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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 18-28]
Kaniz F. Khan-Jaffery, M.D.; Decision and Order

I. Procedural History

On April 12, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension Order (hereinafter collectively, OSC) to Kaniz F. Khan-Jaffery, M.D. (hereinafter, Respondent), of Absecon, New Jersey. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of her DEA Certificate of Registration No. BK9710939 pursuant to 21 U.S.C. § 824(d) "because . . . [her] continued registration constitute[d] an imminent danger to the public health and safety." *Id.* The OSC also proposed the revocation of Respondent's Registration pursuant to 21 U.S.C. § 824(a)(4) and the denial of "any pending applications for renewal or modification of such registration, because [her] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." *Id.*

Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances to six individuals outside the usual course of the professional practice and beneath the standard of care for the State of New Jersey in violation of 21 C.F.R. § 1306.04(a) and N.J. Stat. §§ 24:21-15.2 and 45:9-22.19. OSC, at 2-5.

On April 12, 2018, based on his preliminary finding that Respondent issued multiple prescriptions to one individual without a legitimate medical purpose, and to five individuals, while ignoring inconsistent urine screens that indicated abuse or diversion of controlled

substances, 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] would continue to issue prescriptions for controlled substances, which would result in the abuse or diversion of controlled substances." *Id.*

Pursuant to 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), the former Acting Administrator immediately suspended Respondent's Certificate of Registration and 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 registration. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Respondent's Certificate of Registration BK9710939. *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 C.F.R. § 1301.43).

By letter dated May 1, 2018, Respondent timely requested a hearing. ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles W. Dorman (hereinafter, ALJ). On May 3, 2018, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1, 4. The Government filed its Prehearing Statement on May 15, 2018, and Respondent filed its Prehearing Statement on May 25, 2018. ALJX 4

(hereinafter, Govt Prehearing) and ALJX 5 (hereinafter, Resp Prehearing). On June 6, 2018, the ALJ issued his Prehearing Ruling that, among other things, set out twenty-two Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements, which were filed by both the Respondent and the Government on August 8 and 15, 2018, respectively. ALJX 9 (Prehearing Ruling), at 1-9; ALJX 21 (hereinafter, Resp Supp Prehearing); ALJX 22 (hereinafter, Govt Supp Prehearing). Additionally, on July 18, 2018, Respondent filed a Motion to Strike and for Recommendation for Interim Reinstatement, alleging among other things that the OSC mis-referenced N.J.S.A. 24:21-15.2, because the statute did not go into effect until May 16, 2017. ALJX 12 (Resp Motion to Strike), at 2-3. The Government filed an opposition on July 23, 2018. ALJX 15 (Govt Opposition). The ALJ denied Respondent's Motion to Strike, finding that Respondent's argument is fact-based and is "best left for either resolution between the Parties or at the hearing." ALJX 17 (Motion to Strike Denial), at 2.[1] I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

The hearing in this matter spanned five days.[2] The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereafter, RD) is dated January 31, 2019. Both parties filed exceptions to the RD on March 13, 2019. ALJ Transmittal

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[1] It is noted that on November 15, 2018, the ALJ sent notice to the parties that I had concluded that the DEA ALJs had not been properly appointed under Article II of the Constitution at the time of the hearing and the ALJ set a deadline to bring a challenge based on the Appointments Clause, which the ALJ then extended after the Respondent requested clarification regarding the implications of a challenge. ALJX 51 (Notice); ALJX 52 (Respondent Letter); ALJX 53 (Response and Extension). Respondent then sent a letter to me requesting indemnification for the cost of the initial hearing so that she could request a new hearing and also moved for an adjournment of the proceedings until I responded to her request for indemnification. ALJX 55 (Respondent's Letter to the Acting Administrator). The ALJ denied the Adjournment, finding that he had extended the deadline already once and that Respondent had waived her opportunity to make an Appointments Clause challenge. ALJX 56 (Order Denying Respondent's Request for Adjournment). I agree with the ALJ that Respondent's Appointments Clause challenge did not comply with the terms of the ALJ's notice authorizing such a challenge. Further, Respondent made no further argument about the Appointments Clause in either her Posthearing Brief or her Exceptions to the RD; therefore, I find that Respondent waived her right to challenge the ALJ's appointment.

[2] Hearings were held in New York, New York on September 17-21, 2018.

Letter, at 1. On March 20, 2019, the ALJ transmitted his RD, along with the certified record, to me. *Id.*

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

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

II. Findings of Fact

A. Respondent's DEA Registration

Respondent is registered with the DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. BK9710939, at the registered address of 1129 North New Road, Absecon, New Jersey, 08201. Government Exhibit (hereinafter, GX) 1 (Respondent's Certificate of Registration). This registration expires on December 31, 2020. *Id.* This registration was suspended pursuant to the Immediate Suspension Order dated April 12, 2018. OSC, at 1.

B. The Government's Case

The Government's documentary evidence consisted primarily of medical records for six individuals treated by Respondent between January 30, 2015, and October 18, 2017, which included the records for one undercover Special Agent. The Government called three witnesses; a DEA Special Agent, who posed undercover as patient A.D. on six occasions (hereinafter, the UC); a DEA Diversion Investigator (hereinafter, DI), who participated in the investigation of Respondent; and an expert witness, Dr. Andrew Kaufman. RD, at 7-10.

The UC testified about her role in the investigation of Respondent and her role-related and investigatory experience. Tr. 36-38. On each of the six occasions in which the UC visited Respondent, she wore a recording device that provided audio and video recordings of each visit.[3] *Id.* at 38. Those video recordings and transcripts of the recordings are provided in Government's exhibits.[4] GX 6-11 (Video Files of the UC's visits with Respondent on October 17, 2016, November 23, 2016, December 22, 2016, January 19, 2017, March 7, 2017, and April 4, 2017, respectively); GX 12-17 (Transcripts of UC visits). The Government also provided copies of the UC's patient file for her six visits and the prescriptions issued to her by Respondent. GX 18, 19, 21, 23, 25, 27, 29 (patient file and visit notes); GX 20, 22, 24, 26, 28 (copies of prescriptions issued to the UC by Respondent). Having read and analyzed all of the record evidence, including the video recordings of the UC's visits, I agree with the ALJ's conclusion that the UC's relevant testimony was "sufficiently objective, detailed, plausible, and internally consistent," and therefore, credible.[5] RD, at 7-8.

The Government presented the testimony of a DI assigned to the DEA Camden Resident Office, who participated in the administrative investigation of Respondent. Tr. 125-26. The DI testified that she first became aware of Respondent while investigating a pharmacy. *Id*. at 126; *see also* RD, at 8. She testified that one of the pharmacy's suppliers had "seen that pharmacy had an unusually high volume of narcotic prescriptions being filled, and that [Respondent] was

[3] The UC testified that during her final visit with Respondent, the recording device malfunctioned and provided only an audio recording of the visit. Tr. 38, 71; *see also* RD, at 7.

