligram tablets of Valium at 90 tablets to be take one four times a day. Tr. 291–92 (citing GX 3, at 1). Dr. Munzing testified that the closest medical record that corresponded with this visit was on October 10, 2014, which was a pain assessment questionnaire. Tr. 292–93 (citing GX 4, at 19). He further testified that the controlled substance prescriptions were not issued within the California standard of care, because there was no documented ''medical

[18] The relevant portions of Cal. Health & Safety Code § 11153(a) have not been amended during the relevant time period in this matter.

[19] Cal. Bus. & Prof. Code § 2242(a) was amended in 2019. This Decision cites to the law that was in effect during the time of the alleged misconduct and when the OSC was issued. *See* Stats. 2019, c. 741 (A.B.1264), § 1, eff. Oct. 11, 2019.

[20] The relevant portions of Cal. Health & Safety Code § 11190(a) have not been amended during the relevant time period in this matter.

[21] The relevant portions of Cal. Bus. & Prof. Code § 725(a) have not been amended during the relevant time period in this matter.

[22] Respondent's attorney noted during the hearing that many of the forms, *see e.g.,* GX 4, at 5–7, were samples contained in the Guide to Laws Governing the Practice of Medicine in Exhibit 14. Tr. 459–60. However, Dr. Munzing testified, that ''I have no problem with this form. My concern is that if that's all you have and you don't specifically on a specific patient, a specific date, say exactly what your management plan is.'' *Id.* at 460. I find that Dr. Munzing credibly testified that the information on the forms in the Government's Exhibits did not meet the applicable standard of care in California.

[23] Norco is hyrdrocodone/APAP. Tr. 886.

[24] It is noted that Respondent's Exhibits for R.D. included a laboratory report, and Dr. Malik testified that ''the labs basically are complimentary to your history and physical examination.'' Tr. 755 (citing RX 5, at 4). Respondent's Supplemental Record for J.M. did not include lab reports and I find Dr. Munzing's testimony regarding the need for blood work to meet the standard of care to be more credible than Dr. Malik's.

[25] Additionally, Dr. Munzing testified that none of the patient records for J.M., R.D., or C.B. included blood work or any urine drug testing, which he said ''is important because one wants to (a) confirm that they're actually taking what you're prescribing. And equally as important is they're not taking something that you're not prescribing, legal or illegal.'' *Id.* at 456–57. However, when asked on cross examination whether urine screens were required under the standard of care, Dr. Munzing stated that monitoring was required and urine screens were ''increasingly encouraged but not required.'' *Id.* at 458. I am not finding the lack of urine screens to be evidence of a violation of the standard of care; however, it is noted that the Government's Exhibits do not appear to include monitoring of any kind.

justification.'' Tr. 294. Further, Dr. Munzing testified that, ''I see some very alarming things, such as the very high Morphine-equivalent [26] dosing, which when you calculate this out, puts you about 660'' and further that the prescriptions ''qualif[y] for the trinity, or the holy trinity, that we talked about earlier as the oxycodone, carisoprodol or Soma, and benzodiazepine. So not only is there not justification, but I see some very alarming things from that prescription.'' *Id.* at 295. He also noted that the oxycodone was prescribed at the highest dosage available.[27] *Id.* at 298.

On November 10, 2014, Respondent prescribed J.M. 40 tablets of Soma at 350 milligrams per tablet; 40 tablets Valium at 10 milligrams per tablet; 46 tablets of Oxycontin at 80 milligrams per tablet, and 60 tablets of Roxicodone at 30 milligrams per tablet. GX 3, at 3–4. Dr. Munzing testified that there were no corresponding records to demonstrate that Respondent had comported with the standard of care in issuing these prescriptions to J.M. He further testified that the note from the pharmacist on the prescriptions indicated that the pharmacist had spoken to Respondent and ''he says patient's pain is not well controlled,'' but that there was no indication in the patient records that J.M.'s pain was not controlled. Tr. 303 (citing GX 3, at 4). Dr. Munzing testified that these prescriptions also were concerning for being a trinity cocktail and having a morphine equivalent dosage of 495, which was ''still way over the 100 milligram threshold.'' Tr. 310–11. He stated that J.M. is ''at extremely high risk for overdose and death with the dosage, not just the trinity, but the morphine-equivalent dosing that's you know, exceedingly high.'' *Id.* at 487. He concluded that the controlled substance prescriptions were issued outside of the standard of care in California. *Id.* at 310.

On November 20, 2014, Respondent prescribed J.M. 40 tablets of Soma at 350 milligrams per tablet; 40 tablets Valium at 10 milligrams per tablet; 46 tablets of Oxycontin at 80 milligrams per tablet, and 60 tablets of Roxicodone at 30 milligrams per tablet. GX 3, 5–6. Dr. Munzing testified that nothing in the J.M.'s patient file in the Government's Exhibits justify the prescriptions. Tr. 312–13 (citing GX 4, at 17–20). He concluded that the controlled substance prescriptions were issued outside the standard of care in California for ''the same reasons [he] mentioned for the previous two prescriptions,'' including ''the trinity cocktail, the morphine equivalent doing, as well as the fact that the progress notes—there's nothing there to medically justify the appropriateness of these medications.'' Tr. 313.

On November 9, 2015, Respondent prescribed J.M. 40 tablets of Soma at 350 milligrams per tablet; 40 tablets Valium at 10 milligrams per tablet; 40 tablets of Oxycontin at 80 milligrams per tablet, and 55 tablets of Roxicodone at 30 milligrams per tablet. GX 3, 7–6. Dr. Munzing testified that the Government's evidence contained no patient records dated after June 24, 2015 for J.M. Tr. 313–14. On November 19, 2015, Respondent prescribed the same medications at the same dosages and amounts, except that the quantity of oxycodone was 40 tablets. GX 3, at 9–10; Tr. 315. On November 29, 2015, Respondent issued a prescription for the same medications at the same dosages and amounts as the previous prescription to J.M. GX 3, at 11–12. On April 9, 2016, and April 19, 2016, Respondent issued a prescription for the same medications at the same dosages at smaller amounts with the addition of Motrin 600 milligrams at 60 tablets. *Id.* at 13–16.[28] Dr. Munzing testified that the prescriptions ''all fell outside the medically legitimate prescribing for controlled substances'' and for all of the reasons previously stated including the morphine equivalent dosages and the trinity cocktail. Tr. 318–19. He testified that nothing in the medical records would justify prescribing to J.M. that level of opioids and that the state of J.M.'s patient files were ''not even close'' to the standard of care in California. *Id.* at 321. Dr. Munzing testified that to meet the standard of care, Respondent would have needed to include a ''new or updated history,'' ''side effects from the medications,'' ''is it helping you,'' ''an exam'' and a ''treatment plan.'' *Id.* at 322. He further testified that J.M.'s first visit appeared to be November 9, 2012, and the records for J.M.'s first visit were not the type of record that the standard of care required for a first visit. *Id.* at 325–26 (citing GX 4, at 37).

