Company	FR Docket	Published
SpecGx LLC	84 FR 26447	June 6, 2019.
Sigma Aldrich Research	84 FR 27659	June 13, 2019.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: October 16, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–23500 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–21]

Lesly Pompy, M.D.; Decision and Order

On March 2, 2017, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registrations to Lesly Pompy, M.D. (hereinafter, Respondent), of Monroe, Michigan. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause and Immediate Suspension of Registrations (hereinafter collectively, OSC)), at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificates of Registration BP2527058 and FP2665478 pursuant to 21 U.S.C. 824(d) ''because . . . [his] continued registration constitute[d] an imminent danger to the public health and safety.'' *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Respondent ''committed such acts as would render . . . [his] registrations under 21 U.S.C. 823(f) inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4).'' *Id.* at 2. Specifically, the OSC alleges that Respondent issued numerous prescriptions, including to an undercover investigator, outside the usual course of the professional practice of medicine in violation of 21 CFR 1306.04(a) and in violation of the minimal standards of medical practice in Michigan. *Id.* at 2–3. The OSC also alleges that, at one of his registered locations and at his (unregistered) residence, Respondent unlawfully possessed numerous controlled substances including, but not limited to, varying quantities of Schedule II controlled substances that had been dispensed to patients. *Id.* at 4 (citing 21 CFR 1301.12, 1317.30, and 1317.40; Mich. Comp. Laws § 333.7403). Finally, the OSC alleges that Respondent was unable to provide any of the records that DEA requested concerning his two registrations—an inventory at both registered locations and records for each controlled substance received, sold, and delivered. OSC, at 4 (citing 21 CFR 1304.11 and 1304.21).

On March 2, 2017, based on his preliminary findings that Respondent prescribed controlled substances outside the usual course of the professional practice, unlawfully possessed controlled substances at both his home and his office, and committed numerous recordkeeping violations, the former Acting Administrator concluded that Respondent's ''continued registration . . . [was] inconsistent with the public interest.'' OSC, at 5. Citing 21 U.S.C. 824(d), he also made the preliminary finding that Respondent's continued registration during the pendency of proceedings ''would constitute an imminent danger to the public health or safety because of the substantial likelihood that . . . [Respondent] will continue to prescribe controlled substances in a manner that . . . creates a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur.'' *Id.* Pursuant to 21 U.S.C. 824(f) and 21 CFR 1301.36(f), the former Acting Administrator authorized the DEA Special Agents and Diversion Investigators serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances Respondent possessed pursuant to the immediately suspended registrations. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Respondent's Certificates of Registration BP2527058 and FP2665478 and any unused prescription forms. *Id.*

The OSC notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 5–6 (citing 21 CFR 1301.43). According to the Government's Notice of Service, a member of the DEA Detroit Field Division personally served the OSC on Respondent on March 3, 2017. ALJX 2 (Government's Notice of Service of OSC/ISO), at 1.

By letter dated March 16, 2017, Respondent timely requested a hearing. ALJX 3, at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ). On March 16, 2017, he established a schedule for the filing of prehearing statements. ALJX 4 (Order for Prehearing Statements), at 1. On April 20, 2017, the Chief ALJ issued a Prehearing Ruling that, among other things, set out the six Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements. ALJX 11 (Prehearing Ruling) at 1–2.[1]

The Government filed its Prehearing Statement on March 29, 2017, and its Supplemental Prehearing Statement on June 8, 2017. ALJX 9 and 17, respectively. Respondent filed his Prehearing Statement on April 19, 2017, and his Supplemental Prehearing Statement on June 7, 2017. ALJX 10 and 20, respectively.

The hearing in this matter spanned seven days and took place at multiple locations.[2] On August 4, 2017, after the sixth day of hearings, the Government filed a Notice of Respondent's Lack of State Authority. ALJX 29 (hereinafter,

[1] The parties agreed to an additional 26 stipulations. ALJX 26 and ALJX 30. The first 31 stipulations are set out on pages 3 to 5 of the Chief ALJ's recommendations. The last stipulation is: ''On August 4, 2017, Dr. Pompy was served with a copy of an Order of Summary Suspension by the State of Michigan Department of Licensing and Regulatory Affairs. This order became effective upon service and summarily suspended Dr. Pompy's medical license.'' ALJX 30.

[2] Hearings were held in Detroit, Michigan on July 11, 12, 13, and 14, 2017 and in Arlington, Virginia on July 31, August 1, and August 21, 2017.

Notice). According to the Notice, the Government learned hours before filing the Notice that the Michigan Department of Licensing and Regulatory Affairs had served Respondent with a summary suspension of his medical license. *Id.* at 1. Although lack of State authority was not charged in the OSC, the Notice states that this allegation may be raised at any stage of a proceeding, even *sua sponte* by the Administrator. *Id.* (citing *Hatem M. Ataya, M.D.,* 81 FR 8,221, 8,224 (2016)). The Notice states the Government's intention to continue litigating the OSC to its final conclusion. Notice, at 2.

The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereafter, R.D.) is dated December 20, 2017. Neither party filed exceptions to the R.D. Transmittal Letter, at 1.

Having considered the record in its entirety, I agree with the R.D. that the record establishes, by substantial evidence, two independent grounds for the revocation of Respondent's registrations: (1) Respondent committed acts rendering his continued registration inconsistent with the public interest and (2) Respondent lacks authority in Michigan to practice medicine and to handle controlled substances.[3] R.D., at 124–126. I further agree with the R.D. that Respondent's acceptance of responsibility is insufficient and that, even if it were sufficient, Respondent did not offer adequate remedial measures. *Id.* at 126–127.

Accordingly, I conclude that the appropriate sanctions are (1) For both of Respondent's DEA Certificates of Registration to be revoked; (2) for any pending application by Respondent to renew or modify these registrations to be denied; (3) for any other pending application by Respondent for registration in Michigan to be denied; (4) for the Order of Immediate Suspension of Registrations issued to Respondent to be affirmed; (5) for all controlled substances seized pursuant to the Order of Immediate Suspension of Registrations to be forfeited to the United States according to statutory provisions; and, (6) for all right, title, and interest in those controlled substances to be vested in the United States according to statutory provisions. *See id.* at 127–129. I make the following findings.

[3] My conclusion that Respondent committed acts rendering his continued registration inconsistent with the public interest would not change if Respondent regains authority to practice medicine in Michigan.

Findings of Fact

Respondent's DEA Registrations

Respondent is registered with the DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. FP2665478, at Interventional Pain Management, 307 Stewart Road, Monroe, Michigan 48162–2934. Government Exhibit (hereinafter, GX) 1 (Respondent's CORs), at 1; *see also* GX 2 (Registration History for Respondent's CORs), at 1, ALJX 11, at 2 (Stipulation No. 3). This registration expires on March 31, 2020. GX 1, at 1; *see also* GX 2, at 1, ALJX 11, at 2 (Stipulation No. 3). Respondent is also registered with the DEA as a practitioner DW/100 in schedules II through V under DEA Certificate of Registration No. BP2527058 at 730 North Macomb Street, Suite #222, Monroe, Michigan 48162. GX 1, at 2; *see also* GX 2, at 3, ALJX 11, at 1 (Stipulation No. 1). On February 27, 2017, DEA received a renewal and change of address for this registration and put this registration in a ''renewal pending'' status. GX 2, at 1, 3; *see also* ALJX 11, at 1–2 (Stipulation No. 2). Both of these registrations were suspended pursuant to the Immediate Suspension Order dated March 2, 2017, ''after which date no controlled substances could be legally obtained, stored, administered, prescribed, or dispensed.'' GX 2, at 1, 3.

The Investigation of Respondent

The Monroe Area Narcotics Team and Investigative Service in Michigan (hereinafter, MANTIS) investigated Respondent and his medical practice, Interventional Pain Management. The investigation concerned whether Respondent issued controlled substance prescriptions without a medical need and included information from search warrants and undercover visits to Respondent's medical practice.

According to MANTIS, Blue Cross Blue Shield of Michigan (hereinafter, BCBS) documents report that Respondent ''prescribed the most overall prescription medication of the . . . [2,304] providers in his same specialty during the date range of 01/2014 to 12/2014.''[4] GX 11 (Michigan Department of State Police ''MTS Supplemental Incident Report 0002'' dated Sept. 21, 2016), at 1. MANTIS also cited BCBS documents as stating that, based on claims submitted to BCBS, Respondent prescribed the ''most controlled prescription medication'' and the ''most days [sic] supply of controlled prescription medication'' of the same 2,304 providers during the same time period. *Id.* at 1–2. The MANTIS report states that BCBS documents also report that Respondent ranked first in 2015 for the ''total day supply of controlled medication (52,026) . . . and total quantity dispensed of controlled prescription medication (136,267).'' *Id.* at 2.

[4] BCBS was also involved in the MANTIS investigation, at least initially. Transcript page (hereinafter, Tr.) 140.

The Allegations of Dispensing and Non-Dispensing Violations

The OSC alleges three bases for the revocation of Respondent's registrations pursuant to 21 U.S.C. 824(a)(4) and for the denial of any pending applications pursuant to 21 U.S.C. 823(f). In addition, as already discussed, the Government filed Notice of the Respondent's lack of State authority during the hearing. Notice, at 1 (citing 21 U.S.C. 824(a)(3)).