[4] The UC testified that the transcripts of the recordings were accurate depictions of the visits, with the exception of the transcript in GX 12 at page 8, where the UC testified that she told Respondent that she got her medicine in "New York," rather than "Newark." Tr. 44, 50; RD, at 7.

[5] The ALJ noted that he found some irrelevant testimony of the UC confusing, but he also noted that the testimony does not detract from her overall credibility. RD, at 8 (citing tr. 81-88). I agree that the topic was irrelevant. Further, I determine that due to the Government's objections regarding law enforcement sensitivity during the hearing, it does not appear to me that the facts were fully explored on this topic, and therefore, I do not find the testimony confusing. I agree with the ALJ that this testimony does not detract from the UC's credibility.

the No. 1 prescriber for that pharmacy and for those controlled substances." Tr. 127. The DI testified that an administrative subpoena was issued to Respondent to obtain complete patient records for seventy-four named individuals, who were identified based on red flags for diversion, and another subpoena was issued for updates on thirty of those individuals named in the earlier subpoena. Tr. 128, 129; *see* GX 4 (first administrative subpoena issued November 3, 2017) and GX 5 (second administrative subpoena served April 13, 2018); *see also* RD, at 8. The Government's evidence includes six patient files obtained through those subpoenas. GX 29, 84, 130, 175, 259, 344.

I agree with the ALJ that the DI's testimony was "sufficiently objective, detailed, plausible, and internally consistent." RD, at 8. Although the ALJ ultimately concluded that D.I.'s testimony was unnecessary, I credit her testimony regarding the Agency's initiation of an investigation into Respondent's practice and the results of the subpoenas to the extent that they provide the foundations of this administrative matter.

The Government's expert witness, Professor Andrew Kaufman, M.D., is a professor of anesthesiology at Rutgers University, and testified that he has "extensive clinical responsibilities, seeing patients in two offices" in New Jersey. Tr. 155-57. He also teaches medical students and residents and serves as the Executive Director of the New Jersey Society of Interventional Pain Physicians. *Id*. at 157-58; GX 345 (Curriculum Vitae of Dr. Kaufman); *see also* RD, at 8. The ALJ accepted Dr. Kaufman as "an expert in the treatment of pain with controlled substances in the State of New Jersey." RD, at 8; tr. 168.[6] The matters about which Dr. Kaufman testified

[6] I agree with the ALJ in overruling the objection of Respondent's counsel to Dr. Kaufman's expertise, which counsel appeared to be basing on the grounds that Dr. Kaufman only treats approximately ten percent of his patients with controlled substances, and that, given his preference for not prescribing controlled substances, his experience is not relevant to the case. RD, at 8; tr. 167-68. I find that the percentage of patients to whom controlled substances have been prescribed by Dr. Kaufman has no bearing on his expertise in the treatment of pain with controlled substances or the applicable standard of care in the State of New Jersey.

included his review and standard-of-care analysis of medical records belonging to six of Respondent's patients, including the UC. Tr. 171-72. In forming his opinion, he also reviewed the video tapes and one audio tape of the UC visits with Respondent. *Id.* at 169.

The ALJ found, and I agree, that Dr. Kaufman's testimony was "presented in a professional, candid, and straightforward manner" and "was sufficiently objective, detailed, plausible, and internally consistent," and therefore credible.[7] RD, at 10.

C. The Respondent's Case

Respondent presented the testimony of four witnesses at the hearing, including her own. The first witness, Dr. Lawrence J. Epstein, M.D., has treated pain patients for thirty years and is an Associate Professor of Anesthesiology and Neurology at the Icahn School of Medicine, Mt. Sinai Hospital, and has held professorial appointments and staff positions at multiple hospitals in New York. RD, at 11; *see also* tr. 687-97. Dr. Epstein is also the Chair of the New York State Board of Medicine, which is responsible for all medical licensure in that state and has input into all medical policy for the state. RD, at 11; tr. 691-93. Dr. Epstein was involved in writing New York's law concerning its Prescription Monitoring Program. RD, at 11; tr. 696. Dr. Epstein testified that he is familiar with the standard of care for prescribing pain medicine and has published articles and spoken publicly about prescribing opioids, including the "over-prescribing" of opioids since about 2008 or 2009. RD, at 11 (citing tr. 699). Dr. Epstein submitted a written report on his assessment of the medical files of the patients at issue in this proceeding. ALJX 5, Attachment 1.

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[7] However, in comparing Dr. Kaufman's testimony with the testimony of Dr. Epstein, Respondent's expert witness, the ALJ frequently gave Dr. Epstein's testimony more weight, because "Dr. Epstein supported his opinions with more well-reasoned analysis and explanation than did Dr. Kaufman." RD, at 17; 10 n1. I disagree with the ALJ's decision to give Dr. Epstein's testimony more weight as explained in the standard of care section below. *See infra* II(E)(1).

Dr. Epstein holds a license to practice medicine in New Jersey since "somewhere between" 1986-88, but has never practiced there, and his license is inactive. Tr. 703; RD, at 11.[8] He testified that he has read some of the New Jersey statutes concerning pain management, but that the standard of care does not include the statutes, and it differs by region and the number of patients a doctor sees on a daily basis. RD, at 12; tr. 704, 708, 711. With respect to prescribing opioids, Dr. Epstein testified there is a nationwide standard of care, which he applied in evaluating this case. RD, at 12; tr. 722, 729.

The ALJ admitted Dr. Epstein as an expert in pain management practice in "standard of care, on proper medical procedures with respect to pain management, and the appropriate use of controlled substances in medical practice." RD, at 12 (citing tr. 702, 730). The Government objected on the ground that he lacked experience and knowledge of the standard of care in New Jersey. RD, at 12; tr. 716-17, 730. The ALJ found, and I agree, that Dr. Epstein's testimony regarding several aspects of the case was "concerning." RD, at 14. In particular, the ALJ found that his testimony about Patient J.C.'s inconsistent urine screens did not withstand close scrutiny, because the patient records did not support his statements. *Id.* at 14-15 (citing tr. 1583-84). Dr. Epstein also testified that the UC was an established patient by the time Respondent issued her a prescription for controlled substances on the second visit, which the ALJ believed was a "bit of a stretch." RD, at 15 (citing tr. 1454). The ALJ also found that Dr. Epstein placed too much weight on the UC's previous medical records, about which even the Respondent "expressed concern." RD, at 15 (citing GX 13, at 6-7; RX 7, at 2). Finally, the ALJ found that Dr. Epstein's testimony regarding Patient A.P.'s alcohol counseling was not based on the evidence. RD, at 15 (citing tr. 1542-44; tr. 1640-41; GX 80). Despite these concerns, the ALJ found that "Dr.

[8] The RD noted 1980, but in the transcript, Dr. Epstein hesitated and then said 86-88. Tr. 703.