In contrast to Dr. Munzing, Dr. Malik testified based on his review of Respondent's Exhibit 4 for J.M. in Respondent's Supplemental Records. Tr. 747. He stated that ''if you gather all the information from all the progress notes, the documentation was giving me enough information to say it was within the standard of care.'' [29] *Id.*

On cross examination, Dr. Malik stated that he reviewed RX 4 in preparing his expert report contained in RX 10, and that the records for J.M. in this exhibit ranged from November 19,

[26] As discussed in *supra* II.C., Dr. Munzing explained that calculating the morphine equivalent dosing or MME is ''vitally important'' to determine the amount of opioids to prescribe to a patient, and that the Centers for Disease Control and Prevention (CDC) recommends that doctors prescribe less than 90 MME per day and that the risks are high when 50 MME is exceeded. Tr. 288–89; RD, at 73.

[27] Dr. Munzing testified that even if the patient had a tumor on his nerve and Respondent was treating the pain while the patient was ''going through the process of having an ENT review this mass,'' he did ''have concerns with the incredibly high dosage.'' Tr. 523. He further testified on cross examination that a patient's ability to pay to see a specialist is irrelevant to the standard of care. *Id.* at 526. If a patient could not afford a specialist, a responsible physician ''would need to document that I've advise x, x, x, x, and they're not doing it.'' *Id.* He also noted that the prescriptions themselves were ''very expensive'' and that would be something that would be required to be discussed and documented with the patient. *Id.*

[28] On cross-examination, Dr. Munzing testified that it was ''possible'' that the reduction of the oxycodone from 40 to 28 tablets was tapering, but that there was ''no ability to be able to come to that conclusion in light of the sparse progress notes that were available.'' Tr. 474–75. Further, Dr. Munzing testified that ''the prescriptions are not reflecting an active effort on [Respondent] to taper those medicines because one would usually go from three to four times a day, back to three times a day, back to twice a day.'' *Id.* at 487. He additionally testified that for tapering, you ''would actually see not only verbally to the patient documented in the records, but also on the scripts, you would see that there's a progression in tapering over time.'' *Id.* at 544. Dr. Munzing did testify that the reduction of the pills from 46 down to 26 ''could be'' a taper, even though the daily instructions remained the same. Tr. 555. However, he testified that J.M. was still receiving the trinity over the course of prescriptions in the Government's records. Tr. 562. Further, he clearly testified that the standard of care required that tapering would have required documentation as such on both the patient's records and on the prescriptions. It is noted that Respondent's Supplemental Records did include notations regarding tapering for these prescriptions. *See* RX 4, at 23 (''taper off at all medications gradually''). I do not find that the April 2016 prescriptions were issued outside the standard of care due to the additional documentation in the Respondent's Supplemental Records, which was not examined by Government's expert; therefore, whether this reduction was tapering is irrelevant to the violations I am finding.

[29] The Government argued that Dr. Malik's standard of care analysis was flawed, because he created a derivative product of all of Respondent's treatment notes to determine that Respondent had met the standard of care. Govt Posthearing, at 44–45; Govt Exceptions, at 45–46. The Government further argued that this method of justifying a prescription was not consistent with California law. Govt Exceptions, at 19. I agree with the Government and I found this method of Dr. Malik's standard of care analysis to be dubious; however, because I have no expert testimony to refute whether or not this is an appropriate manner to evaluate Respondent's care and no expert review of the Respondent's Exhibits opining that they do not demonstrate that Respondent met the standard of care, I have agreed with the Chief ALJ that Dr. Malik's testimony is unrefuted on the prescriptions that he reviewed as part of Respondent's Exhibits. *See e.g.,* RD, at 70. This issue is not central to the resolution of this case, because I find herein that the Government has established a *prima facie* case that Respondent's registration is inconsistent with the public interest based on the prescriptions that were not included in Respondent's Supplemental Exhibits.

2015, to April 19, 2016. *Id.* at 811. As such, the Government's counsel at the hearing noted that the records in GX 3, included prescriptions for J.M. dated October 30, 2014, November 10, 2014, November 20, 2014, and November 9, 2015, all of which predate the records that Dr. Malik reviewed in preparing his expert report. Tr. 812–13. Dr. Malik was asked to look at GX 4, at 17–20, and was then asked whether the records provided information needed to determine whether the controlled substance is being prescribed for a legitimate medical purpose. *Id.* at 821. He responded that ''there's no physical examination documented here, so only talking about the pain doesn't say anything about anything else. I wouldn't say this is good enough for me to start the patient on the trinity cocktail,'' and he concluded the same regarding the decision to prescribe the high dose of opiates. *Id.* Dr. Malik later stated that if he were basing his evaluation as to whether Respondent met the standard of care in California for controlled substance prescribing based on GX 4, ''[h]e does not meet the standard of care based on only the records provided by the Government.'' *Id.* at 850.

Based on the uncontroverted evidence presented by the Government, I find that the controlled substance prescriptions issued on October 30, 2014, November 10, November 20, 2014, and November 9, 2015,[30] were issued outside the usual course of professional practice and beneath the applicable standard of care in California. *See also* RD, at 69. Furthermore, I agree with the RD, and find that based on the uncontroverted testimony of Dr. Munzing that the record is required to include the patient's name, the date, the character and the quantity of the Schedule II controlled substance[31] prescribed on the records from the visit where the controlled substance was prescribed and the patient's address in the file, Tr. 241–42, the record contains substantial evidence that Respondent did not comply with recordkeeping requirements under Cal. Health & Safety Code § 11190(a) for the same Schedule II prescriptions. RD, at 71. The RD further found, and I agree, that the evidence in neither the Government's Exhibits nor Respondent's Exhibits include a patient's address until after the November 19 and 29, 2015 prescription dates and reflect an incorrect amount of oxycodone than what was prescribed. *Id.* at 72 & n.171 (citing RX 4, at 61–62; RX 4, at 1 (demonstrating the first patient's address recorded on December 9, 2015); *compare* RX 4, at 61 *with* GX 3, at 11–12 (oxycodone quantity of forty on patient record, while prescription was for sixty). Finally, I agree with the RD that Dr. Munzing's testimony regarding Respondent's ''excessive prescribing'' in violation of Cal. Bus. & Prof. Code § 725(a), was ''more persuasive'' than Dr. Malik's. RD, at 74. ''J.M. continuously received OxyContin 80mg and Roxicodone 30mg at either three or four times daily, resulting in a 660 MME daily dose (if each taken four times per day) or a 495 MME daily dose (if each taken three times per day). At a minimum, that is about five times the daily CDC-advised limit that Dr. Munzing explained arises out of the increase in risk to the patient once exceeded.'' *Id.* (citing GX 3). The Chief ALJ found, and I agree, that the Government has established that Respondent's prescribing to J.M. was excessive.[32]

2. R.D.

The Government alleged that Respondent issued a total of thirty controlled substance prescriptions on fifteen dates to R.D. outside the usual course of professional practice and without a legitimate medical purpose and in violation of California law, on July 8, 15, 22, and 29 of 2015; November 4, 11, 18 and 25 of 2015; June 2, 11, 20 and 28 of 2016; and July 6, 14, and 22, 2016. OSC, at 5; RD, at 77–79.