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply the R.D.'s credibility recommendations, all of which I adopt. *See* R.D., at 5–106.

The Government's Case

The Government's documentary evidence consists primarily of medical records for six patients, including records concerning an undercover investigator. The Government called five witnesses: A DEA Diversion Investigator (hereinafter, DI); a Detective assigned to MANTIS (hereinafter, MANTIS Det); a BCBS investigator who made undercover visits to Respondent's medical practice (hereinafter U/C); a Detective assigned to the Monroe County Sheriff's Office (hereinafter, Monroe Det); and its expert, Dr. Carl Christensen.

DI testified about his investigation-related actions, including his roles in executing search warrants at Respondent's property and in interviewing Respondent and Respondent's employees. Tr. 34–114, 1811–23; *see also* R.D., at 5–9. Having read and analyzed all of the record evidence, I agree with the R.D. that DI ''presented as an objective, rational, careful regulator who was not prone to exaggeration or hyperbole.'' R.D., at 9. I also agree that DI's testimony is ''sufficiently detailed, plausible, and internally consistent'' to be given full credibility. *Id.*

MANTIS Det testified about the investigative work that MANTIS did regarding Respondent, including search warrants and U/C visits. Tr. 117–29, 134–60; *see also* R.D., at 9–11. He testified as the drafter of the search warrant for one of Respondent's offices

and the supervisor of the execution of that search warrant. He also testified that he drafted and served a search warrant on a bank regarding Respondent's financial records. Having read and analyzed all of the record evidence, I agree with the R.D. that MANTIS Det ''presented as an objective, rational, careful law enforcement officer'' and that his testimony deserves ''full credibility.'' R.D., at 11.

U/C testified about his role in the investigation of Respondent and his role-related training and experience. Tr. 164–246, 247–311, 884–90; *see also* R.D., at 11–25. U/C's interactions with Respondent and Respondent's medical practice are recorded in videos and transcriptions of those videos. GX 9 (Transcript of U/C Visits from January 5, 2016 through May 17, 2016 (hereinafter, U/C Visits Transcript)); *see also* GX 8 (U/C patient file).

Monroe Det testified about the scope of the search warrant executed at Respondent's office and home, iPatientCare, and his role in the investigation.[5] Tr. 895–914; *see also* R.D., at 25–26. Having read and analyzed all of the record evidence, I agree with the R.D. that Monroe Det ''presented as an impartial law enforcement officer and provided testimony that was sufficiently plausible, detailed, and internally consistent to be afforded full credibility.'' R.D., at 26.

The Government's expert, Dr. Carl Christensen, is a physician licensed and practicing in Michigan. GX 18 (Curriculum Vitae of Dr. Carl Christensen, M.D., Ph.D.). He is Board certified in Addiction Medicine, holds doctorates in Medicine and Biochemistry, and is registered with the DEA and the State of Michigan to handle controlled substances.[6] *Id.;* Tr. 314–15. The Chief ALJ accepted Dr. Christensen as an expert in the treatment of pain and in the standard of care for controlled substance prescribing in the State of Michigan. Tr. 325–26. The matters about which Dr. Christensen testified included his review and standard-of-care analysis of medical records belonging to six of Respondent's patients, including U/C. *E.g., id.* at 326–44, 363–464, 466–533, 536–90, 594–95, 603–38, 645–809, 816–69, 871–80, 1789–1810; *see also* R.D., at 26–54. Having read and analyzed all of the record evidence, I agree with the R.D. that Dr. Christensen, ''[o]verall, . . . presented persuasive testimony regarding the standard of care applicable to controlled substance prescribers in Michigan.'' R.D., at 53. I also agree that Dr. Christensen is a ''well-credentialed, thoughtful, candid expert witness who presented the most persuasive expert testimony received at the hearing.'' [7] *Id.* at 54.

Respondent's Case

Respondent testified and called five witnesses: A medical assistant (hereinafter, MA), who worked for him; a lab technician (hereinafter, LT), who worked at Respondent's practice; a Licensed Practical Nurse (hereinafter, LPN), who worked for Respondent and has known him since 1992; the Office Manager (hereinafter, OM) for Respondent's practice since about 2010 who, prior to working for him, was one of his patients; and his expert, Dr. Lynn Webster, an anesthesiologist board certified in Anesthesia, Pain Medicine, and Addiction Medicine.

Respondent testified over the course of several days.[8] The topics addressed in his direct testimony included: His background, education, and accomplishments (*e.g.,* Tr. 924–37, 941, 942–43); the administration and staffing of his medical practice (*e.g., id.* at 942–50, 1292–95, 1392–1418, 1472, 1477–86); policies, procedures, and practices concerning new and existing patients (*e.g., id.* at 936–41, 1393, 1414–69); diversion-related issues (*e.g., id.* at 1398–1400, 1433–36); his practice's medical records (*e.g., id.* at 1404–13, 1494); search warrant execution (*e.g., id.* at 1472–76, 1498–99); the unlawful possession of controlled substances allegation (*e.g., id.* at 1486–94); the recordkeeping allegations (*e.g., id.* at 1494–99); the TIRF REMS [9] Program, including Subsys prescriptions and presentations (*e.g., id.* at 1499–1522); and his treatment of specific patients (*e.g., id.* at 1529–48 (RB), 1556–87 (DA), 1587–1610 (RF), 1611–28 (ES), 1628–44 (JH), 1644–94 (U/C).[10] *See also* R.D., at 84–106.

Having read and analyzed all of the record evidence, I agree with the R.D. that Respondent is the witness with the most at stake in these proceedings and that his testimony and interview statements are marked by numerous implausibilities and internal inconsistencies. *Id.* at 104–06. Before issuance of the OSC, for example, Respondent told law enforcement officers that all documents, including Michigan Automated Prescription System (hereinafter, MAPS) reports, are ''definitely'' scanned into iPatientCare. GX 24, at 10. During the hearing though, Respondent variously testified that (1) his policy is to put the first visit's MAPS report into the medical record, ''but I don't always put them in after that;'' (2) there is no rhyme or reason for why he would or would not put MAPS reports into the medical record; and, (3) if he sees something ''abnormal'' on a MAPS report, he would put it into the medical record as ''standard practice . . . the vast majority of the time.'' Tr. 1442. The differences between Respondent's

[5] Respondent uses iPatientCare for his office's electronic medical records.

[6] Dr. Christensen is the Medical Director at the Substance Abuse Treatment Center at Wayne State School of Medicine (Detroit, Michigan), the Medical Director of Dawn Farm Treatment Center (Ann Arbor, Michigan), the Medical Director at the Michigan Health Professional Recovery Program, and a Clinical Associate Professor in Psychiatry and OB/GYN at Wayne State School of Medicine. Tr. 315.

[7] The R.D. states that the ''utility'' of Dr. Christensen's testimony, as opposed to its credibility, is diminished for a few reasons. R.D., at 53. First, the ''principal issue of hesitation regarding Dr. Christensen's testimony . . . [is] teasing out those portions of his opinions motivated, not by state practice standards, but rather by his own views related to best practices.'' *Id.* at 54. Given the expert testimony in the record, all of the evidence that the parties put in the record concerning the standard of care in Michigan, and the care that counsel took to focus their questioning and argument on Michigan's standard of care, I am confident that this proceeding's record is sufficient for me to make a decision on the OSC's standard of care-related allegations, including OSC paragraph 4(b)(3) and 4(d)(3).

Second, Dr. Christensen is a BCBS consultant and BCBS, as the R.D. notes, is ''motivated, at least in part, by cost concerns related to healthcare fraud'' and is ''motivated, in no small measure, by interests of cost containment.'' *Id.* at 53–54. Yet, regarding this utility concern, Dr. Christensen testified that he ''initially reviewed files on . . . [U/C for BCBS], and then sometime during that time period, the DEA assumed the case, and after that . . . [his] dealings were all with the DEA.'' Tr. 324. Thus, I do not share this ''utility'' concern.

Third, ''some of Dr. Christensen's testimony addressed treatment matters outside the . . . [Controlled Substances Act's] goal of preventing abuse and diversion.'' *Id.* at 54. This third concern goes to Subsys treatment matters that the R.D. suggests are outside the scope of the statute. I agree to the extent that the record evidence and analysis concerning Subsys and Food and Drug Administration requirements are insufficient to answer legal issues raised by some of the Government's Subsys-related allegations. *See, e.g., Gonzales* v. *Oregon,* 546 U.S. 243, 268 (2006) (''Were this argument accepted, he could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered.''). Thus, those Subsys-related allegations are given no weight and play no role in my public interest assessment or my decisions about the Government's requested relief.

[8] In addition to Respondent's hearing testimony, the record includes transcriptions of parts of two interviews of Respondent that law enforcement conducted. GX 24 and GX 26. GX 24 was offered and admitted without objection. Tr. 37–38. GX 26 was admitted over Respondent's ''context'' objection. *Id.* at 1812–15. I agree with all of the Chief ALJ's pre-hearing and hearing evidentiary rulings and orders.

[9] Transmucosal Immediate Release Fentanyl Risk and Evaluation Mitigation Strategy.