Epstein's testimony was compelling in several aspects." RD, at 15. The ALJ credited Dr. Epstein's opinion about urine screens being positive for alcohol metabolites and documentation of counseling after inconsistent urine screens. *Id.* at 15-16. In all, the ALJ stated, "After having closely observed Dr. Epstein during his testimony, as well as having attentively listened to his testimony during the hearing, I have carefully reviewed the transcript of his testimony. I find that Dr. Epstein's testimony was sufficiently objective, detailed, plausible, and internally consistent to be considered credible in this Recommended Decision." *Id.* at 16. I defer to the ALJ's assessment of Dr. Epstein's overall credibility, and in particular, the ALJ's observations of his testimony. However, as further explained herein, I do not concur with the ALJ's finding that Dr. Epstein's testimony regarding the applicable standard of care in New Jersey was more credible than Dr. Kaufman's regarding prescribing after inconsistent urine screens. RD, at 16.

Respondent testified on her own behalf. Tr. 775-1120. She testified that she earned her medical degree in Pakistan and completed a neurology residency and a fellowship in pain management at Louisiana State University. RD, at 17; tr. 784-87. In 2008, Respondent began practicing pain management in New Jersey, and worked for two years at a neurosurgeon's office, then she worked with her husband's practice, as well as consulted in pain management at AtlantiCare Regional Medical Center. Tr. 788-89, 793-94. Respondent testified as to her standard pain management practice with respect to the patients in question, including her use of monthly urine screens, her practice of obtaining MRIs before prescribing controlled substances, her use of an electronic recordkeeping program called eClinical (hereinafter, eClinical), and her counseling practice. *Id*. at 799-805, 827, 882, 991-92, 933-35, 1040; *see also* RD, at 18-19. She also testified specifically to her treatment of the six patients. RD, at 19-22. She testified that she sees fifty to fifty-five patients per day and bills about ten minutes per patient. Tr. at 985, 988.

Additionally, she testified to the controls that she has put in place in her practice. Specifically, she requires a referral from a physician to make an appointment. *Id*. at 815. She also requires all of her patients to take urine drug screens on a monthly basis, which she does at her own volition and expense, despite the burden it imposes. *Id*. at 799-800.

The ALJ found, and I agree, that "there were several aspects of [Respondent's] testimony that were problematic." RD, at 22. He found that her testimony regarding Patient L.M.'s urine screen showing Suboxone was not credible. *Id.* at 22-23. Respondent hypothetically discussed the possibility that the patient had received the Suboxone at a hospital or rehabilitation facility after running out of her medication, but "two of the three times L.M. screened positive for Suboxone, she was also positive for oxycodone," and the other time the laboratory did not test for oxycodone. RD, at 22-23 (citing tr. 1095-96, 1099, 1100; GX 175, at 139, 141, 144). If the patient had run out of oxycodone in order to receive the Suboxone for withdrawal, she would not have tested positive for it. The ALJ also found that Respondent's "explanation of why she did not conduct a physical examination of [UC's] shoulder to be unconvincing." RD, at 23. Specifically, Respondent testified at one point that a physical exam would be painful because of arthritis, but she also testified that she observed the UC's "range of motion to be 'pretty good.'" *Id.* at 23 (citing tr. 824, 1065). He found that her testimony about L.M.'s urine screen that was positive for fentanyl was also inconsistent. RD, at 23. Finally, he found that her testimony regarding the UC's diagnosis of arthritis was "inconsistent with her own records." *Id*. at 23-24. The ALJ stated:

> While the five concerns discussed above detract from [Respondent's] overall credibility, I find that most of her testimony was sufficiently objective, detailed, plausible, and internally consistent. I do not find that [Respondent] was engaged in intentional fabrication . . . . Therefore, I merit her testimony to be credible in all non-contested matters in this Recommended Decision.

Id. at 24.

Although I believe that the ALJ analyzed the Respondent's testimony thoroughly and honestly, and I defer to his determination of credibility as to Respondent's demeanor, I do not believe that there is practical value in meriting her testimony in non-contested matters for purposes of this proceeding, particularly because she did not offer much, if any, acceptance of responsibility, as further discussed in the sanctions section herein. *See infra* IV. The ALJ credited Respondent's testimony that she had counseled her patients for their urine screen results—a fact which is contested in this matter. *See* RD, at 43 (citing tr. 853, 974-75, 981, 993-94, 1336, 1344-45, 1354). I found additional instances of inconsistencies in Respondent's testimony that undermine her credibility as well. For example, she testified that she relied on the UC's MRI in lieu of a physical exam to form her diagnosis, but the transcript demonstrates that Respondent was repeatedly confused about whether or not she had seen the MRI. *See infra* II(F)(1); GX 14, at 11, 13; GX 15, at 5; GX 16, at 9. Respondent also testified that when L.M. tested positive for Suboxone, she had called the lab and the lab had said to recheck the urine "[a]nd I tested her again; she didn't come back positive the next time." Tr. 857. This description of events is undermined by the evidence on the record that shows that L.M. testified positive three times in a row for Suboxone and by Respondent's own subsequent testimony. *See infra* II(F)(5); tr. 1092-95.

Respondent also presented the testimony of Dr. Thomas Gutheil as an expert in medical documentation and medical records. RD, at 24-28; tr. 1123-1325. Dr. Gutheil is a practicing psychiatrist and professor of psychiatry at Harvard Medical School and lectures on electronic medical recordkeeping, among other medical subjects. RD, at 24; tr. 1123-1124. He testified that as a hospital records committee chairperson reviewing medical records for quality assurance

for many years, he developed his study of medical recordkeeping, and has published several peer review articles on medical documentation, and lectures on the subject worldwide. RD, at 24-25. He also provided a written report, which was submitted in Respondent's initial Prehearing statement. ALJX 5, Attachment 2. Dr. Gutheil testified that he is not licensed to practice medicine in New Jersey, but he follows the developments of medical documentation in New Jersey, and he reviewed some of the New Jersey regulations and laws about medical recordkeeping in preparation for the hearing. RD, at 28 (citing tr. 1135-36, 1136-38). He also testified that he was not familiar with Respondent's recordkeeping eClinical when he wrote his report, and that he did not know which version of eClinical Respondent used in her practice. RD, at 28; tr. 1155, 1281-82.

The ALJ accepted Dr. Gutheil as an expert in "medical documentation and medical records." RD, at 28; tr. 1132. He also found Dr. Gutheil's testimony was presented in a professional, candid, straightforward manner, and it was "helpful in understanding the standards of medical documentation and electronic medical recordkeeping." RD, at 28. He merited it as sufficiently objective, detailed, plausible and internally consistent to be fully credible. *Id.* Overall, I agree that Dr. Gutheil's testimony was credible, but I do not believe that the use of the word "standards" in the ALJ's assessment is appropriate, because Dr. Gutheil testified on numerous occasions that his testimony had nothing to do "with issues of legal standards and so forth or even medical care. And that's not my subject." Tr. 1138.[9] Additionally, the ALJ clarified to Respondent's attorney during the hearing that he was not accepting Dr. Gutheil as an expert in the standard of care. *Id.* at 1157-1161, 1216-1217 (ALJ stating that he was "not going to allow the question, because it's going to a standard. I don't—what sort of standard?"