(a) R.D.'s Medical Records in Government Exhibits

The Government's evidence related to R.D. demonstrated a patient questionnaire, dated March 11, 2009. GX 10, at 3. There is a progress note form that ''actually has more information on it,'' but is undated. Tr. 328–29 (citing GX 10, at 4). The patient file also included an opioid risk tool, an undated, unnamed pain scale, a depression checklist, which shows ''kind of on the border of mild depression,'' and a patient agreement. *Id.* at 332 (citing GX 10, at 8–12). The Family and Personal Health History form in the R.D. file stated that the last physical examination date was November 15, 2014, which was ''just over six months before.'' *Id.* at 333; (citing GX 10, at 13). Dr. Munzing testified that the progress note dated May 26, 2015, was deficient under the standard in California for many reasons to include there being no ''assessment, and the treatment plan, all it says is pain management.'' *Id.* at 334 (citing GX 10, at 14). He further testified that the other records for R.D. on May 26, 2015, did not meet the standard of care in California, stating that, ''[t]here's practically no information on them'' and further that the records related to Schedule II controlled substances were inadequate under to California Health and Safety Code 11190. Tr. 344–45 (citing GX 10, at 21–24). Dr. Munzing testified that the records related to R.D. on December 9, 2015, taken together as a whole do not meet the California standard of care. Tr. 354 (citing GX 10, at 43–46). Dr. Munzing further testified that the patient record, dated April 13, 2016, did not fulfill the requirements for listing controlled substances under California law, because there was ''no strength, no amount, no directions . . .'' and that although ''the exam portion for the musculoskeletal is consistent. There are no vital signs listed. There's no heart and lung exam listed,'' and therefore the documentation is not consistent with the standard of care for a controlled substance prescriber in California ''in entirety.'' Tr. 361–63, 365 (citing GX 10, at 67).

(b) R.D.'s Prescriptions

On July 8, July 15, July 22, July 28, 2015, Respondent prescribed R.D. 60 tablets of Norco at 10/350 milligrams per tablet. GX 7, 1–2, 3–4, 5–6, 7–8; Tr. 369–70. Further, the Government presented a dispensing report from White Front Pharmacy that also indicated that on each of these dates, Respondent prescribed R.D. 2 milligrams of alprazolam. GX 8, at 3; Tr.

[30] The Chief ALJ found that the Government had not provided enough evidence to sustain a violation for the remaining prescriptions for which Respondent had provided additional documentation and which Dr. Malik had testified were issued within the standard of care in California, because ''the Government declined to elicit an opinion from its expert Dr. Munzing, regarding the J.M. supplemental file, including whether the Respondent's supplemental paperwork contained in that file brought his prescribing to within the standard of care . . .'' for those prescriptions. RD, at 70. Although I agreed with the Chief ALJ in finding credibility issues with Dr. Malik, *supra* II.C., and I agree with the Government that the origin of the Respondent's Supplemental Records was suspicious, *supra* II.D., I also agree with the Chief ALJ that the Government's failure to rebut the testimony of Respondent's expert regarding the additional files leaves the question of whether the prescriptions in the supplemental files were issued within the standard of care unresolved. I also find that the record contains more than enough uncontroverted evidence to demonstrate that it is against the public interest for Respondent to maintain his registration, and therefore, I have not violations of the DEA regulations for the supplemental file records.

[31] Roxicodone and OxyContin are Schedule II controlled substances. Stip. 5.

[32] Although the RD noted that Dr. Munzing did not ''specifically testify as to what constitutes excessive prescribing in the Respondent's local community,'' his testimony as to the CDC recommendations, which were so extremely exceeded in this case, was sufficient to establish the excessive prescribing. RD, at 73. I agree. I further find that Dr. Malik's testimony on the issue of MMEs was less persuasive than Dr. Munzing's.

370–71. Dr. Munzing testified that the closest date to these prescriptions in Respondent's records for R.D. was May 26, 2015, and that the prescriptions for alprazolam and Norco were issued ''far below the standard of care,'' and the records ''practically have no information written on them.'' Tr. 372, 374–75. Dr. Munzing further testified that the number of Norco pills ''is a pretty hefty amount of Norco'' and that the large number of pills raises the potential for additional risk of diversion or abuse. *Id.* at 377.

On November 4, November 11, November 18, and November 25, 2015, Respondent prescribed R.D. 60 tablets of Norco at 10/350 milligrams per tablet GX 7, 9–10, 11–12, 13–14, 15–16; Tr. 379–85. On November 11, Respondent prescribed an additional 10 pills of 2 milligrams per pill of Xanax. GX 7, at 11. The Government presented a dispensing report from White Front Pharmacy that also indicated that on each of these dates, Respondent prescribed R.D. 10 tablets of alprazolam at 2 milligrams. GX 8, at 4; Tr. 382–83. Dr. Munzing testified that these prescriptions were ''an extreme departure from the standard of care'' based on the records and the amounts. Tr. 384.

On June 2, June 11, June 20, June 28, July 6, July 14, July 22, 2016, Respondent prescribed R.D. 55 tablets of Norco at 10/325 milligrams per tablet. GX 7, at 17–18, 19–20, 21–22, 23–24, 25–26, 27–28, 29–30; Tr. 386. Additionally, on June 2, and July 22, 2016, Respondent prescribed 9 pills of 2 milligrams per pill of Xanax. GX 7, at 17–18, 29–30. The Government presented a dispensing report from White Front Pharmacy that also indicated that on June 11, 20, July 6 and July 14, 2016, Respondent prescribed 9 tablets of alprazolam at 2 milligrams to R.D. GX 8, at 7; Tr. 387–88. Dr. Munzing testified that the closest records to the prescriptions for R.D. were dated April 13, 2016. Tr. 389. He further testified that all of these prescriptions were ''prescribed outside the standard of care'' due to the lack of documentation of the history, imaging, evaluation, and that the amount, although slightly lower than the previous amounts, were still ''a pretty hefty amount'' and raised concerns about diversion and abuse. *Id.* at 389–91. Further, he testified that the combination of the alprazolam and the Norco was a concern, because ''[i]t's been well known for quite some time both in literature and in practice the combination increases the risk of overdoes and potential death.'' *Id.* at 392.