[10] Some testimony fits in more than one category. Respondent also testified on re-direct and the Government's cross-examination.

statements before the OSC was issued and his testimony at the hearing are troubling. For example, the marked change from Respondent's pre-OSC statement (all documents including MAPS reports are ''definitely'' scanned into iPatientCare) to his testimony during the hearing (not all MAPS reports are put in the patient's medical record) does not indicate candor or forthrightness, particularly given Respondent's position that MAPS reports would have helped his case.[11] *See also* R.D., at 104–06. For all of these reasons, I agree with the R.D. that Respondent's testimony must be considered with much caution when his testimony conflicts with credible record evidence. *Id.* at 106.

MA's testimony summarizes the work she did for Respondent. Tr. 1212–64. She corroborated Respondent's testimony that Respondent schedules new patient visits for one hour, patients' second visits for 30 minutes, and ''[a]nything other than that, if they're just coming in for, say, just a refill or they say they're just to refill, it's a five-minute appointment slot.'' [12] *Id.* at 1260. Regarding MAPS, MA stated that ''there should be a MAPS report on every new patient.'' *Id.* at 1242. Having read and analyzed all of the record evidence, I agree with the R.D. that, ''while there was no foundation laid upon her testimony regarding patient volume . . . which could be sufficiently based on actual knowledge to be credited, she did present testimony in other areas that was sufficiently detailed, plausible, and internally consistent to be deemed credible.'' R.D., at 58.

LT testified about the work he did for Respondent's practice. He stated that the method he employed to confirm drug screens was liquid chromatography, mass spectrometry. Tr. 1267. He testified that, according to his manager, every patient sample would be confirmed starting in approximately August 2016. *Id.* at 1273. Based on his experiences visiting an office where Respondent saw patients, LT found an ''unusually high number of patients or people there waiting to see . . . [Respondent].'' *Id.* at 1274. He did not, however, see any illegal activity. *Id.* Having read and analyzed all of the record evidence, I agree with the R.D. that, ''overall, the testimony . . . [LT] presented was sufficiently detailed, plausible, and internally consistent to merit credibility here.'' R.D., at 59.

The topics about which LPN testified included: Appointment scheduling (*e.g.,* Tr. 1301–02, 1330–34, 1336–40); the process of becoming a new patient (*e.g., id.* at 1310–14); tests that Respondent might order for a new patient (*e.g., id.* at 1302–03, 1320–22); a new patient's initial visit with Respondent (*e.g., id.* at 1315–20, 1322–23); and diversion-related issues (*e.g., id.* at 1304–10, 1325–29, 1330). Having read and analyzed all of the record evidence, I agree with the R.D. that LPN and Respondent ''shared a professional relationship spanning two and a half decades, and the testimony . . . [LPN] provided regarding the practices prevalent at . . . [Respondent's office] inextricably reflect on her own level of professionalism, and must be viewed through that prism.'' R.D., at 62. In addition, the meaning of some of LPN's testimony is unclear. I find that lack of clarity, whether due to common semantic vagueness, imprecision by the questioner and the witness, or something else, diminishes the value of LPN's testimony. Nevertheless, areas of LPN's testimony are ''sufficiently detailed, plausible, and internally consistent to be deemed generally credible.'' *Id.*

The subject areas of OM's testimony included: Her work as Respondent's office manager (*e.g.,* Tr. 1342–43, 1344–46, 1382, 1385–86); the genesis of the lab in Respondent's office (*e.g., id.* at 1346–50, 1363–64); office configuration and use for patient visits (*id.* at 1350–51); office policies and employee training (*e.g., id.* at 1352–53, 1359–62, 1367–70); controlled substances in Respondent's office, including a controlled substances inventory (*e.g., id.* at 1355–59, 1379–83, 1386–87); the process of becoming a new patient (*e.g., id.* at 1360–61, 1364–65, 1370–71); diversion-related issues (*e.g., id.* at 1362–63, 1376–79); and a new patient's initial visit with Respondent (*e.g., id.* at 1365–67, 1370, 1387). Having read and analyzed all of the record evidence, I agree with the R.D. that, ''[a]s an employee of the Respondent's and the . . . office manager, . . . [OM] has a significant stake in the outcome of the proceedings.'' R.D., at 65. I also agree that ''inasmuch as the manner in which . . . [Respondent's] office is managed and run perforce reflects on her own level of professionalism, . . . [OM] can hardly be viewed in the same light as an independent evaluator of office procedures.'' *Id.* In addition, portions of OM's testimony are internally inconsistent. *Compare* Tr. 1359 (OM's testimony on direct examination that she has not seen the controlled substances inventory since the execution of the search warrant and that she does not ''know what happened to it''), *with id.* at 1386–87 (OM's testimony on cross-examination that she saw the inventory after execution of the search warrant). Otherwise, I agree with the R.D. that OM's hearing testimony, overall, is ''sufficiently detailed, plausible, and internally consistent to be deemed generally credible.'' R.D., at 65.

Dr. Webster was offered and accepted as Respondent's expert ''in the . . . [subject] of pain medicine and addiction medicine, . . . the prescribing of controlled substances in the State of Michigan, . . . [including] transmucosal Fentanyl, . . . [and] overall for the prescribing of pain medicine in Michigan.'' Tr. 986. Dr. Webster is an anesthesiologist, who is Board certified in anesthesia, pain medicine, and addiction medicine. *Id.* at 966. When he practiced medicine, he was not located in Michigan; he is not and never has been licensed to practice medicine in Michigan. *Id.* at 986–87. Dr. Webster reviewed Respondent Exhibit (hereinafter, RE–) C to form his opinion of the standard of care in Michigan.[13] *Id.* at 987–90. He also reviewed ''a summary of records of the six subjects . . . but not the videotapes'' of the U/C visits.[14] *Id.* at 1121.

[11] At the hearing, the Government moved GX 27 for identification into evidence. I agree with the Chief ALJ's exclusion of the document due to an inadequate foundation. Tr. 1816–23. Further, in connection with the colloquy during this portion of the hearing, I note my disagreement with Respondent's suggestion that law enforcement, during search warrant execution, mishandled Respondent's records thereby impeding Respondent's defense, or that the Government is the reason Respondent does not have access to MAPS reports that ''would've been very helpful in this case to me.'' Tr. 544 (Dr. Christensen's testimony that the history of present illness or the interval history should include information about relevant past treatments or treatment failures or medications); *id.* at 551 (Dr. Christensen's testimony that one medical decision-making area lists all of the patient's diagnoses); *id.* at 157 (MANTIS Det's testimony that Respondent need not use his personal computer to access his patients' medical records on iPatientCare because those records are on the internet, not his personal computer); *id.* at 895, 899–900, 914 (Monroe Det's testimony that he learned from Respondent's staff that patient records are kept in the cloud and that iPatientCare searched for and provided law enforcement with responsive records).

[12] *Accord* Tr. 948–49 (Respondent's testimony); 1301–02 (LPN's testimony regarding new patient visits and second visits); *cf. id.* at 1366 (OM's testimony that new patients' first visits with Respondent last ''a long time, an hour, hour and a half''); *but see id.* at 1302 (LPN's testimony that the normal allocation of time for visits by patients who are stable is ten to 15 minutes).

[13] RE–C is the Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain (hereinafter, Michigan Guidelines).

[14] *See* R.D., at 83 (''The (presumably tactical) decision to avoid reviewing the video footage of . . . [the U/C visits], when viewed in context with the balance of his testimony[,] strikes as a technique to avoid explaining events and dynamics that may not lend themselves to defensible explanations.''). I agree.

Dr. Webster repeatedly answered questions about the applicable standard of care by referencing what doctors actually do instead of referencing the actual provisions of the standard of care. For example, when asked about the standard of care in Michigan regarding a pain patient's first visit and ordering a MAPS report, Dr. Webster stated that ''there is no standard . . . [b]ecause, actually, today there's recent publications that show that only now, after a lot of education and recommendations, about 50 percent of physicians order them because they're afraid.'' [15] *Id.* at 1006. By way of an additional example, when asked whether prescribing a benzodiazepine, such as Xanax, along with an opioid is a ''departure from the standard of care,'' Dr. Webster answered that it is not, again referencing what doctors actually do, while opining that the practice is unsafe and should be avoided: ''Unfortunately, it's common. . . . There's still about 30 percent of the people who are taking opioids have a Benzodiazepine onboard, but it's unsafe . . . [because] the dose at which an opioid can cause respiratory depression is much lower if a Benzodiazepine is onboard.'' *Id.* at 1080–81. By way of a further example, when asked if the standard of care requires a doctor to have a discussion with a patient whose drug screen tests negative for a prescribed controlled substance, Dr. Webster answered, ''[N]o. . . . It's what's done most often.'' *Id.* at 1111. On cross examination, Dr. Webster admitted his view is that ''what is good medicine is a higher standard than what is the standard of care.'' *Id.* at 1163.

According to Dr. Webster, a physician is ''always looking at aberrant behavior.'' *Id.* at 1150. He explained that this is different from ''checking'' for aberrant behavior. *Id.* He stated, ''[I]t's passive. That's passive because it's not an active thing you do. It's passive. It happens.'' *Id.* When asked whether there is a point when such aberrant behavior imposes a duty on a physician to do something, Dr. Webster responded, ''Oh, yes. I think if you *know* that a patient has diverted, you *know* a patient has been injecting intravenously, manipulating their medicines, I think you have to intervene.'' [16] *Id.* at 1151 [emphasis added].