[9] Respondent agreed that "Dr. Gutheil was not qualified to, and could not, testify to the standard of care." Resp Exceptions, at 16 (citing Tr. 1158-1159).

Respondent's attorney responded, "Is there a standard for medical documentation?" The ALJ then sustained the Government's objection that no standard was mentioned in Dr. Gutheil's report); *accord* tr. 1239, 1241, 1250, 1270, 1291, 1294-97, 1308. To the extent that the ALJ permitted limited testimony differentiating a standard of recordkeeping from the standard of care, it seems largely irrelevant to the underlying charges of prescribing beneath the applicable standard of care in the State of New Jersey. *See* OSC, at 2-5. I agree with the ALJ that Dr. Gutheil's testimony supported the reasons why documentation is important "to create a record for the continuity of care, including care provided by subsequent practitioners; create a permanent record about the patient's medical history; aid the practitioner in planning treatment; and to prevent liability." RD, at 116 (citing tr. 1214, 1272, 1280-81, 1287 and ALJX 60 (Respondent's Posthearing Brief (hereinafter, Resp Posthearing), at 16)). However, I find that overall, Dr. Gutheil's testimony is largely irrelevant to this proceeding, because he did not testify about the applicable standard of care.[10] His testimony was presented to mitigate the Respondent's inadequate recordkeeping. *See* Resp Posthearing, at 17 (arguing that Dr. Gutheil's testimony established that "there is always something more that a physician could write in a chart; if a physician spent all her time writing, there wouldn't be any time to see the patients." (citing tr. 1215)). This mitigating testimony may have been persuasive had Respondent accepted responsibility for her actions and demonstrated how she would prevent the recurrence of her violations of law as discussed in *infra* Section IV.

Finally, Respondent offered the testimony of Patient J.C., who was one of the six patients whose records were at issue in this proceeding. Tr. 1327-69; RD, 28-31. J.C. testified that Respondent had been treating him since 2016 for neuropathy in his feet and pain in his lower

[10] Respondent specifically highlighted this fact in stating, "The ALJ also ignored the fact that Dr. Gutheil was not qualified to, and could not, testify to the standard of care." Respondent's Exceptions, at 16 (citing tr. 1158-1159).

back due to a pinched nerve and degenerative disc disease in his lower back. RD, at 28; tr. 1328-29, 1330. He testified generally about Respondent's care, including her counseling on his inconsistent urine screens. RD, at 29-30. The ALJ found several "discrepancies," which "detract from J.C.'s overall credibility." *Id.* at 30. The ALJ meticulously matched J.C.'s statements with his patient records and found that he inaccurately testified that Respondent had first prescribed tramadol to him after his inconsistent urine screen to help alleviate his pain, when the records demonstrated that she had prescribed tramadol on his second visit. *Id.* at 30 (citing tr. 1343-44, 1354; ALJX 45, at 2). He also determined that J.C. had inaccurately testified that his second inconsistent urine screen occurred because of a cancelled appointment, whereas the record demonstrated that the inconsistent screen had occurred "on June 20, 2017, and he had filled the previous prescription for 120 oxycodone tablets on May 22, 2017, 30 days before he provided his urine sample." RD, at 30 (citing tr. 1355-57, 1367; ALJX 45 (Spreadsheet of PMP Data), at 2). Despite the inconsistencies, the ALJ found that "he testified in a professional, candid, and straightforward manner," and that his testimony "[w]as sufficiently objective, detailed, plausible, and internally consistent." RD, at 30-31. Therefore, the ALJ merited the testimony as "fully credible concerning whether [Respondent] counseled him regarding his three inconsistent urine screens." *Id*. I defer to the ALJ's assessment of J.C.'s demeanor and his professionalism, but I struggle with accepting his finding that, despite the large inconsistencies that he, himself, found, J.C.'s testimony was "consistent." *Id.* However, because I am basing my findings regarding J.C. on Respondent's failure to document her counseling, as opposed to her failure to counsel, I find that his testimony regarding counseling does not affect my Decision and Order. *See infra* II(E)(3)(a).

D. The ALJ's Conclusions of Law Regarding New Jersey Statutes and Regulations

The Government alleged that Respondent violated a New Jersey statute and two New Jersey regulations. *See* OSC, at 2; Govt Prehearing, at 4, 5. Overall, the ALJ did not sustain the Government's allegations of violations of the New Jersey statute and regulations, "[b]ecause neither Dr. Kaufman nor Dr. Epstein testified that [Respondent] had violated any particular New Jersey statute or regulation in issuing any of the 17 prescriptions." RD, at 139. The Government filed Exceptions to the Recommended Rulings, Conclusions of Law, and Decision of the Administrative Law Judge, in which it argued that the ALJ's findings were in error, and that the error led the ALJ to credit Dr. Epstein's testimony over Dr. Kaufman's and to find "Respondent's violations to be less numerous and egregious [than] they in fact were, and this finding contributed to his recommendation of a sanction less than revocation." Govt Exceptions, at 4. The Respondent also filed Exceptions to the Recommended Decision (hereinafter, Resp Exceptions), in which she specifically argued that the statutory language was essential to understanding that a physical exam under New Jersey law was only required "as appropriate." Resp Exceptions, at 8-9. Although on close examination of the violations that the ALJ sustained, the effect of his finding regarding New Jersey law is potentially not as critical as the Government argued, I am addressing this issue at the outset because the law does lay a foundation for the applicable standard of care in New Jersey in this case.

1. New Jersey Administrative Code § 13:35-7.1A

New Jersey Administrative Code § 13:35-7.1A requires in relevant part that practitioners shall not dispense drugs or issue prescriptions (not solely controlled substances) "without first having conducted an examination, which shall be appropriately documented in the patient record." N.J. ADMIN. CODE § 13:35-7.1A (West 2020) (effective September 15, 2003).

The ALJ noted that the first time that the Government cited to this section was in its Supplemental Prehearing Statement. RD, at 101 n.49, 102 n.50 (citing ALJX 22, at 4). He determined that this regulation was never mentioned during the hearing, and "[f]urthermore, the Government expert did not rely on N.J. Admin. Code § 13:35.71A in reaching his conclusion that the Respondent's prescriptions to A.D. were issued beneath the standard of care in New Jersey." RD, at 101, n.49 (citing tr. 272, 674-77). He therefore concluded that Respondent "was not put on notice that any of her prescriptions violated" this provision. *Id.* The ALJ further noted that his recommended sanction would not have changed had he considered those provisions. RD, at 102 n.50. I disagree that N.J. ADMIN. CODE § 13:35.71A was not sufficiently noticed or litigated during the hearing.