Dr. Munzing also testified that R.D.'s file included a ''huge red flag'' [33] due to his acknowledgement that he had been arrested for drunk driving, and that the standard of care would require a doctor to ''[t]ake a history and document a history and resolve that that's not an issue if you're going—if and when you're going to prescribe controlled substances.'' *Id.* at 393–95; GX 10, at 59; *see also* GX 10, at 68 (acknowledgement of drunk driving). Dr. Munzing explained that R.D. had another unresolved red flag stating that R.D. ran out of medications early, because ''it would indicate that presumably the patient's taking more than—more medications than they have prescribed'' or that ''they were selling, giving—they were diverting the medication.'' Tr. 396–97; GX 10, at 71. He stated that to resolve this red flag under the California standard of care, the physician would need to ''resolve that issue as far as is it a reasonable, appropriate reason for running out early or not,'' and that he saw no resolution of the red flag in the patient file. Tr. 397. Finally, Dr. Munzing testified that R.D.'s file contained a red flag of distance traveled from Perris, California to Costa Mesa, which is approximately 63–65 miles, which is a red flag and would require a practitioner to document the rationale for traveling the distance. *Id.* at 399–401; *see* RD, at 30.[34] Again, he explained that the standard of care in California is that a practitioner must resolve the red flags, ''and document because others are going to be reviewing these charts, and one needs to determine here is a red flag. How is this okay or not okay.'' *Id.* at 402.

Dr. Malik testified based on his review of Respondent's Exhibit 5 for R.D. *Id.* at 751. He stated that in order to determine that Respondent's documentation was within the standard of care, he had to ''go[ ] through a different progress note to compile everything, and in the very end, one particular which [he] had pretty much had everything which the recommendations, our guidelines say.'' *Id.* He further testified that, based on the records that he had reviewed, Respondent had complied with the standard of care in California in prescribing controlled substances to R.D. Tr. 752–53.

On cross examination, Dr. Malik stated that he reviewed RX 5 in preparing his expert report contained in RX 17, and that the records for R.D. in RX 5 ranged from August 26, 2015,[35] to July 6, 2016. *Id.* at 826–30 (citing RX 5, at 82 and 1). As such, the Government's counsel at the hearing noted that the records in GX 7, included prescriptions for Norco dated July 8, 2015, July 15, 2015, July 26, 2015, July 29, 2015, July 14, 2016, July 22, 2016 (Xanax and Norco), which either predated or postdated the records that Dr. Malik reviewed in preparing his expert report. Tr. 831–32 (citing GX 7, at 1–8, 27–30). Further, GX 8 was a dispensing report from a pharmacy demonstrating prescriptions for alprazolam on July 8, 2015, July 15, 22, 29, 2015, July 14, 2016, which either predated or postdated the records that Dr. Malik reviewed in preparing his expert report. Tr. 833–35 (citing GX 8, at 3, 7). Dr. Malik testified that the prescriptions for Xanax and Norco that postdated the Respondent's Supplemental Records would still be within the standard of care because the progress note that he reviewed on July 6, 2016 ''tells about the patient's condition or the overall scenario of the patient for over a period of time.'' Tr. 841–42 (citing GX 7, at 27 and 29).

Based on the uncontroverted evidence presented by the Government, I find that the controlled substance prescriptions issued on July 8, 15, 22, and 29, 2015,[36]

[33] It is noted that although Dr. Malik testified that he saw no red flags in Respondent's exhibits, the forms indicating this red flag were not included in the records that Dr. Malik reviewed. Tr. 763–64. Dr. Malik did testify that a physician ''has to'' evaluate the risk of a patient abusing controlled substance under the California standard of care and document the conversations regarding the red flags in the record. *Id.* at 762; 796. He also testified that driving under the influence would be a red flag. *Id.* at 794.

[34] On cross-examination, Dr. Munzing testified that if R.D. had lived closer at one point to Respondent's office and then moved, ''it certainly could be a resolution of the red flag.'' Tr. 463. Dr. Munzing had testified that he would expect to see ''[a] small notation in the chart,'' but he did not elaborate on whether it would be required under the standard of care if the red flag had already been resolved. *Id.* at 462. I find that the record was ultimately unclear about whether the distance red flag could have been resolved, but there were several other red flags regarding R.D. that were unresolved in the Government's Exhibits. *See also* RD, at 78 n.177 (not sustaining the distance red flag on other grounds).

[35] Although RX 5 included a cholesterol report from June 2, 2014, Dr. Malik testified that it would ''not affect [Respondent's] decision to continue or not continue or change the dose of the pain medications.'' Tr. 830 (citing RX 5, at 4).

[36] The Chief ALJ noted that, as with J.M., the Government's expert and Respondent's expert had testified solely to the legitimacy of the R.D. prescriptions as documented in their respective exhibits. RD, at 76–77. He also noted that the Government had not provided enough evidence to sustain a violation for the prescriptions in Respondent's Supplemental records and which Dr. Malik had testified were issued within the standard of care in California, because Dr. Munzing had not reviewed or testified as to whether Respondent's Supplemental Records were within the standard of care. RD, at 79. As explained in *supra* n.24, I will follow the Chief ALJ's rationale in not including these prescriptions in my consideration of Public Interest Factors Two and Four.

were issued outside the usual course of professional practice and beneath the applicable standard of care in California. *See also* RD, at 77–78.[37] Furthermore, I agree with the RD, and find, based on the uncontroverted testimony of Dr. Munzing, that the records for Schedule II[38] controlled substances are required to include the patient's name, the date, the character and the quantity of the controlled substance prescribed on the records from the visit during which the controlled substance was prescribed and the patient's address must be in the file prior to prescribing, Tr. 241–42, the record contains substantial evidence that Respondent did not comply with recordkeeping requirements under CA Hlth & S § 11190(a) for the same prescriptions. RD, at 84. The RD further found, and I agree, that Respondent's Exhibits for November 4, 11, 25, 2015, and June 20, 28, July 14, and 22, 2016,[39] did not include all of the information that Dr. Munzing testified was necessary for Schedule II controlled substances under California law. *Id.* at 84 (citing RX 5, at 72–73, 66–67, 61–62).[40]

I generally agree with the Chief ALJ that the Government did not adequately demonstrate that the red flags that Dr. Munzing identified with respect to R.D. were unresolved in the prescriptions that coincided with and postdated Respondent's Supplemental Records, because Dr. Munzing never reviewed or opined on the Respondent's files to determine whether the red flags had been resolved. RD, at 82. However, Dr. Munzing identified what he described as a ''huge red flag'' regarding R.D.'s arrest for a DUI, GX 10, at 59, 68, which was documented by R.D. in the April 13, 2016 R.D. records in the Government's Exhibits, and which Dr. Munzing stated ''needs a lot of explanation.'' Tr. 397. Respondent's records for R.D. include dates from April 13, 2016, to July 6, 2016, RX 5, at 1–25, and yet, nowhere in these records, nor in the Government's Exhibits, are any notes that could possibly resolve the red flag of the DUI. There is no mention of alcohol or a DUI on any of the Respondent's exhibits after this date. Dr. Malik testified that a DUI would be a potential red flag, and that ''after fair warning, the physician should stop prescribing these pain medications with the patient anymore, but there have to be significant red flags for that to happen'' and also that these conversations with the patient need to be documented by the doctor. Tr. 794–96. It is apparent that both experts agreed that a DUI is a red flag and must be documented. My reading of the records in evidence shows no mention of the red flag of the DUI and I believe that both experts testified that the DUI must be addressed in some manner, which it is clear from the record that it was not. Therefore, I also find that the controlled substance prescriptions issued to R.D. after the admission that raised the red flag on April 13, 2016, were issued outside of the usual course of the professional practice and beneath the applicable standard of care.[41]

3. C.B.

The Government alleged that Respondent issued a total of eight controlled substance prescriptions on four dates to C.B. outside the usual course of professional practice and without a legitimate medical purpose and in violation of California law. OSC, at 7; RD, at 86.