[15] Dr. Webster explained that ''doctors are afraid of having data in their chart that could be used against them.'' Tr. 1007.

[16] When asked, ''And when you say you know the patient's been injecting, what do you—can you describe how that happens in patients,'' Dr. Webster responded, ''Yeah. They take their Percocet and grind it up, put it in a solution and inject it in their vein.'' Tr. 1151–52.

Having read and analyzed all of the record evidence, I agree with the R.D. that Dr. Webster's testimony is ''punctuated with the variety of vagueness and equivocation that presented the unmistakable appearance of an expert unwilling to draw any standard, for fear of conflicting with anything the Respondent may have done or not done in his prescribing.'' R.D., at 83. I also agree with the R.D. that, ''to the extent that . . . [Dr. Webster] actually believed that a prescriber-registrant had even the slightest duty to minimize diversion, that conviction could not be discerned from even the closest reading of his testimony.'' *Id.* When Dr. Webster's testimony conflicts with other persuasive expert testimony, I do not credit Dr. Webster's testimony. *Id.* at 84; *see also id.* at 65–84.

Michigan Physicians' Standard of Care

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

The OSC is addressed to Respondent at his registered locations and medical practice in Michigan. Therefore, I also evaluate Respondent's actions according to Michigan's laws and standard of care.[17] The State of Michigan, similar to the CSA, requires that a ''practitioner . . . shall not dispense, prescribe, or administer a controlled substance for other than legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice of the practitioner.'' Mich. Comp. Laws § 333.7401(1) (Westlaw, current through P.A. 2019, No. 18 of the 2019 Regular Session, 100th Legislature). Respondent offered into evidence the Michigan Guidelines, RE–C, and the Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain that was adopted as policy by the House of Delegates of the Federation of State Medical Boards in July 2013 (hereinafter, FSMB Model Policy), RE–D. Both documents were admitted into evidence without objection. Respondent used these documents to present his case, including during examination and cross-examination of his and the Government's expert witness. I find that the provisions of the Michigan Guidelines and the FSMB Model Policy are consistent with each other.

[17] *See Gonzales* v. *Oregon, supra,* 546 U.S. at 269–71.

The intent of the Michigan Guidelines is to ''communicate what the Boards [of Medicine and Osteopathic Medicine & Surgery (hereinafter, Boards)] consider to be within the boundaries of professional practice.'' Michigan Guidelines, at 2. According to Section I of the Michigan Guidelines, the Preamble, the ''medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities.'' *Id.* at 1. The Preamble also states, ''Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain.'' *Id.* It further states, ''Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.'' *Id.*

The Preamble specifically addresses prescribing and dispensing standards, indicating that the Boards will consider prescribing and dispensing to be ''for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds.'' *Id.* at 2. According to the Preamble, ''All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.'' *Id.* The Preamble advises that the Boards will evaluate prescribing for pain ''on an individual basis'' and ''will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation.'' *Id.* Instead, according to the Preamble, the physician's conduct ''will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.'' *Id.* The stated goal is to ''control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors'' and, thus, the Boards ''will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation,

rather than on the quantity and chronicity of prescribing.'' *Id.*

Section II of the Michigan Guidelines, the ''Guidelines,'' is used to ''evaluat[e] the use of controlled substances for pain control.'' *Id.* at 3. First, the Guidelines state that a ''complete medical history and physical examination must be conducted and documented in the medical record.'' *Id.* The Guidelines specifically address the Boards' expectations regarding documentation.

> The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id.

Second, the Guidelines address the content of the written treatment plan, stating that it ''should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* This section states that ''[a]fter treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient.'' *Id.*

Third, the next section of the Guidelines addresses informed consent and agreement for treatment. It states, ''The physician should discuss the risks and benefits of the use of controlled substances with the patient. . . . The patient should receive prescriptions from one physician and one pharmacy where possible.'' *Id.* This section suggests that the physician may use a written agreement between the physician and the patient ''[i]f the patient is determined to be at high risk for medication abuse or have a history of substance abuse.'' *Id.* According to the Guidelines, the written agreement's patient responsibilities include ''urine/serum medication levels screening when requested; number and frequency of all prescription refills; and, reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement).'' *Id.*

Fourth, the Guidelines state that the physician, ''[a]t reasonable intervals based on the individual circumstances of the patient, . . . should review the course of treatment and any new information about the etiology of the pain.'' *Id.* at 4. This ''Periodic Review'' section of the Guidelines states that ''[c]ontinuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, *i.e.,* ability to work, . . . activities of daily living and quality of social life.'' *Id.* It also states that ''the physician should reevaluate the appropriateness of continued treatment . . . [i]f treatment goals are not being achieved . . . despite medication adjustments.'' *Id.* The ''Periodic Review'' section also states, ''The physician should monitor patient compliance in medication usage and related treatment plans.'' *Id.*

Fifth, the Guidelines state, ''The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.* This ''Consultation'' section also states, ''Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose[s] a risk for medication misuse or diversion.'' *Id.* Here, the Guidelines specifically warn, ''The management of pain in patients with a history of substance abuse . . . may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.'' [18] *Id.*

Sixth, the next section of the Guidelines concerns medical records and states, ''The physician should keep accurate and complete records to include the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and, periodic reviews.'' *Id.* This section also states that these medical records ''should remain current and be maintained in an accessible manner and readily available for review.'' *Id.*

Seventh, the last section of the Guidelines reminds physicians that they must be licensed in Michigan to prescribe or dispense controlled substances, and that they must comply with applicable Federal and State regulations. *Id.* at 5. This section refers physicians to the ''Physicians Manual of the U.S. Drug Enforcement Administration and . . . any relevant documents issued by the state medical board . . . for specific rules governing controlled substances as well as applicable state regulations.'' *Id.*

The stated goal of the FSMB Model Policy is to ''provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations.'' FSMB Model Policy, at 3. It ''emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate.'' *Id.* at 1. It states that ''adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically'' and that ''[p]hysicians and other health care professionals have contributed—often inadvertently—to these increases.'' *Id.* at 2 (reference omitted). Regarding ''the criminal patient, whose primary purpose is to obtain drugs for resale,'' the FSMB Model Policy advises that, ''[p]hysicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities.'' *Id.* at 3 (references omitted). The FSMB Model Policy ''highly'' recommends ''consulting the state's PDMP before prescribing opioids for pain and during ongoing use.'' *Id.* at 10.

The FSMB Model Policy ''makes it clear'' that ''inappropriate management of pain . . . [is] a departure from accepted best clinical practices.'' *Id.* at 3. It discusses six ways that pain is not managed appropriately. First, there is inadequate attention to an initial assessment to determine if opioids are clinically indicated and to determine the risks associated with their use in a particular patient. *Id.* Second, monitoring during the use of potentially abusable medications is inadequate. *Id.* Third, education for the patient about the risks of opioid therapy and the patient's informed consent to opioid therapy are inadequate. *Id.* at 4. Fourth, unjustified dose escalation without adequate attention to risks, such as concurrent alcohol use, or to alternative treatment is a departure from accepted best clinical practices. *Id.* Fifth, relying excessively on opioids, particularly high dose opioids for chronic pain management, and continuing opioid therapy that does not meet clear and objective outcomes are departures from

[18] ''Substance abuse,'' according to the Michigan Guidelines, is ''the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.'' Michigan Guidelines, at 6.

accepted best clinical practices. *Id.* Sixth, not using available risk mitigation tools, such as the state PDMP, in advance of prescribing opioids and during ongoing monitoring is a departure from accepted best clinical practices. *Id.*

The Preamble of the FSMB Model Policy defines ''inappropriate treatment of pain'' to include non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments. *Id.* at 5. The use of opioids for pain management is considered to be for a legitimate medical purpose when the use is based on sound clinical judgment and current best clinical practices, is appropriately documented, and demonstrably benefits the patient. *Id.* The use of opioid therapy for pain management is within the usual course of professional practice when a legitimate physician-patient relationship exists, the use is appropriate for the identified diagnosis, there is careful follow-up monitoring of the patient's response to treatment and the patient's safe use of the medication, the opioid therapy is adjusted when needed, and appropriate referrals are documented. *Id.* Physicians are expected to incorporate safeguards into their practices to minimize the risk of misuse and diversion of controlled substances. *Id.* at 6.

The goal of a physician treating a patient in pain is to manage the pain while effectively addressing the patient's functioning and mitigating the risk of misuse, abuse, diversion, and overdose. *Id.* The validity of the physician's treatment is judged on the basis of available documentation, not solely on the quantity and duration of medication administered. *Id.*

The FSMB Model Policy Guidelines include criteria for evaluating a physician's management of a patient's pain. The physician ''must understand the relevant pharmacologic and clinical issues in the use of . . . [opioid] analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use'' for the patient.[19] *Id.* The patient's medical record ''should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation.'' *Id.* (references omitted). The assessment of the patient's pain typically includes ''the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning.'' *Id.* at 7 (reference omitted). For every patient, ''the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated.'' *Id.* (references omitted).