The Government's Supplemental Prehearing Statement used bold type to emphasize changes to the testimony of Dr. Kaufman, stating, "Dr. Kaufman will also testify that the New Jersey standard of care is also governed by N.J. Stat. Section 13.35-7.1A and 13:35-7.6." Govt Supp Prehearing, at 4, 5. On August 20, 2018, Respondent filed a motion objecting to the Government's Supplemental Prehearing Statement, and made a correction to the Government's citation of the regulation, stating, "Among other things, Dr. Kaufman's testimony has been changed to allege respondent's violation of New Jersey regulations – improperly identified as statutes – in the revised proposed testimony." Respondent's Pre-Trial Motions, at 9.

During the hearing, the Government's attorney asked Dr. Kaufman if the requirement for a physical exam had recently changed in New Jersey and Dr. Kaufman said that it had not. Tr. 271-72. The Government's attorney then asked if, in 2015, someone would be required to do a physical exam to which the witness responded, "[W]ithout reviewing the statute[11] again, I

[11] Dr. Kaufman used the word "statute" here, but he appears to be confusing the regulation and statute.

believe so." *Id*. The Government's attorney clarified by asking if the "standard of care require[d] a physical exam, regardless of what the statute says," to which Dr. Kaufman answered, "Yes." *Id.* Later, Dr. Kaufman testified that the regulation requires that a physical exam must be conducted, and in response, the Respondent's attorney specifically cited to this regulation to pose an argument that the regulation contained exceptions to the physical examination requirement and he presented copies of the regulation to the ALJ and Dr. Kaufman. *Id*. at 399-405.

Ultimately, the ALJ agreed with the Government's allegations regarding Respondent's failure to conduct a physical examination of the UC before prescribing controlled substances, because he found that Respondent's actions were beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey. RD, at 38. Even though the ALJ recommended dismissing the allegations of a regulatory violation, he did not change his overall conclusion that the lack of a physical examination violated the applicable standard of care in New Jersey. I agree with the Government, and the Respondent, that the Government adequately noticed the regulatory and statutory violations, and at the very least, this regulation was clearly litigated by consent during the hearing, as exemplified by the Respondent's arguments during the hearing and in Respondent's Exceptions. *See Farmacia Yani*, 80 Fed. Reg. 29,053, 29,059 (2015). Therefore, I will consider the allegations regarding New Jersey Administrative Code § 13:35-7.1A.

2. New Jersey Administrative Code § 13:35-7.6

The Government also cited to New Jersey Administrative Code Section 13:35-7.6 in its Supplemental Prehearing Statement, which sets forth numerous requirements for practitioners prescribing controlled substances, including entering a pain management plan by the third visit

and monitoring compliance. There are two affirmative obligations in this Section of the regulations that are applicable to this record – "[w]hen controlled dangerous substances are continuously prescribed for management of chronic pain[12]" (defined as pain continuing for three months), the practitioner shall "assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment" and "monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion." N.J. ADMIN. CODE §§ 13:35-7.6(f)(2), (f)(5) (West 2020).[13] Respondent testified that all of the patients whose treatments were the subject of this action signed a pain management agreement with her. Tr. 948; *see, e.g.,* GX 29, at 4 (pain management agreement with the UC). She further testified that she would use her "clinical judgment" to determine whether a patient's conduct broke her agreement. Tr. 1007-08. One of the pain management agreements for J.C. stated, "I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate will result in my being without medication for a period of time."[14] GX

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[12] "'Chronic pain' means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically." N.J. ADMIN. CODE 13:35-7.6(a) (West 2020). Due to the fact that the patients in this case were prescribed opioids for more than three months prior to this regulation, I find that they fall under this definition.

[13] The requirement related to the assessing, monitoring and documenting of compliance in N.J. ADMIN. CODE § 13:35-7.6(f)(2) and (5) became effective on March 1, 2017, through an Emergency Rule. 2017 NJ REG TEXT 452254 (NS) (Emergency Rule). The regulation became permanent on June 5, 2017. 2017 NJ REG TEXT 452254 (NS) (Rule Adoptions).

[14] The record reflects that Respondent had two pain management agreements. The record contains one pain management agreement that makes no reference to taking the medicine as prescribed, but the other states that "I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or anti-anxiety medications from any other doctor." GX 130, at 12; *cf* GX 130, at 2 (different pain management agreements with J.C.). To the extent that the pain management agreements do not address the required portions of the regulation, they appear to be inadequate. Regardless of the content of the actual pain management agreements, the regulation is clear about what would constitute a breach: not taking the medication as prescribed and taking drugs

130, at 12. The plain language of the regulation requires that a practitioner discuss with the patient "breaches that reflect that the patient is not taking the drugs as prescribed," which would include inconsistent urine screens that clearly demonstrate that the patient has not been following the prescription. N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020); *see infra* Section III(A)(1)(b)(ii) for further discussion.

The ALJ concluded that despite discussion of Respondent's pain agreements in the testimony,[15] the Government had failed to adequately notice "that the Respondent failed to enter into such agreements or conduct urine drug screens."[16] RD, at 105 n.59. The Government argued not, as the ALJ contended, that she failed to enter into agreements, but that the regulation required Respondent to discuss breaches of the pain management agreement and document within the patient record the plan after the discussion, and alleged that Respondent issued eleven prescriptions for controlled substances in violation of this regulation. Government's Posthearing Brief (hereinafter, Govt Posthearing), at 17. The Respondent posed arguments both in her testimony and in her Posthearing Brief regarding her monitoring of the patients for dependence and her discussion of the inconsistent urine screens and how her documentation complied with the regulation. *See, e.g.*, tr. 1024-1025; Resp Posthearing, at 18-20, 23. Respondent's arguments before the hearing,[17] during the hearing, and after the hearing, demonstrate that she was on notice of the alleged violation of the New Jersey regulation;

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not prescribed or prescribed by other practitioners. I am basing my Decision and Order on the regulatory requirements as opposed to Respondent's agreements.

[15] *See, e.g.*, tr. 947-950.

[16] The ALJ seemed to be confused between this regulation and New Jersey Stat. § 24:21-15.2, but substantively, as further explained herein in *infra* Section III(A)(1)(b)., the regulation implements the statute; therefore, they are very similar. *See* RD, at 105 n.59. I also disagree that the Respondent was not on notice of the allegations regarding pain management agreements, because they are identical in scope to the requirement to document the resolution of evidence that the patient was not taking the medication as prescribed or was taking controlled substances that were not prescribed.

[17] *See* Respondent's Pre-Trial Motions, at 9 n.1.

therefore, I disagree with the ALJ that this allegation was not adequately noticed, and I will consider the alleged violations of this regulation after its effective date of March 1, 2017.

Further, at the very least, this regulation fully supports the testimony of Dr. Kaufman and discredits the testimony of Dr. Epstein regarding whether the applicable standard of care in New Jersey requires documentation of inconsistent urine screens as further explained below in Section II(E)(1) and (3).