(a) C.B.'s Medical Records in Government Exhibits

Dr. Munzing testified that C.B.'s medical complaints seemed to be that she had a skiing accident, but that ''[t]he timing of the accident seems to move through the records, whether it be in the late 1990s or early 2000s.'' [42] Tr. 404. The Government's evidence related to patient C.B.'s file consisted of many of the same forms as the files for R.D. and J.M., including Pain Assessment Questionnaires filled out by the patient, *see e.g.,* GX 12, at 22, Pain medication agreements, *id.* at 17, and exam notes that are either blank or have some information filled out, *id.* at 36, 44; Tr. 410–45. The evidence also contains several Controlled Substance Utilization Review and Evaluation System (hereinafter, CURES) reports for C.B. Dr. Munzing testified that the CURES reports ending on April 23, 2015, indicated several red flags, in that there is a ''combination of two different opioids'' prescribed by two different doctors, and ''[t]here is also Suboxone prescribed by Dr. T[ ], and the majority of the time that Suboxone is used, it's used for substance use disorder or addiction . . . '' and ''pharmacy shopping.'' Tr. 416 (citing GX 12, at 40–41). Dr. Munzing testified that the CURES report in April showed similar red flags, including multiple doctors and pharmacies and also the ''trinity'' of controlled substances. Tr. 418 (citing GX 12, at 9–10). Dr. Munzing testified that there is a handwritten note in C.B.'s file stating that patient should not have multiple doctors and that she signed a renewed pain agreement; however, he testified that the note alone does not resolve all of the red flags in the file, such as the combination of medicines, the Suboxone [43] and multiple pharmacies. Tr. 418–21 (citing GX 12, at 10). According to Dr. Munzing, the records in C.B.'s file closer to the time of the Government's allegations, had ''significant missing information,'' such as ''no vital signs,'' ''limited historical information,'' no dosages of the controlled substance, ''no comment as far as whether the patient's getting better, worse, etc.'' Tr. 431 (citing GX 12, at 316–19). Although some of the records were ''the best that [Dr. Munzing had] seen'' in Respondent's records, they were still missing ''aspects of vital signs, of medications prescribed.'' Tr. 436 (citing GX 12, at 322–24).

[37] For R.D., there were additional prescriptions that were issued after the majority of the records in Respondent's Exhibits, which the Chief ALJ designated ''Patient R.D. Group 3 Prescribing Events.'' The Chief ALJ concluded that Respondent had ''produced significant additional documentation that was not considered by Dr. Munzing,'' when he opined that R.D.'s file contained red flags that were not resolved in the documentation. RD, at 82. I agree with the Chief ALJ regarding the limitations of the Government's case based on red flags in the Respondent's Supplemental Records, except for the red flag of the DUI as explained below.

[38] Norco has been a Schedule II controlled substance since October 6, 2014. Stip. 4.

[39] Respondent's Exhibits did not contain any additional records for these particular June and July visits.

[40] I agree with the RD that the Government has demonstrated substantial evidence that Respondent was excessively prescribing to R.D., because Dr. Munzing never testified that the ''hefty amount'' of Norco amounted to excessive prescribing. RD, at 84–85 (citing Tr. 377).

[41] Although I am finding that these additional fourteen prescriptions, in what the Chief ALJ has entitled the Patient R.D. Group 3 prescribing events, RD, at 80–81, were issued outside the usual course of the professional practice and beneath the applicable standard of care in California, even without the finding of these additional violations, there is more than enough evidence on the record to indicate that Respondent's registration is inconsistent with the public interest.

[42] *Compare* GX 12, at 278 (09/08/2004 Questionnaire indicating immediate pain onset in January 2008), *with id.* at 288 (05/12/2004 PAQ indicating pain onset in 1996 from snow skiing accident). *See* RD, at 31 n.74 (full assessment of various dates claimed for pain onset for C.B. file).

[43] The Government's records do include a note regarding ''Cures problems,'' which mentions the Suboxone prescription and that the note states that it was discontinued, but it was unclear whether the psychiatrist was the one who had discontinued the prescription. GX 12, at 22; Tr. 549. Dr. Munzing testified that this note does not resolve the red flag that the patient was ''taking the trinity based on the prescriptions that she was obtaining from two doctors,'' Dr. Munzing testified that there was nothing in the record to demonstrate that the red flag was resolved regardless of the timing being near the surgery. Tr. 550; 562. However, Dr. Munzing did not testify as to whether the Respondent's Supplemental Records included any resolution of the red flag.

(b) C.B.'s Prescriptions

On January 6, January 25, Respondent prescribed C.B. 60 tablets of Vicodin at 7.5/300 milligrams per tablet and 30 tablets of Soma at 350 milligrams per tablet. GX 11, at 1–2, 3–4; Tr. 443–45. Dr. Munzing testified that these prescriptions do not meet the standard of care in California, because ''there's no progress note or evidence that supports the medical justification.'' Tr. 446. On February 11, 2016, Respondent prescribed C.B. 55 tablets of Vicodin at 7.5/300 milligrams per tablet and 55 tablets of Soma at 350 milligrams per tablet. GX 11, at 5–6. Dr. Munzing again testified that this prescription did not meet the standard of care in California, due to the lack of documentation. Tr. 447–48 (citing GX 12, at 325 (Patient records for C.B. dated January 27, 2016)). On March 3, 2016, Respondent prescribed C.B. 50 tablets of Vicodin at 7.5/300 milligrams per tablet and 30 tablets of Soma at 350 milligrams per tablet. GX 11, at 7–8. Dr. Munzing testified that this visit ''does not fall within the standard of care, though in re-review in preparation for this hearing, I think that for this one visit, I would call this a simple departure . . . .'' Tr. 449 (citing GX 12, at 322–24 (Patient records for C.B. dated March 3, 2016)).