According to the FSMB Model Policy, ''Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics.''[20] *Id.* (references omitted). The reasons for these criteria include that ''[p]atients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy.'' *Id.* (references omitted). Further, patients with an ''active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional.'' *Id.* (reference omitted). Here, again, the FSMB Model Policy states that the state PDMP ''should be consulted to determine whether the patient is receiving prescriptions from any other physicians'' and that the PDMP results ''should be documented in the patient record.'' *Id.* at 7–8 (reference omitted).

The FSMB Model Policy states that opioid therapy ''should be presented to the patient as a therapeutic trial or test for a defined period,'' during which ''progress will be carefully monitored for both benefit and harm.'' *Id.* at 9 (reference omitted). Monitoring ''should'' continue at each visit ''by assessing what have been called the '5As' of chronic pain management.''[21] *Id.* (references omitted). The continuation, modification, or termination of opioid therapy ''should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion.'' *Id.* at 9–10 (references omitted).

The FSMB Model Policy suggests that ''[p]eriodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs.'' *Id.* at 10 (references omitted). According to the FSMB Model Policy, ''[t]est results that suggest opioid misuse should be discussed with the patient . . . [and b]oth the test results and subsequent discussion with the patient should be documented in the medical record.''[22] *Id.* (reference omitted). When drug tests show the presence of illicit or unprescribed drugs, prescriber action is required. *Id.* at 11. If the patient does not receive a benefit, including demonstrated functional improvement, from opioid therapy, the treatment ''should not continue.'' *Id.* at 12.

The FSMB Model Policy emphasizes that ''the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases.'' *Id.* at 2 (references omitted). Yet, ''[i]nappropriate treatment . . . can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects.'' *Id.* at 3.

The FSMB Model Policy states, ''Every physician who treats patients for chronic pain must maintain accurate and complete medical records.'' *Id.* at 12. It provides a list of ''[i]nformation that should appear in the medical record.''[23] *Id.* (references omitted). Most

[19] ''The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function.'' FSMB Model Policy, at 8 (references omitted).

[20] ''This can be done through a careful clinical interview . . . . Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers. '' FSMB Model Policy, at 7 (references omitted).

[21] ''[T]hese involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect).'' FSMB Model Policy, at 9 (references omitted).

[22] According to the FSMB Model Policy, ''Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion.'' FSMB Model Policy, at 10.

[23] The FSMB Model Policy list of information that should appear in the medical record includes: (1) Copies of the signed informed consent and treatment agreement; (2) the patient's medical history; (3) results of the physical examination and all laboratory tests; (4) results of the risk assessment, including results of any screening

Continued

notably, the list includes ''[a]ny other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors.'' *Id.* (references omitted). According to the FSMB Model Policy, ''[r]ecords should be up-to-date and maintained in an accessible manner so as to be readily available for review.'' *Id.* (reference omitted). The FSMB Model Policy states that, ''Good records demonstrate that a service was provided . . . [and] establish that the service provided was medically necessary. . . . [T]horough records protect the physician as well as the patient.'' *Id.* (references omitted).

Having read and analyzed all of the record evidence, I find that Dr. Christensen's testimony concerning a Michigan physician's standard of care when prescribing controlled substances accurately applies the Michigan Guidelines.[24] As already discussed, the credit I afford the testimony of Dr. Webster and Respondent is limited. As such, I afford Dr. Christensen's Michigan standard of care-related testimony controlling weight in this proceeding.

Allegation That Respondent Lacks the Requisite State Authority To Hold a DEA Certificate of Registration

On August 3, 2017, the Michigan Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing (hereinafter, MBPL) summarily suspended Respondent's Michigan license to practice medicine based on a finding that the public health, safety, or welfare required emergency action.[25] Notice (Attachment A, Michigan Department of Licensing and Regulatory Affairs Bureau of Professional Licensing Board of Medicine Disciplinary Subcommittee Order of Summary Suspension), at 1. The MBPL further determined that, pursuant to Michigan law, Respondent's Michigan controlled substance license is ''automatically void'' because his license to practice medicine is suspended. *Id.* (citing Mich. Comp. Laws § 333.7311(6) (Westlaw, current through P.A. 2019, No. 18 of the 2019 Regular Session, 100th Legislature)). Respondent entered into a Joint Stipulation with the Government in which he stipulated to the summary suspension of his medical license effective August 4, 2017. ALJX 30, at 1.

According to the MBPL Administrative Complaint issued the same day as the summary suspension, Respondent ''ranked among Michigan's highest-volume prescribers of commonly abused and diverted controlled substances in 2015 and during the first three quarters of 2016.'' Notice (Attachment A, Administrative Complaint), at 3 (citing MAPS data). The Administrative Complaint alleges that, based on MAPS data for the same time period, Respondent prescribed about 26% of all hydrocodone combination products, about 19% of all oxycodone combination products, and about 65% of all strengths of hydrocodone combination products, oxycodone combination products, buprenorphine/naloxone, and methadone. *Id.* On average, according to the Administrative Complaint, Respondent authorized more than 89 controlled substance prescriptions for every workday between January 1, 2015 and September 30, 2016. *Id.*

The Administrative Complaint further alleges that the investigation of Respondent, including the analysis of the medical records of ten of Respondent's patients, ''discovered . . . deficiencies consistently across files.'' *Id.* at 4. The identified deficiencies included: ''Unnecessarily voluminous'' patient files due to ''cut-and-pasted segments repeated from note to note;'' ''poorly organized and frequently unintelligible'' patient notes; descriptions of the patient's pain problem that were not ''adequate to permit informed prescription decision-making;'' the use of the word ''guarded'' for each patient's prognosis, ''which suggests Respondent made no actual consideration of individual patient prognosis;'' negative symptoms usually noted for the musculoskeletal element of the review of systems, despite the fact that each patient was apparently seen for a chronic pain diagnosis; ''failure to document consideration of alternative treatments to opioid prescribing, except for pain blocks Respondent himself performed and for which he billed;'' no ''treatment records from previous physicians . . . [or] documentation of any contact with other health care providers (except for imaging study reports);'' no patient narcotic agreements; multiple dates of service with ''no clinical information at all;'' no ''document[ed] responses to evidence of abuse or diversion of controlled substances;'' the prescribing of high addiction-potential controlled substances without documenting that Respondent ''ask[ed] patients if they exhausted their previously prescribed supply;'' and, the routine prescribing of ''high opioid dosages, consistently exceeding 50 MMEs, and in some cases exceeding 100 MMEs, without adequate explanation for the high level of narcotic dosage.'' [26] *Id.* at 4–5. The MBPL expert also noted that Respondent's patient files, while ''occasionally stating that MAPS records were reviewed, . . . often do not contain any MAPS reports.'' *Id.* at 5. The Administrative Complaint also includes more than three pages listing the deficiencies the expert discovered in the individual medical files Respondent produced. *Id.* at 5–9.

Further, according to Michigan's online records, of which I take official notice, Respondent's medical license is currently ''Lapsed—Suspended.'' [27] Michigan Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, Bureau of Community and Health Systems website, *https://www.michigan.gov/lara* (last visited September 25, 2019). As such, I find that Respondent is still not authorized to practice medicine in Michigan.

Accordingly, I find that Respondent currently is without authority to engage in the practice of medicine or to handle controlled substances in Michigan, the State in which he is registered.

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

Having read and analyzed all of the record evidence, I agree with the R.D.'s conclusion and find that the record contains substantial evidence that Respondent prescribed controlled substances outside of the usual course

instruments used; (5) a description of the treatments provided; (6) instructions to the patient, including discussions of risks and benefits; (7) results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement; and, (8) notes on evaluations by, and consultations with, specialists. *Id.* at 12.

[24] Further, I find that Dr. Christensen's testimony is also consistent with the provisions of the FSMB Model Policy.

[25] The MBPL emergency summary suspension was effective the next day, August 4, 2017, upon service of the Summary Suspension Order on Respondent. Notice, at 1; ALJX 30, at 1.

[26] MME means morphine milligram equivalent.

[27] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a motion, the Government shall have 15 calendar days to file a response.

of the professional practice in Michigan. R.D., at 124. Respondent did not follow up on MAPS reports indicating an abnormality. *See, e.g.,* Tr. 417–18, 535–38; Michigan Guidelines, at 1; FSMB Model Policy, at 1, 3, 6, 10. Despite his noting a diagnosis of ''opiate dependence continuous,'' Respondent failed to document in the patient's medical records either a referral or an evaluation for an addictive disorder, as the standard of care mandates. *See, e.g.,* Tr. 418–21, 424–25; Michigan Guidelines, at 4; FSMB Model Policy, at 7. When Respondent switched a patient's diagnosis from ''opiate dependence continuous'' to ''long-term use'' of medications, and when he changed a controlled substance prescription he issued to a patient, Respondent did not document his decision making or any of the reasons for the change, as called for by the applicable standard of care. *See, e.g.,* Tr. 427–28, 443–44, 478–79; Michigan Guidelines, at 2, 4; FSMB Model Policy, at 6. After receiving the results of abnormal urine drug tests, Respondent did not document any discussion of those results with the patient, as the applicable standard of care mandates. *See, e.g.,* Tr. 429, 452–53, 458–61, 480–81, 482–83, 488–89, 498–99, 515–16; Michigan Guidelines, at 1–4; FSMB Model Policy, at 1, 6, 9–12. Despite abnormal urine drug tests, Respondent re-issued controlled substance prescriptions without sufficiently documenting that he had appropriately addressed the abnormalities. *See, e.g.,* Tr. 444, 447–50, 459, 469–72, 477, 488–89, 490–92, 515–16, 582–84; Michigan Guidelines, at 1, 3, 4; FSMB Model Policy, at 1, 6, 9–11.