3. New Jersey Statute 24:21-15.2

The OSC alleged that Respondent did not "comply with New Jersey Stat. []§ 24:21-15.2[18] (requirements for opioid and Schedule II controlled substances prescriptions)."[19] ALJX 1 (OSC) at 2. The OSC alleged that New Jersey Stat. § 24:21-15.2:

> requires, among other things, that a physical exam take place prior to the issuance of a Schedule II controlled substance prescription or opioid prescription; that a doctor prescribing opioids enters [*sic*] into a pain management agreement with patients; and that patients receiving opioids be monitored for compliance with the pain management agreement through various measures such as urine drug screens.

OSC at 2.

During cross examination, Respondent's attorney asked Dr. Kaufman about the statutes to which he was testifying and Dr. Kaufman replied that he didn't know them by number, but he knew them in substance. Tr. 297-298. He testified that the substance was:

> that you must do a full history, in general, an appropriate physical exam. You must also check the prescription monitoring programs, and then issue a prescription. On subsequent visits, you need to make an assessment of the prescribed medicine. Is it working? Is it not working? You need to, again, do a physical exam, and then come up with a plan to then say do we continue the medication, or do we not continue it? That's the general substance of that.

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[18] It is noted that the OSC alleged a violation of this statute for the prescriptions written to the UC (all of which were issued prior to its effective date and which were the only allegations on the record regarding a lack of physical examination); therefore, the physical examination portions of the statute are not directly relevant to the findings herein.

[19] The OSC also alleged violations of N.J. Stat. § 45:9-22.19 (requirements for additional schedule II controlled substances prescriptions), but the Government did not offer further argument related to that provision—apparently abandoning it. Thus, I am not considering it.

Id. at 299-300.

Later, on cross examination, the ALJ overruled Government's objection when Respondent's attorney required Dr. Kaufman to read a statute,[20] holding "[h]e has testified based on his understanding of the statutes. It's appropriate to allow Counsel to ask him, looking at the statutes, based on your reading of the statutes, do you think you've interpreted it correctly." *Id.* at 303.

The Government and Respondent both presented arguments about N.J. STAT. § 24:21-15.2 in prehearing and posthearing filings, and therefore, I find that it was adequately noticed and will consider it below for prescriptions issued after its effective date. *See, e.g.*, Govt Supp Prehearing, at 4; Resp Supp Prehearing, at 2.

E. The Applicable Standard of Care in New Jersey

1. Expert Testimony

In accepting Dr. Epstein as an expert witness despite his lack of specific expertise in the New Jersey standard of care, the ALJ cited *Jacobo Dreszer, M.D.*, in which my predecessor stated that, due to an "expert's academic and professional credentials, and the expert's testimony that he reviewed the state's regulations[21] governing the standards of prescribing controlled substances, the expert was 'clearly qualified to provide expert testimony.'" RD, at 12 (citing *Jacobo Dreszer, M.D.*, 76 Fed. Reg. 19,386, 19,387 (2011)). The ALJ opined that it was significant that Dr. Epstein testified that there is a nationwide standard of care with respect to prescribing opioids, which, he testified, "establishes the floor." RD, at 13; tr. 722, 725. The ALJ

[20] Although not explicit in the transcript, the contextual clues demonstrate that the "statute" was New Jersey Stat. § 24:21-15.2 (effective May 16, 2017). Tr. 302-303.

[21] It is noted that although Dr. Epstein stated that he read recent statutes, he stated that the standard of care "doesn't include the statute" and he appeared to be unfamiliar with the New Jersey laws. Tr. 704, 708-709, 711

noted that while Agency decisions exist to tailor analysis of medical practice to state standards, DEA "has also accepted the propriety of analyzing the usual course of professional practice with reference to generally recognized and accepted medical practices that exist on a national level." RD, at 16 (citing *Mirielle Lalanne, M.D.,* 78 Fed. Reg. 47,750, 47,759 (2013)). He found, however, that in this case neither Dr. Kaufman nor Dr. Epstein based their opinions on New Jersey law or regulations, and that "absent such controlling state laws or regulations . . . it is appropriate to focus upon whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States.'" RD, at 16 n.2 (citations omitted). As noted in the previous section, Dr. Kaufman did acknowledge the substance of New Jersey law, and although he did not quote those authorities directly, they were part of his understanding of the applicable New Jersey standard of care and support the standard to which he testified. *See, e.g.*, tr. 272.

I do not disagree with the ALJ's determination regarding Dr. Epstein's general credibility or his admission as an expert; however, it is important to emphasize that the OSC alleges that Respondent prescribed "outside the usual course of practice and beneath the standard of care in New Jersey." OSC, at 2-5; *see* RD, at 12; tr. 721-722. The question in this case is, regardless of the rationality, credibility, and impressive credentials of an expert in a national standard of care, whether such an expert's view can outweigh expert testimony concerning the applicable New Jersey standard of care, which in several aspects has been codified in state law and regulation.

Dr. Epstein testified that New Jersey laws and regulations "can further limit the prescribing," and agreed with the Government attorney that "Federal law[22] sets maybe a floor but

[22] In discussing federal law, Dr. Epstein seemed to be referring to the Center for Disease Control Guidelines that he referenced earlier in his testimony. Tr. 723-724. This demonstrates Dr. Epstein's general misunderstanding about the weight of applicable laws and guidance and the manner in which they affect the applicable standard of care in New Jersey.

the community can have higher standards, but the community can't have lower standards." Tr. 725. Dr. Epstein then asserted that the standard of care is "dictated by communities rather than by states," and that the New York metropolitan area is one community, including parts of New Jersey, and suburban practitioners have different standards of care than those in urban areas. RD, at 13; tr. 704, 711, 715. When asked if the standard of care in New York is different from New Jersey, he stated, "[i]n my opinion, they are the same. The Board of Medicine in New Jersey may feel they're different." Tr. 713.

In this case, New Jersey has enacted laws and regulations, which, as Dr. Epstein predicted, have put in place "higher standards" than those upon which Dr. Epstein relies. *Id*. at 725. To the extent that Dr. Epstein discussed a baseline national standard of care, the laws and regulations of New Jersey and the direct testimony of a New Jersey practitioner directly contradict Dr. Epstein's depiction of the applicable standard of care. Although I recognize that some of the New Jersey laws and regulations in question were enacted after some of Respondent's alleged violations, because those authorities are consistent with the standard of care described by Dr. Kaufman, I give Dr. Kaufman's testimony more credibility than Dr. Epstein's.[23]

2. Physical Examination

The ALJ found, and I agree, that, before prescribing a controlled substance, the applicable standard of care in New Jersey "requires a full medical history, a targeted physical examination based on the patient's complaint, a review of relevant documents, and checking the

[23]Additionally, I note that it would defy logic to find Dr. Epstein more credible on matters of standard of care for the prescriptions that occurred after the effective date of these New Jersey laws, as the standard that he describes would be in direct violation of state law. *See* N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020) (requiring documentation of breaches of the pain management agreement that demonstrate that the patient is not taking the medication as prescribed); *but see* tr. 1629-41 (Dr. Epstein testifying that documentation is a best practice, not the standard of care in New Jersey).