Dr. Malik testified that C.B. was prescribed the ''trinity cocktail'' for brief period of time, but that ''for that particular patient, these three medications for a certain period of time after the breast surgery in a patient whose body is already used to a high dose of opiates I think brought enough comfort to her pain.'' Tr. 745. He testified that ''[Respondent's] documentation was probably very down there, pretty bad, but . . . if I can gather all the information from all the records . . . I will say it was all within the standard of care.'' *Id.* at 745–46.

The Chief ALJ found that Respondent's Supplemental Records contained notes that correspond with all of the prescriptions and dates included in the OSC for C.B. RD, at 86 (citing GX 12 and RX 3). I agree with the Chief ALJ that because Dr. Munzing did not consider the detailed records in the Respondent's Supplemental Records and the Government did not present expert testimony regarding whether the Supplemental Records resolved the standard of care issues that Dr. Munzing had identified in the Government's Exhibits, ''Dr. Malik's testimony that the prescribing to C.B. on those dates was within the standard of care based upon a review of that documentation stands unrefuted.'' RD, at 88.

However, the Chief ALJ found, and I agree, that based on the uncontroverted testimony of Dr. Munzing, that the records for Schedule II [44] controlled substances are required to include the patient's name, the date, the character and the quantity of the controlled substance prescribed on the records from the visit during which the controlled substance was prescribed and the patient's address must be in the file prior to prescribing, Tr. 241–42, the record contains substantial evidence that Respondent did not comply with recordkeeping requirements under Cal. Health & Safety Code § 11190(a) for the prescriptions on January 6, February 11, and March 3,[45] 2016 because the records do not include the quantity prescribed. RD, at 89–90 (citing RX 3, at 25, 28, 38, and 42).

Overall, I find that the record contains substantial evidence to support the finding that Respondent issued numerous controlled substance prescriptions to J.M. and R.D. outside the usual course of the professional practice and beneath the applicable standard of care and in violation of several California laws and that Respondent issued controlled substance prescriptions to C.B. without complying with California law.

III. Discussion

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

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

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

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

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

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

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

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

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Under DEA's regulation, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[46] I address Factor One briefly

[44] Vicodin is and has been a Schedule II controlled substance since October 6, 2014. Stip. 4.

[45] The Chief ALJ noted that the record on this date appeared to reflect what might be considered to be a quantity, but it was inconsistent with the actual prescription. RD, at 90 n.208 (citing RX 3, at 22–27, GX 12, at 322–24).

[46] I agree with the Chief ALJ with regard to Factor Three that ''although the record contains evidence of a pending criminal matter (Stips. 3, 9), there is no evidence in the record that the Respondent has been convicted of a crime related to controlled substances.'' RD, 60 n.146. Therefore, I find that Factor Three does not weigh for or against revocation in this case. Although this hearing was completed several years ago and the criminal case may have come to a conclusion in the interim, I am not taking notice of any additional facts on the record, as I find that doing so is unnecessary based on the completeness of the record that is before me.

because Respondent introduced evidence into the record that is potentially relevant to Factor One as explained below. Overall, I find that the Government's evidence with respect to Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factor One—the Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

In determining the public interest, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC. *John O. Dimowo, M.D.,* 85 FR 15800, 15810 (2020); *see also Vincent J. Scolaro, D.O.,* 67 FR 42060, 42065 (2002).

In this case, neither the Medical Board of California (hereinafter, the State Board) nor any other state entity has made a direct recommendation to the Agency regarding whether the Respondent's registration should be suspended or revoked. However, during the hearing, Respondent introduced an ''Interim Suspension Order'' (hereinafter, Suspension Order) issued by the State of California Office of Administrative Hearings on December 7, 2016. RD, at 95 (citing RX 16). The Suspension Order stated that ''Respondent shall not prescribe any Schedule II, III, or IV controlled substances.'' RX 16, at 7. Respondent argued that ''a petition for Interim Suspension Order to stop [Respondent] from practicing altogether was denied by the California Medical Board after they found he was not a danger to public safety, and [Respondent] is permitted to continue practicing medicine.'' Resp Posthearing, at 7.

The fact that the State Board did not choose to immediately suspend Respondent's state medical license carries minimal-to-no weight under Factor One, because there is no evidence that the State Board would have made the same decision after a full hearing on the merits was completed, and additionally, the State Board did significantly restrict Respondent's prescribing authority pending a full determination on the allegations.[47] Accordingly, the terms of the State Board Order have been considered, but I find that they have no impact on the public interest inquiry in this case. *See John O. Dimowo, M.D.,* 85 FR at 15810.

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

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

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

In defense of Respondent's continued registration, he has submitted supplemental records, which are far more detailed than the records in the Government's Exhibits. RX 3–5. However, Respondent's Supplemental Records only address a subset of the prescriptions at issue in this case, and the Government has established through unrefuted expert testimony that the records that Respondent did not supplement constituted ''an extreme departure from'' the standard of care in California. Tr. 384. Even Respondent's own expert testified that the records in the Government's Exhibits alone did not justify the prescriptions to J.M. *Id.* at 850.

The end result remains that Respondent issued numerous controlled substance prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in California. DEA decisions have found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51592, 51601 (1998).

The violations I have found demonstrate that Respondent repeatedly violated the applicable standard of care and state law and that his conduct was not an isolated occurrence, but occurred with multiple patients. *See Wesley Pope, M.D.,* 82 FR 42961, 42986 (2017).

The Respondent asserted that ''[t]he fact is that [Respondent's] biggest failure was over documenting not under documenting.'' Resp Posthearing, at 6. This is simply not true based on the facts on the record. If Respondent's Supplemental Records are legitimate, an assumption to which I have applied a large degree of latitude in this case, he has not presented supplemental records to support many of the controlled substances prescriptions in the Government's *prima facie* case. Therefore, I cannot assume that this so-called ''over documentating'' exists. Furthermore, Respondent's own expert testified with regard to Respondent's Supplemental Records that ''[Respondent is] a very poor documenter,'' which directly contradicts Respondent's assertion. *Id.* at 743.

''Diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .'" *Id.* (citing *Roy S. Schwartz,* 79 FR 34360, 34363 (2014)). In this case, I have found that Respondent issued controlled substance prescriptions without complying with his obligations under the CSA and California law. *See George Mathew, M.D.,* 75 FR 66138, 66148 (2010)).

Furthermore, Agency decisions highlight the Agency's interpretation that ''[c]onscientious documentation is

[47] In *Dimowo,* the Acting Administrator found that ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state;'' however, *Dimowo* also limited the ''recommendations'' DEA would consider to the ''actions of an appropriate state entity on the same matters, particularly where it rendered an opinion regarding the practitioner's medical practice in the state due to the same facts alleged in the DEA OSC.'' *John O. Dimowo,* 85 FR at 15810. In this case, I have no indication that the State Board would make a similar decision after a full adjudication, and even in the interim, the State Board did significantly restrict Respondent's ability to prescribe controlled substances.

repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.' '' *Cynthia M. Cadet, M.D.,* 76 FR 19450, 19464 (2011). DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that he prescribed a controlled substance—adequate documentation is critical to that assessment. Here, Respondent's sparse documentation, and even his organization of such documentation, made it impossible to evaluate his prescribing practices in any meaningful way. Further, as Dr. Munzing stated regarding maintaining accurate and complete records, ''I guess I can't emphasize enough they're incredibly important, again for patient safety and for knowing what happened at any particular time. They're also important, again, for any kind of transfer of care, whether it's temporary or, you know, permanent.'' *Id.* at 249. Therefore, recordkeeping is not only important for compliance, but also for the safety of the patients.