Further, despite the appearance in a patient's urine drug test of controlled substances that Respondent had not prescribed, or illegal substances, Respondent continued to issue controlled substance prescriptions and did not put adequate documentation of his decision making in the medical records. *See, e.g.,* Tr. 463–64, 467, 561–70; Michigan Guidelines, at 1–2, 4; FSMB Model Policy, at 1, 6–7, 9–11; *see also* Tr. 494–95, 572–76, 590. Respondent prescribed an ultra-rapid schedule II controlled substance to a patient for whom he had not prescribed sufficient long-acting medication to control the patient's baseline pain. *See, e.g.,* Tr. 430–33, 443, 445; Michigan Guidelines, at 1–4; FSMB Model Policy, at 4–6. Respondent issued a prescription for double the strength of an ultra-rapid schedule II medication without documenting the change or decision making. *See, e.g.,* Tr. 446; Michigan Guidelines, at 2–4; FSMB Model Policy, at 5–6. Respondent's prescribing violated the standard of care relating to patient safety. *See, e.g.,* Tr. 446, 521–31, 578–80, 587; Michigan Guidelines, at 1, 3–4; FSMB Model Policy, at 5, 9–12. Respondent re-prescribed the same controlled substance prescriptions to a patient even though the controlled substances lacked efficacy as evidenced by the patient's complaint of uncontrolled pain. *See, e.g.,* Tr. 438, 439, 443, 445; Michigan Guidelines, at 1, 3–4; FSMB Model Policy, at 5–6, 9–12; *see also* Tr. 366–67.

While the record includes statements from Respondent and his staff about the protocols Respondent purportedly follows to ensure that the issuance of a controlled substance prescription is warranted, the record evidence, most vividly the video-related evidence, shows Respondent acting contrary to the so-called protocols and authorizing unwarranted controlled substance prescriptions. For example, U/C repeatedly states he feels ''stiff'' or has ''stiffness'' when Respondent and his staff ask him about being in ''pain.'' U/C Visits Transcript, at 19–22, 23–25. Regardless, Respondent issues controlled substance prescriptions to U/C that are not justified by test results or by U/C's symptoms.[28] *Id.* at 25 (''You know you gotta get your testing done and all that. Your urine drug screen.''); *see also id.* at 48–49; Tr. 370.

The U/C visits also document that Respondent authorized the issuance of controlled substance prescriptions to U/C without appropriately addressing abnormal drug screens. U/C Visits Transcript, at 64–65 (authorizing prescriptions for Norco (schedule II) and Lyrica (schedule V) without addressing the abnormal drug screen from the prior visit). At a subsequent visit, Respondent authorized the same two controlled substance prescriptions for U/C after verbally noting an abnormal drug screen but not implementing the follow-up mandated by the applicable standard of care. *Id.* at 77–80 (''Hold on one second. Um, no hydrocodone. That's a problem. Ok. We're gonna have to see him . . . in one week.''). According to Dr. Christensen's testimony about meeting the standard of care in Michigan, ''an abnormal urine drug screen should be addressed immediately, either with referral or evaluation, and definitely starting off with an interview.'' Tr. 402. Dr. Christensen's opinion is that Respondent's above-quoted statements do not meet the interview requirement of the Michigan standard of care. *Id.*

> Since there are alternate explanations for an abnormal drug screen the initial evaluation should include asking the patient . . . how are you taking it, are you taking it, are you taking too little, too much, and then going from that point on. . . . I would include either referral or evaluation, depending on who the prescriber was. And this appears almost certainly to be a drug screen. So if you have a negative result for a prescribed drug, you should also send out for confirmation. I wasn't able to find any confirmation for that date. And then the patient should be asked to return at an early date for another visit, which was done.

Id. at 402–03.

Further, Respondent authorized controlled substance prescriptions for U/C without addressing any of U/C's statements about his use of alcohol. U/C Visits Transcript, at 12, 18, 22, 43, 63, 93. Dr. Christensen, addressing the standard of care for prescribing controlled substances, explained that alcohol use indicates a possible addictive or substance-use disorder and, when mixed with an opioid, could result in death.

> [Alcohol use is] one of the indications of possible addictive disorder or substance use disorder. And if you're evaluating a patient for pain, you need to take that into account if you're attempting to make a legitimate diagnosis or write a legitimate prescription. And if you decide that it's a legitimate prescription, it is extremely dangerous to mix alcohol and opioids. . . . Because both of them act upon the brain's respiratory center, and when they are combined together, they are worse than either one alone. It's called a super-additive effect, and the patient is more likely to have respiratory arrests, overdose, and death.

Tr. 369.

While it is clear that Respondent noticed U/C's drug-seeking behavior, it is also clear that Respondent failed to address that behavior as the applicable standard of care requires. *Id.* at 385–87.[29] Instead, Respondent reacted by

[28] According to Dr. Christensen's testimony about the standard of care for prescribing controlled substances:

> Stiffness is not the same complaint as pain. Stiffness can be either due to muscle contractions, to a joint disorder, to deconditioning, to an underlying immune disorder. But it is not a complaint of pain. It is not an indication for opioids. . . . [A] non-pharmacologic treatment would initially be physical therapy, hydrotherapy, exercise programs, psychological programs, mindfulness programs. And pharmacologic treatment typically includes Tylenol, which is acetaminophen, non-steroidals. And if there is a flare, if somebody is having an usually [sic] difficult time, you can add for a short period of time what we call a muscle relaxer, which is a centrally acting, sedating medication that typically works for about a week.

Tr. 367, 370.

[29] According to Dr. Christensen:

> Requesting opiates without a confirmed diagnosis is concerning, and requesting opiates by name is also concerning . . . [because it is] consistent with

Continued

telling U/C, ''You look like an undercover agent to me right now'' and asking him, ''Are you trying to trap me? All right now, we've been through this with the cops.'' U/C Visits Transcript, at 25.[30] The facts encapsulate the breadth of Respondent's departure from the applicable standard of care: Respondent undoubtedly identified U/C's drug-seeking behavior; responded immediately and solely out of his self-interest to protect himself from law enforcement detection; ignored the standard of care ramifications of the drug-seeking behavior; and, ultimately issued controlled substance prescriptions to U/C.

In sum, based on all of the evidence in the record, I find substantial evidence that Respondent prescribed controlled substances outside of the usual course of the professional practice in Michigan.

Allegation That Respondent Unlawfully Possessed Controlled Substances

Respondent admits that he stored controlled substances previously prescribed to patients and controlled substance samples in his office at North Macomb Street and his residence. Tr. 1486–87, 1490–91, 1719–28. There is no evidence in the record that Respondent is registered as a reverse distributor or is authorized in any way to possess these controlled substances. Thus, I agree with the R.D. and find that the record contains uncontradicted evidence that Respondent possessed large quantities of controlled substances in his office at North Macomb Street and his residence without the authority to do so. R.D., at 117.

Recordkeeping Allegations

According to Respondent's testimony, he maintained at his Stewart Road office, and still possesses, an inventory of controlled substances that he ''can introduce . . . any time that you wish.'' Tr. 1732; *see also* Tr. 1729–32. I do not credit Respondent's testimony due to the fact that he did not offer any inventory into evidence at any time during the proceeding. *See also* R.D., at 105 (''In view of the level of professional exposure attendant upon the potential loss of his DEA registration, the Respondent's account that exculpatory inventories and logs laid motionless in his office while proceedings were initiated and conducted is simply not believable.''). Also according to Respondent's own testimony, he transferred controlled substances between his two offices and did not document the transfers. Tr. 1733. Thus, I agree with the R.D. and find that there is substantial evidence in the record that Respondent did not maintain the required inventory of controlled substances and did not record his transfer of controlled substances. R.D., at 117–18.

Discussion

Allegation That Respondent Lacks the Requisite State Authority To Hold a DEA Certificate of Registration

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. *See, e.g., Hooper, supra,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Blanton, supra,* 43 FR at 27,617.

According to the Michigan statute concerning controlled substances, ''A license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance is automatically void if the licensee's license to practice is suspended or revoked under article 15.'' [31] Mich. Comp. Laws § 333.7311(6) (Westlaw, current through P.A. 2019, No. 18 of the 2019 Regular Session, 100th Legislature).

The evidence in the record before me is not in dispute. The Additional Stipulation consists of Respondent's admission that his medical license was summarily suspended on August 4, 2017 and, as already discussed, that summary suspension is still in effect. ALJX 30, at 1. Respondent's controlled substance registration is void under Michigan law since his medical license is suspended. Mich. Comp. Laws § 333.7311(6) (Westlaw, current through P.A. 2019, No. 18 of the 2019 Regular Session, 100th Legislature). As such, Respondent currently lacks authority in Michigan to practice medicine and to handle controlled substances. He is not, therefore, eligible for a DEA registration. For this reason, I will order that Respondent's DEA registrations be revoked. At the Government's request, however, I am also ruling on the allegations in the OSC.