PMP." RD, at 38 (citing tr. 174, 180, 271, 1442). Dr. Kaufman credibly testified that the applicable New Jersey standard of care requires a physical examination[24] of a patient before prescribing a Schedule II controlled substance, including on return visits, and that observing a patient would not satisfy the applicable standard of care. RD, at 9 (citing tr. 181, 398, 462). He also testified that a component of a physical exam is "[c]ould you please move while I watch you and observe you and measure how much you can move it, that's part of a physical exam," but that undirected movement is an "observation [] that's not a physical examination." Tr. 415, 430. He testified that "[e]ach time before prescribing a controlled substance, one needs to examine to see if the medication that you're giving is helping. Is it efficacious? Is the examination changed? Do you want to then continue therapy?" *Id*. at 398.

Dr. Epstein stated that the standard of care requires a diagnosis obtained by "a thorough history and then a physical that's directed, which can vary in scope[25] and [] enough at least to get the right diagnosis, and to get a working diagnosis, and to do whatever diagnostic tests that you need to do if you need to do them, and to provide a diagnosis, provide a plan, discuss risks, and

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[24] Respondent insinuated that Dr. Kaufman testified that "[i]f a physician knows the reasons for a patient's pain, there isn't necessarily a need to actually palpate the patient (Kaufman [304])." Resp Posthearing, at 11. The transcript does not support this statement. Dr. Kaufman testified, "How could you never need a physical exam when someone's complaining of pain in a body part" and explained that the only time the standard of care would not require a physical examination is if "a patient's coming in to me with terminal cancer pain, I'm not going to subject them to what could be a very painful examination to know that they have cancer in bones or other organs, which we're now trying to alleviate their suffering." Tr. 304.

[25] Respondent argued, among other things, that the variance in scope that Dr. Epstein describes supports her argument that a physical exam is only necessary as appropriate in the physician's sound medical opinion. Resp Exceptions, at 9. In making his initial assessment, Dr. Epstein relied on Respondent's records for the UC that had misleadingly indicated that a physical exam was performed, because Respondent's system auto-populated the template. Tr. 176; GX 29; tr. 827, 904, 914. I note that Dr. Epstein did not state that a physical exam required palpation, but his statements about the requirements of a physical exam were minimal and did not elucidate the appropriate contents of a physical examination, because he had assumed that the physical exam had occurred. Further, Dr. Epstein's testimony undermines Repondent's argument that an MRI is adequate in lieu of a physical examination, because he sequences the physical examination first and differentiates between the physical and the "diagnostic tests that you need to do if you need to do them." Tr. 1442. However, due to the limited nature of Dr. Epstein's testimony on this issue, Dr. Kaufman's testimony regarding what constitutes a physical examination is the only expert testimony on the record that addresses the contents of the physical examination, and I fully credit his testimony on this issue.

then implement the plan, and then to follow-up on the plan . . . ." Tr. 1442. As further evidence of the applicable New Jersey standard of care, the Government cited to New Jersey Administrative Code § 13:35-7.1A, which was in effect at the time of the prescriptions to the UC, and requires in relevant part that practitioners shall not dispense drugs or issue prescriptions "without first having conducted an examination, which shall be appropriately documented in the patient record" and part of that examination requires the practitioner to "perform an appropriate history and physical examination." N.J. ADMIN. CODE § 13:35-7.1A(a) and (a)(1) (West 2020).

As further explained below, I find that the applicable standard of care in New Jersey requires a physical examination, including a directed physical examination of the area of complaint, and that observation without directed movement, is not adequate under the applicable standard of care.[26]

3. Urine Screens Inconsistent with Prescribed Medication

Dr. Kaufman testified that a urine screen[27] that is negative for the controlled substance that the practitioner has prescribed is an inconsistent urine screen, and further that, when a patient's urine screen is inconsistent, the applicable standard of care in New Jersey requires a practitioner to "have a discussion with the patient and to say, I gave you X amount of medication to last you from one visit to the other. And I'm not seeing anything, not the parent compound, which you would see if you had taken it that day, nor the breakdown products that you would see anywhere from three to four days later, why did you finish these sooner than how I prescribed

[26] Respondent's arguments related to the extent of the physical exam are further discussed below. *See infra* Section II(F)(1) and III(A)(1)(b)(i).

[27] The ALJ found that "[a] doctor's first assumption when reviewing an abnormal urine screen for a patient is that the test is wrong. Laboratories make mistakes all the time." RD, at 42 (citing tr. 1492). Respondent noted that the ALJ seemingly ignored this finding of fact when sustaining the allegations. Resp Exceptions, at 27. I do not find this finding of fact to be inconsistent with Dr. Kaufman's testimony about the applicable New Jersey standard of care's requirement to document inconsistent urine screens as described herein. Without such documentation, for example, there is no way to know how an incorrect laboratory result was resolved or why a practitioner believed it to be incorrect.

them?" Tr. 200. Further, he testified that the applicable standard of care requires the practitioner to document that conversation in the patient record "for the record[] to show that you've had this discussion," because "within the State of New Jersey, each time the patient comes in, you're supposed to assess the patient, to make sure that, A, that they're taking it. B, that it is efficacious, are there any side effects? And then, make a justification as to continuation of therapy." *Id.* at 201-202.

Dr. Epstein testified at several points that a urine screen that comes back negative for the controlled substance that was prescribed has two possible answers: "the patient used the medication, finished the medication;" or that "they're diverting it, that they're not using it at all." *Id*. at 1501-02. He testified that the urine screens of diverters would be positive for opioids, because Respondent was conducting regular and predictable urine tests, so diverters would know to "take the oxycodone for three or four days so that they develop a blood level and the metabolites" to avoid detection, because "[t]hey're not stupid. They're making a lot of money at this." *Id.* at 1502. Later, Dr. Epstein stated, "There's zero way to defend against patients selling half or a third of their medication" and that because of the low dose "if it was positive on every urine tox, [he] would actually kind of wonder about that . . . how did they have enough to take this all the time." *Id*. at 1566. Dr. Epstein later testified that he had not "thought about the one that [the Government] came up with, which is they're putting them—they're—they're hoarding which, honestly, I hadn't really thought of as a possibility." *Id*. at 1584.[28] He also testified that

[28] Reading the transcripts, I find it difficult to agree with the ALJ's assessment of Dr. Epstein's testimony when he stated that it was "far more cogent and convincing than was Dr. Kaufman's" on the issue of counseling and documentation. RD, at 116. The ALJ seemed concerned with "why the standard of care required documentation of counseling about an inconsistent urine screen." *Id.* at n.64. The policy rationale for the requirements can be useful in understanding the applicable standard of care, but it should not be used to confuse the evaluation of what the applicable standard of care actually requires, particularly regarding bright line issues such as the documentation of counseling. Additionally, as shown here, Dr. Epstein's rationale about diverting patients who are purposefully taking the medication before the test to not raise suspicion at his own admission did not consider patients who might

the applicable standard of care on an inconsistent urine screen is based on "being judicial" and asking whether the patient has a "good excuse." *Id*. at 1504. He testified later that the applicable standard of care for a patient who has doubled the medication is to say "that's dangerous, you should not do that, why did you do that. Said my pain was completely out of control. You—you counsel them. You tell them not to do that . . . ." *Id*. at 1575. His testimony does appear to agree with Dr. Kaufman that inconsistent screens require counseling. In contrast with Dr. Kaufman, Dr. Epstein testified that documenting the conversation after inconsistent urine screens is a "best practice," as opposed to the standard of care, and that "[i]t should be done, [b]ut it's not technically standard of care." *Id*. at 1629-41; *id.* at 1630-31.