I find that in issuing prescriptions to J.M. and R.D. beneath the applicable standard of care and outside the usual course of the professional practice in California, Respondent violated 21 CFR 1306.04(a) (''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice'').

(b) Allegations of Violations of California [48] Law

California law also requires that a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a). Therefore, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Respondent violated this provision with respect to some of the prescriptions for J.M. and R.D. in *supra* II.F.1.b. I also find based on the uncontroverted evidence that Respondent issued these same controlled substance prescriptions without documenting a medical examination or legitimate medical indication in violation of Cal. Bus. & Prof. Code § 2242(a).

Additionally, California law states that ''repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment . . . as determined by the standard of the community of licensees is unprofessional conduct for a physician.'' Cal. Bus. & Prof. Code § 725(a). The Chief ALJ opined, and I agreed, that the record contains substantial evidence that Respondent's prescribing to J.M. was excessive in violation of this California provision of law. *Supra* II.F.1.b.

California Health & Safety Code § 11190(a) requires that practitioners who prescribe Schedule II controlled substances must keep certain specific records, to include, ''[t]he character, including the name and strength, and quantity of controlled substances involved.'' Cal. Health & Safety Code § 11190(a)(3) (Westlaw, current with all laws through Ch. 372 of 2020 Regular Session). I found above that Respondent's recordkeeping for all three patients—J.M., R.D. and C.B.—were missing elements of the required specific records, and therefore, I find that the record contains substantial evidence that Respondent was in violation of this provision of state law and this is evidence that Respondent's registration is not in the public interest under Factors 2 and 4. *Supra* II.F.1.b, F.2, & F.3.

Ultimately I find that the record contains substantial evidence that Respondent issued multiple prescriptions of high dosages of controlled substances to multiple patients beneath the applicable standard of care and outside the usual course of the professional practice and in violation of state law. I therefore find that Factors Two and Four weigh in favor of revocation. *See Wesley Pope,* 82 FR 14944, 14985 (2017).

3. Factor Five

Under Factor Five, the Administrator considers ''[s]uch other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). Although Factor Five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Zvi H. Perper, M.D.,* 77 FR 64131, 64141 (2012) (citing *Tony T. Bui,* 75 FR 49979, 49988 (2010)).

The Government alleged that ''[d]espite being arrested and charged for unlawfully prescribing, Respondent continued to prescribe to J.M., R.D., and C.B. in violation of state and federal law.'' Govt Posthearing, at 39. Therefore, the Government argued that ''it is thus clear that being arrested and later arraigned for allegedly unlawfully prescribing was not enough of a deterrent for Respondent to stop such conduct. That he would continue to do so highlights the egregious nature of his actions and heightens the probability that Respondent is 'a probable or possible threat . . . to the public health and safety.' '' *Id.* (citing *Drezer,* 76 FR at 19386 n.2). Respondent argued that his ''prescribing after his arrest was not unlawful because there was a legitimate medical purpose.'' Resp Posthearing, at 6.

Until Respondent had entered into an agreement with the Orange County District Attorney's Office on August 30, 2016, whereby he ''agreed to not prescribe Schedule II–IV controlled substances,'' it was not *per se* a violation of this agreement for him to prescribe controlled substances in these schedules to these patients; however, the fact that I have found that in some instances, he continued to violate federal and California law after his arrest on December 15, 2015, certainly demonstrates both the egregious nature of his actions and the improbability of his ability to meaningfully prevent the reoccurrence of similar acts. *See* Stips. 3&10. In this case, I agree with the Chief ALJ that this particular misconduct has already been considered under Factors Two and Four, and I believe that, in this case, the Government's arguments regarding the deterrent effect of his arraignment and the issues of trust that this misconduct necessarily implicates are more appropriately considered in my assessment of the correct sanction for Respondent as set forth below. *See* RD, at 92–93.

Overall, I conclude that the Government has met its *prima facie* burden of showing that Respondent's continued registration is ''inconsistent with the public interest.'' I further find that Respondent did not rebut the Government's *prima facie* case.

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to his violations pertaining to controlled substance prescribing and non-compliance with federal and state

[48] The OSC alleged a violation of Cal. Health & Safety Code § 11154(a) (prescribing to persons not under practitioner's treatment) and OSC, at 8. Although listed in the Government's briefings, I did not find any explanation on the record regarding the legal theory supported by evidence on the record specifically related to this citation; therefore, I am not evaluating it in the final decision. *See, e.g.,* Govt Posthearing, at 32.

law, the burden shifts to the Respondent to show why he can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. at 259. A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that [she] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual 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).

In evaluating the degree of a respondent's acceptance of responsibility required to entrust him with a registration, in *Mohammed Asgar, M.D.,* 83 FR 29569, 29572 (2018), the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' *Id.* (citing *Lon F. Alexander, M.D.,* 82 FR 49704, 49728 (2017)). The Chief ALJ found, and I agree, that ''[t]he record is devoid of any inclination on the part of the Respondent to accept any level of responsibility for his prescribing, unequivocal or otherwise. He remains doggedly committed to the proposition that he did nothing wrong.'' RD, at 97 (citing Tr. 882). Respondent's assertion that ''[t]he fact is that [Respondent's] biggest failure was over documenting not under documenting'' is unsupported by the record evidence and demonstrates no acknowledgment of fault or wrongdoing. Resp Posthearing, at 6. *See Hoxie* v. *Drug Enf't Admin.,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician'' and ''admitting fault'' is an ''important factor[] in determining whether the physician's registration should be revoked'').

Respondent's mitigating evidence has reduced the number of violations found in this case; however, I see no evidence from Respondent that demonstrates that he will ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.* 75 FR 8194, 8236 (2010). Acceptance of responsibility is an important part of that demonstration. *Id.* In fact, as noted herein, the evidence indicates that Respondent will do nothing to prevent the reoccurrence of similar acts, because after being arrested under allegations of the same state law violations at issue in this case, the record contains substantial evidence that in some instances, Respondent continued the unlawful prescribing activity and continued to violate state recordkeeping law. *See supra* II.F.2&3.