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

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title

drug-seeking behavior, and it's a red flag. . . . A red flag is a sign or a piece of information that is indicative of possible abuse or addiction, which would require additional evaluation or referral if you're not an addiction specialist in order to prescribe controlled substances [under the applicable Michigan standard of care]. . . . I did not see [the required evaluation of U/C ever done].'' Tr. 385–87.

[30] Members of Respondent's staff later explained that ''the feds are always on him,'' ''they have to watch him very . . . closely,'' ''the other two doctor's [sic] here in Monroe . . . got busted,'' ''[t]he FDA, the state, the government is on him hot and heavy . . . breathing down his neck,'' and ''[h]e's had undercover agents in here before.'' U/C Visits Transcript, at 26–27.

[31] ''Section 7306'' is Mich. Comp. Laws § 333.7306. ''Article 15'' includes Mich. Comp. Laws. § 333.16233 (Investigations; order to cease and desist; hearing; violation of order; summary suspension of license or registration), the statute MBPL cites for taking emergency action in its Order of Summary Suspension of Respondent's medical license.

inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

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

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

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

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

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness 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 One, Two and Four.[32] I find that the Government's evidence with respect to Factors One, 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. 823(f). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

Factors Two and/or Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances Allegation That Respondent 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, supra,* 546 U.S. at 274.

The Agency recently revoked the registrations of two Michigan practitioners based on charges and fact patterns that are similar to, and alleged to have taken place during the same time period as, the charges and fact patterns in this matter. *Garrett Howard Smith, M.D.,* 83 FR 18,882 (2018); *Bernard Wilberforce Shelton, M.D.,* 83 FR 14,028 (2018).

Respondent engaged a skillful team and defended himself against all of the OSC's allegations. I read and analyzed every aspect of Respondent's defense including all of the evidence he put in the record. Regarding the unlawful prescribing charge, Respondent's evidence and argument are not persuasive.[33]

I disagree with Respondent's characterization of the Government's evidence. For example, Respondent attacks Dr. Christensen's testimony by stating that ''he [Dr. Christensen] himself has prescribed a controlled substance to a patient without seeing that patient'' and that ''it is not a violation of the standard of care to rely on past physical examinations of a patient when making medical decisions.'' Respondent's Closing Argument, Proposed Findings of Fact, and Conclusions of Law dated Oct. 19, 2017 (hereinafter, Resp Brief), at 12. The context of this portion of Dr. Christensen's testimony is missing from Respondent's argument, even though it is essential to understand the expert's testimony. That context is ''a patient who is on stable medication, who has shown no aberrant behavior, and who has a normal prescription search on the day of the prescription, and between 60-day visits.'' Tr. 603.

By way of further example, Respondent asserts that, ''Dr. Christensen provided an evasive answer as to whether a whole record or a partial record would be needed to form an opinion as to a physician's standard of care.'' Resp Brief, at 15; *see also id.* at 21–23. Dr. Christensen's testimony, however, clearly debunks the notion of a whole or partial patient record because ''interval history and history of present illness, if done, would reflect what . . . relevant information or relevant events had occurred before.'' Tr. 681. In other words, Dr. Christensen's expert opinion and explanation of the Michigan standard of care support the common sense conclusion that Respondent may not defeat a charge of violating the applicable standard of care by maintaining inadequate patient records.

Respondent's characterization of some of the Government's evidence is also

[32] I already discussed the unrefuted evidence in the record and found that the MBPL summarily suspended Respondent's Michigan medical license after considering matters similar to those alleged in the OSC. I incorporate that discussion into this section regarding Factor One.

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808 (10th Cir. 2011). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[33] As already discussed, the record evidence and analysis concerning Subsys and Food and Drug Administration requirements are insufficient to answer the legal issues raised by some of the Subsys-related allegations. Thus, those Subsys-related allegations are given no weight and play no role in my public interest assessment or my decisions about the Government's requested relief.

unpersuasive when, for example, he argues that ''if a patient was denied Subsys by the insurance company, it is reasonable to assume the patient did not receive the medication.'' Resp Brief, at 33. The insurance company's refusal to pay for a prescription and the supposedly ''reasonable'' assumption that the patient, therefore, did not receive that medication follow the actions that are legally relevant—Respondent's issuance of controlled substance prescriptions—and the Government's resulting allegation—that Respondent issued controlled substance prescriptions outside the usual course of the professional practice. In other words, the issuance of controlled substance prescriptions outside the usual course of the professional practice of medicine violates the law whether or not the patient fills a prescription or ingests one of the prescribed pills.[34]

Respondent invites me to apply alternative analyses to the OSC's allegations. For example, according to Respondent's expert, it is ''rare'' and ''less likely'' for an older patient, such as RF (80 years old) and ES (79 years old), to abuse or divert a controlled substance or medication. *Id.* at 33, 35. I decline to decide this case based on Dr. Webster's estimated probabilities instead of the applicable standard of care. *See also* FSMB Model Policy, at 3 (''Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults).''). By way of further example, Respondent argues that his patient's views of the ''quality of care they received'' were not obtained. Resp Brief, at 5. Respondent fails, however, to provide a sound legal basis for the relevancy of those views in this proceeding. In addition, Respondent asserts that ''Dr. Christensen testified that there were no 'negative outcomes' that he was aware of with any of the patients he reviewed, other than a possible 'confusion' incident from a patient going through chemotherapy.'' *Id.* at 14. Nowhere, however, does Respondent cite legal authority for his argument that the issuance of controlled substance prescriptions outside the usual course of the professional practice only violates the law when there is a certain ''negative outcome.'' I reject Respondent's argument as meritless.[35]

Respondent suggests that his practice of medicine complies with the standard of care. If Respondent's expert were to be believed that good medicine is a higher standard than the standard of care, Respondent's suggestion could be true. Tr. 1163. As already discussed, however, I credit Dr. Christensen's articulation of the Michigan standard of care and his testimony measuring Respondent's actions against that standard of care. I reject the testimony of Respondent's expert to the extent that it conflicts with Dr. Christensen's testimony or posits an untenable ''standard of care.'' In addition, I note that even the testimony of Respondent's own expert indicates that the expert's practice of medicine differs in some respects from how the evidence shows Respondent practices medicine. *See, e.g., id.* at 1067 (Respondent's expert testifying that he ''would expect more'' medical decision making and ''talk about treatment and why certain treatments are implemented''); *id.* at 1073 (Respondent's expert testifying that ''it's just good practice to explain what you've discussed with the patient and their response'').

Respondent offered into evidence both the Michigan Guidelines and the FSMB Model Policy. He argues, unconvincingly, that he complied with both documents' applicable standards of care and did not commit ''malpractice.'' Resp Brief, at 49. In response to the testimony of the Government's expert that the medical records the Respondent created do not establish that Respondent complied with the applicable standard of care, Respondent blames law enforcement's execution of the search warrant for his incomplete patient records. As already discussed, I reject this argument. Respondent also suggests that the standard of care does not mandate a specific level of detail for recordkeeping. *See, e.g., id.* at 49, 51. Respondent's argument is without merit; I reject it. As the above-cited portions of the Michigan Guidelines and FSMB Model Policy show, the requisite recordkeeping is recordkeeping that complies with the requirements articulated in the standard of care and that supports subsequent reviews of Respondent's actions for compliance with the standard of care. In other words, a physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained patient records.

Thus, I agree with the R.D. that the record in this case establishes by substantial evidence that Respondent violated 21 CFR 1306.04(a). R.D., at 124. As such, I find that the record in this case likewise calls for the revocation of Respondent's registrations and the denial of all pending applications by Respondent for registration in Michigan. R.D., at 121–29.

Allegation That Respondent Unlawfully Possessed Controlled Substances

The CSA requires a ''separate registration . . . at each principal place of business or professional practice where the applicant . . . distributes . . . or dispenses controlled substances.'' 21 U.S.C. 822(e)(1); *see also* 21 CFR 1301.12(a), Clarification of Registration Requirements for Individual Practitioners, 71 FR 69,478 (2006); *Joe W. Morgan, D.O.,* 78 FR 61,961 (2013). The CSA's definition of ''dispense'' explicitly includes the delivery of a controlled substance to an ultimate user and the prescribing of a controlled substance. 21 U.S.C. 802(10). There is no evidence in the record that Respondent is authorized to collect controlled substances from ultimate users and other non-registrants for destruction. 21 CFR 1317.30 and 1317.40.

Michigan law prohibits a person from knowingly or intentionally possessing a controlled substance ''unless the controlled substance . . . was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice.'' Mich. Comp. Laws § 333.7403 (Westlaw, current through P.A. 2019, No. 18 of the 2019 Regular Session, 100th Legislature).

As already discussed, Respondent admits that he stored controlled substances previously prescribed to patients and controlled substance samples at his North Macomb Street office and his residence, which is not a registered location. Thus, I agree with the R.D. that Respondent violated both Federal and Michigan law by possessing controlled substances previously prescribed to patients and controlled substance samples at his North Macomb Street office and his residence. R.D., at 117.