The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases). I agree with the Chief ALJ that ''the record evidence here establishes that [Respondent] doled out a steady stream of powerful controlled drugs without applying and documenting even the most rudimentary of applicable standards of care and treatment, which is sufficiently egregious to militate in favor of revocation.'' RD, at 99–100. In addition, Respondent's lack of recordkeeping in the prescriptions in the Government's Exhibits was not simply inadequate. Dr. Munzing described Respondent's records for J.M. and R.D. respectively as ''not even close'' to and ''an extreme departure from'' the standard of care in California; therefore, I would characterize Respondent's misconduct as egregious. Tr. 321, 384.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10083, 10095 (2009); *Singh,* 81 FR at 8248. With regard to general deterrence, I agree with the Chief ALJ that ''[t]o continue the Respondent's registration privileges on the present record would send a message to the regulated community that no meaningful consequences will likely result from repeatedly and unabashedly prescribing controlled substances while maintaining sparse, unintelligible, incomplete documentation and storing it in random piles in a manner that makes it virtually unavailable (to the prescriber, to his patients or their future caretakers, or to anyone else) in the absence of a scavenger hunt by any federal or state regulators seeking to evaluate compliance.'' RD, at 99. Furthermore, as previously discussed, I have no confidence that any measure short of revocation would specifically deter Respondent from future misconduct, given that he continued his woefully inadequate medical recordkeeping and prescribing practices after he was arrested for similar behavior. *See Singh, M.D.,* 81 FR at 8248 (''until . . . [a] Respondent can convincingly show he [or she] accepts the authority of the law and those bodies charged with enforcing it and regulating his [or her] activities, granting [ ] a DEA registration will gravely endanger the public.'').

Here, there is insufficient evidence in the record to demonstrate that Respondent can be entrusted with a registration. *See Leo R. Miller, M.D.,* 53 FR at 21932 (describing revocation as a remedial measure ''based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.'').

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

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration BW5359004 issued to Mark A. Wimbley, M.D. Further,

pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Mark A. Wimbley, M.D., to renew or modify this registration, as well as any other applications of Mark A. Wimbley, M.D. for additional registration in California. This Order is effective May 21, 2021.

D. Christopher Evans,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michael Jones, M.D.; Decision and Order

On September 19, 2019, the Drug Enforcement Administration (hereinafter, DEA or Government) Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ), issued an Order Granting Government's Motion for Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD) on the action to revoke the DEA Certificate of Registration Number BJ5665281 of Michael Jones, M.D. The ALJ transmitted the record to me on October 15, 2019, and asserted that no exceptions were filed by either party. ALJ Transmittal Letter, at 1. Having reviewed and considered the entire administrative record before me, I adopt the ALJ's RD with minor modifications, where noted herein.*A

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BJ5665281 issued to Michael Jones, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Michael Jones to renew or modify this registration, as well as any other pending application of Michael Jones, for additional registration in Louisiana. This Order is effective May 21, 2021.

D. Christopher Evans,

Acting Administrator.

Paul E. Soeffing, Esq., for the Government

Robert C. Jenkins, Esq., for the Respondent

Order Granting Government's Motion for Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

The Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (''DEA''), issued an Order to Show Cause (''OSC''), dated June 19, 2019, proposing to revoke the Certificate of Registration (''COR''), Number BJ5665281, of Michael Jones, M.D. (''Dr. Jones'' or ''Respondent''), and to deny any applications for renewal or modification of such registration, and any applications for any other DEA registrations, pursuant to 21 U.S.C. 824(a)(5). The OSC alleges that revocation is warranted because Respondent has been mandatorily excluded from all federal health care programs under 42 U.S.C. 1320a–7(a).

The Office of Administrative Law Judges (''OALJ'') received a copy of the OSC on June 19, 2019. OSC, at 1. Dr. Jones, through counsel, filed a hearing request on July 19, 2019, the 30th day from the date of the OSC. Thus, Dr. Jones's hearing request was timely filed.

On July 19, 2019, I issued an Order for Prehearing Statements (''OPHS''), directing the parties to file prehearing statements and establishing a date for a telephonic prehearing conference. OPHS, at 1–2. The Government timely filed its prehearing statement on August 2, 2019. Dr. Jones did not file a prehearing statement by his deadline for doing so.

I conducted a telephonic prehearing conference with the parties on August 21, 2019. Following the conference, I issued a Prehearing Ruling (''PHR''), in which I directed Dr. Jones to file a prehearing statement and a motion for leave to file his prehearing statement out of time.

On August 26, 2019, Dr. Jones filed his prehearing statement along with a motion for leave to file his prehearing statement out of time. Because the Government did not file an opposition to Respondent's motion for out-of-time filing, on September 10, 2019, I issued an Order Granting Respondent's Motion for Out of Time Prehearing Statement and Notice Concerning Summary Disposition (''Order Concerning Summary Disposition''), which granted Respondent's motion for out-of-time filing as unopposed. My Order Concerning Summary Disposition also established a deadline for the Government to file a motion for summary disposition and for Dr. Jones to respond to the Government's motion for summary disposition.

The Government timely filed its Motion for Summary Disposition on September 13, 2019. Dr. Jones timely filed his Opposition to Government's Motion for Summary Disposition on September 18, 2019 (''Respondent's Opposition''). Accordingly, I base this ruling and Recommended Decision on the Government's Motion for Summary Disposition, Dr. Jones's Opposition, and the Administrative Record before me.

The issue in this case is whether the record as a whole establishes by a preponderance of the evidence that the DEA should revoke the Certificate of Registration of Michael Jones, M.D., No. BJ5665281/XJ5665281, and deny any applications for renewal or modification of such registration, and deny any applications for any other DEA registrations, pursuant to 21 U.S.C. 824(a)(5), because he has been excluded from federal health care programs under 42 U.S.C. 1320a–7(a).

The Facts

I. Stipulations

During the telephonic prehearing conference, the parties agreed to the following stipulations (''Stip.''), which are accepted as facts in this proceeding:

1. Respondent is registered with the DEA as a practitioner-DW/30 in Schedules II through V under DEA Certificate of Registration BJ5665281/XJ5665281 with a registered address of 3405 Saint Claude Ave., New Orleans, LA 70117–6144, and a mailing address of 2433 Bedford Dr., New Orleans, LA 70131–4703. Respondent's registration expires by its terms on December 31, 2021.

2. On or about September 25, 2018, Judgment was entered against Respondent based on Respondent's conviction on one count of ''Conspiracy to Commit Health Care Fraud,'' in violation of 18 U.S.C. 1349, one count of ''Conspiracy to Pay and Receive Illegal Health Care Kickbacks,'' in violation of 18 U.S.C. 371, and seven counts of ''Health Care Fraud,'' in violation of 18 U.S.C. 1347 and 2. *U.S.* v. *Michael Jones,* No. 2:15–cr–00061–SM–JCW (E.D. La. filed Sept. 28, 2018).

3. Based on Respondent's conviction, the U.S. Department of Health and Human Services, Office of Inspector

*A I have made minor, nonsubstantive, grammatical changes to the RD. Where I have made more substantive changes, I have marked the changes with an asterisk, brackets and explanatory footnotes.