Recordkeeping Allegations

The OSC contains two recordkeeping-related charges. First, citing 21 CFR 1304.11, paragraph 10 of the OSC charges Respondent with failing to maintain an inventory at both of his registered locations. OSC, at 4. The CSA and its implementing regulations require registrants to make a complete and accurate record of all controlled substances on hand according to

[34] This important principle applies to all controlled substance prescribing.

[35] *See, e.g.,* FSMB Model Policy, at 12 (''Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.'').

specified time schedules and to keep those records available for inspection by authorized individuals. *See, e.g.,* 21 U.S.C. 827, 21 CFR 1304.11. Respondent admits that he kept controlled substances at both of his registered locations but that he did not maintain an inventory at his North Macomb Street office. Tr. 1729–30. Thus, Respondent admits to violating the inventory requirement as to his Macomb office.

In addition, as already discussed, although Respondent's testimony is that he maintains and still possesses an inventory of controlled substances for the Stewart Road office that he ''can introduce . . . any time that you wish,'' he did not produce that alleged inventory at any time, including during the hearing. *Id.* at 1732; *see also id.* at 1729–32. As such, in addition to the violation to which Respondent admits concerning his North Macomb Street office, I find another violation of 21 CFR 1304.11 by Respondent concerning his Stewart Road office, where he admitted to having controlled substances. *Id.* at 1490.

Second, paragraph 11 of the OSC charges Respondent with failing to maintain required records for controlled substances, including records for controlled substances that were transferred from one registered location to another. OSC, at 4 (citing 21 CFR 1304.21). As a DEA registrant, Respondent is required to keep records that are complete and accurate. 21 CFR 1304.21. Respondent admits that he transferred controlled substances between his registered locations but that he did not complete the records required to memorialize those transfers. Tr. 1733. As such, I find that Respondent admits to violating 21 CFR 1304.21.

Summary of Factors Two and Four and Imminent Danger

As found above, the Government's case establishes by substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice. There is also substantial evidence that Respondent unlawfully possessed controlled substances and violated the recordkeeping requirements incumbent upon a registrant. I, therefore, conclude that Respondent engaged in egregious misconduct which supports the revocation of his registrations. *See Wesley Pope,* 82 FR 14,944, 14,985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice establishes that there was ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registrations. *Id.; see, e.g.,* Tr. 369 (the opinion of the Government's expert, Dr. Christensen, that mixing alcohol and opioids could result in death); Tr. 1080–81 (the opinion of Respondent's expert, Dr. Webster, that mixing opioids and a benzodiazepine is unsafe).

Sanction

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

Regarding all of these matters, I agree with the analyses and conclusions contained in the R.D.'s Recommendations on Disposition. R.D., at 125–29. I agree with the R.D. that the record is ''devoid of any inclination on the part of the Respondent to accept any level of responsibility'' for his controlled substance prescribing in the face of multiple indications of abuse, danger, or diversion. *See id.* at 126. Concerning his recordkeeping, Respondent steadfastly maintained that he kept the required inventories and that he could produce them. Yet, he never produced those inventories and, instead, blamed the law enforcement officers who executed the search warrant for the fact that his inventories were not among the records they seized. I agree with the analysis in the R.D.

> Even beyond the dubious credibility attached to the notion that he would deliberately sit on inventories requested by DEA at the potential cost of a . . . [registration], and the impenetrable logic involved [in] blaming the agents who executed the search warrant, neither tack embodies an acceptance of responsibility under any reasonable definition.

Id. at 126–27.

Respondent stated during his testimony that he accepted responsibility for unlawfully possessing controlled substances at one of his offices and his residence. As already discussed, this limited acceptance of responsibility is unavailing. Further, even if Respondent had unequivocally accepted responsibility for all his unlawfulness such that I would reach the matter of remedial measures, I note that the remedial measures Respondent presented concerning his unlawful possession of controlled substances are not adequate. When asked what he would do if, in the future, a patient wanted to give him unused controlled substances, Respondent said that ''he 'would have the patient either dispose of it or have them call'" DI. *Id.* at 127 (citation omitted). The Chief ALJ, who observed Respondent's demeanor, concluded that Respondent's ''wry addition of . . . [DI] into the solution was an ill-timed attempt at humor.'' *Id.* I agree with the R.D. that, ''[e]ven if the Respondent's acceptance of responsibility on this issue were deemed sincere, his offer of potential remedial measures . . . [was] unpersuasive'' because he had not identified a reverse distributor and could only testify about ''some unspecified'' way of disposing of the medicine ''with coffee grounds.'' *Id.*

In sum, I find that the record supports the imposition of a sanction because the Respondent did not unequivocally accept responsibility.

The interests of specific and general deterrence ''militate in favor of revocation.'' *Id.* at 128. Respondent has evidenced no understanding that his controlled substance prescribing and recordkeeping fell short of legal requirements. As such, it is not reasonable to believe that Respondent's future prescribing and recordkeeping will comply with legal requirements.

Further, given the nature and number of Respondent's violations, a sanction less than revocation would send a message to the regulated community that compliance with the law is not a condition precedent to maintaining a registration. *Id.* at 128–29.

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

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby revoke DEA Certificates of Registration BP2527058 and FP2665478 issued to Lesly Pompy, M.D. I further hereby deny any pending application of Lesly Pompy, M.D., to renew or modify these registrations, as well as any other pending application of Lesly Pompy, M.D. for registration in Michigan. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and (d), I hereby affirm the Order of Immediate Suspension of Registrations issued to Lesly Pompy, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(f), I hereby order the forfeiture to the United States, upon this revocation order becoming final, of all controlled substances seized pursuant to the Order of Immediate Suspension of Registrations. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(f), I hereby declare that all right, title, and interest in all controlled substances seized pursuant to the Order of Immediate Suspension of Registrations are vested in the United States upon this revocation order becoming final. This Order is effective November 27, 2019.

Dated: September 25, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–23503 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Post-Initial Determinations Regarding Eligiblity To Apply for Trade Adjustment Assistance

In accordance with Sections 223 and 284 (19 U.S.C. 2273 and 2395) of the Trade Act of 1974 (19 U.S.C. 2271, *et seq.*) (''Act''), as amended, the Department of Labor herein presents Notice of Affirmative Determinations Regarding Application for Reconsideration, summaries of Negative Determinations Regarding Applications for Reconsideration, summaries of Revised Certifications of Eligibility, summaries of Revised Determinations (after Affirmative Determination Regarding Application for Reconsideration), summaries of Negative Determinations (after Affirmative Determination Regarding Application for Reconsideration), summaries of Revised Determinations (on remand from the Court of International Trade), and summaries of Negative Determinations (on remand from the Court of International Trade) regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act (''TAA'') for workers by (TA-W) number issued during the period of *September 1st through September 30th 2019.* Post-initial determinations are issued after a petition has been certified or denied. A post-initial determination may revise a certification, or modify or affirm a negative determination.

Notice of Revised Certifications of Eligibility

Revised certifications of eligibility have been issued with respect to cases where affirmative determinations and certificates of eligibility were issued initially, but a minor error was discovered after the certification was issued. The revised certifications are issued pursuant to the Secretary's authority under section 223 of the Act and 29 CFR 90.16. Revised Certifications of Eligibility are final determinations for purposes of judicial review pursuant to section 284 of the Act (19 U.S.C. 2395) and 29 CFR 90.19(a).

Revised Certifications of Eligibility

The following revised certifications of eligibility to apply for TAA have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination, and the reason(s) for the determination.

The following revisions have been issued.

TA-W No.	Subject firm	Location	Impact date	Reason(s)
94,455	IKEA Industry Danville LLC	Ringgold, VA	1/11/2018	Worker Group Clarification.
94,513	R1 RCM Inc	Austin, TX	2/5/2018	Wages Reported Under Different FEIN Number.
94,132	REC Solar Grade Silicon LLC	Moses Lake, WA	10/19/2018	Worker Group Clarification.
94,500	Ferro Corporation	Washington, PA	1/31/2018	Worker Group Clarification.
94,540	Schneider Electric	Peru, IN	6/23/2019	Worker Group Clarification.
94,540A	Pinkerton, JLL, Artech LLC, and Berean Group International, Inc.	Peru, IN	2/13/2018	Worker Group Clarification.
94,185	Catalina Marketing Corporation	St. Petersburg, FL	10/1/2017	Worker Group Clarification.
94,185A	Catalina Marketing Corporation	St. Louis, MO	10/1/2017	Worker Group Clarification.
94,657	Hanesbrands, Inc	Clarksville, AR	3/25/2018	Worker Group Clarification.

I hereby certify that the aforementioned determinations were issued during the period of *September 1st through September 30th 2019.* These determinations are available on the Department's website *https://www.doleta.gov/tradeact/petitioners/taa_search_form.cfm* under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC this 9th day of October 2019.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2019–23457 Filed 10–25–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Trade Adjustment Assistance

In accordance with the Section 223 (19 U.S.C. 2273) of the Trade Act of 1974 (19 U.S.C. 2271, *et seq.*) (''Act''), as amended, the Department of Labor