Much of Dr. Epstein's testimony was aimed at justifying why addressing an inconsistent urine screen is not, in his view, critical in preventing the diversion of opioids, but the issue in this case is whether the applicable standard of care in the State of New Jersey requires a practitioner to address an inconsistent urine screen, including with counseling, and whether and to what extent the practitioner must document an inconsistent urine screen.

Support for the credibility of Dr. Kaufman's testimony is that, beginning on March 1, 2017, a New Jersey regulation required that a physician prescribing controlled substances for the treatment of chronic pain enter into a pain management agreement with the patient and monitor the patient's compliance with that agreement to include documentation of any breaches that indicated that the patient was not taking the medication as prescribed. *See* N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020). I find that the existence of this regulation fully supports Dr. Kaufman's testimony that, after an inconsistent urine screen, the applicable standard of care in New Jersey requires the practitioner to counsel and document the resolution of the inconsistent

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be hoarding or patients who are addicted and are taking too much of the medication at once. Tr. 1584. I did not find Dr. Epstein's testimony on this matter to be cogent or convincing.

screen, and after March 1, 2017, this practice was also required by law. Even though the regulation was not in effect for the entirety of the period of violations alleged in the OSC, its existence undermines Dr. Epstein's testimony regarding the applicable standard of care for inconsistent urine screens in this case, some of which occurred after the regulation became New Jersey law. This regulation had been in existence for a year and a half prior to Dr. Epstein's testimony and the language of the regulation clearly requires documentation not just as a "best practice." Therefore, I credit Dr. Kaufman's testimony regarding inconsistent urine screens over Dr. Epstein's and find that documentation of the resolution of the inconsistent urine screens is required under the applicable standard of care in New Jersey.

a) Whether Counseling Regarding the Inconsistent Urine Screens Occurred

The Respondent dedicated substantial time in proffering that she always counseled her patients regarding negative urine screens through her own testimony and that of her patient J.C. *See e.g.,* Tr. 805, 813, 853, 935, 1343-45. The ALJ did "not find that the Government met its burden of proving that [Respondent] did not counsel her patients, rather the weight of the evidence establishes that [Respondent] routinely counseled her patients about the results of their urine screens." RD, at 115. In coming to this conclusion, the ALJ credited the video recording and transcript of Respondent's fourth visit with the UC, in which she said, "your urine last month did not show any medicine," and when the UC said that it wasn't "lasting [her]," Respondent asked how many she needed in one day and increased her dosage. GX 15, at 5; RD, at 115, 149. The Government argued that the ALJ erred in determining that this statement constituted counseling and that he "improperly substituted his medical opinion for that of the medical experts," because the Government's expert provided testimony that the applicable standard of

care requires more than just identifying an issue. Govt Exceptions, at 2-3.[29] When asked about these statements that occurred during the UC's fourth visit, Dr. Kaufman credibly testified that Respondent "rightly questioned why a urine screen that they did came back negative." Tr. at 185. However, Dr. Kaufman also testified that this interaction did not meet the applicable standard of care for counseling a patient with an inconsistent urine screen, because he stated, "[I]f the patient is telling me, well, it's not lasting, and if the patient is saying that the pain is getting worse, I need to investigate why is the pain getting worse, not just say, well, here's another prescription, you need to make it last." *Id*. at 187-188.

Respondent testified that when a urine test comes back clean, she would state, "Last month's urine was – didn't show any of your – any medication, why is that? And, when was the last time you took your medication? How often are you taking it? Are you taking it every – like I wrote it?" *Id*. at 978. She further testified that she would ask, "How are you taking it? Like I'm prescribing it? Did you take more? Do you have any left? Did you go to the emergency room for any reason?" *Id*. at 979. Additionally, she argued that she would tell her patients that if they continued to have inconsistent urines, she would stop prescribing them opiates. Resp Posthearing, at 35 (citing J.C.'s testimony at 1343, 1345). The interaction with the UC demonstrates that she asked one or two of the questions that she said she always asks, but none of the follow up questions or the potential consequences. Her videotaped questioning of the UC regarding her inconsistent urine did not even meet what she had described as her own practices after an inconsistent urine screen.

In the case of patient records, it is impossible to know for certain one way or the other whether the counseling occurred if it was not documented. The evidence in the record shows

[29] This particular interaction between Respondent and the UC was not included in the Government's allegations and therefore, it is only being considered as evidence to show whether Respondent regularly counseled her patients.

that the UC was partially counseled once for her inconsistent urine screen, but the Government presented evidence that that counseling did not meet the applicable standard of care, nor was it documented. The ALJ found and I agree that the Respondent and her patient J.C. had dubious credibility, but the ALJ still deferred to them both that the counseling occurred. The windows through which we can clearly see what likely occurred are the recorded visits between Respondent and the UC, where the Government has demonstrated that the Respondent did not adequately counsel and that her recordkeeping was unreliable. *See, e.g.*, GX 18, at 2 (counseling not to smoke noted in the patient file but did not take place according to video recording and transcript of visit); GX 18, 19, 21, 23, 25 (physical examination noted in the patient file did not take place according to the video recording and transcript of the visit). Therefore, the record shows that Respondent did not always counsel her patients as she repeatedly testified. *See* Tr. 805, 813, 853, 935. Despite the record's demonstration that Respondent did not counsel her patients as she claimed, this deficiency in Respondent's practice is not determinative, because even if appropriate counseling occurred, Respondent did not document required counseling in most instances, the exceptions being a few alcohol-related instances.[30]

b) Timing of an Inconsistent Urine Screen

Establishing that the applicable standard of care in New Jersey requires a practitioner to address and document an inconsistent urine screen, the Government put forward evidence attempting to establish a timeframe for when the patient's negative urine screen would be considered inconsistent and thus the lack of documentation of counseling would implicate a

[30] Dr. Kaufman testified that if counseling is not documented, it did not happen. RD, at 115 (citing tr. 485-86, 632). The ALJ stated that "that premise . . . does not exist in a vacuum." Although I do not disagree with the ALJ that the distinction can be meaningful, the effect of a finding that Respondent *did* counsel her patients for the majority of noticed instances only would mitigate the overall egregiousness of the prescriptions that violated the applicable standard of care and, as explained in *infra* Sections III and IV, I find that the violations solely based on the lack of required patient file documentation are egregious enough to call for revocation, particularly in light of the fact that the Respondent did not accept responsibility.

violation of prescribing beneath the applicable standard of care. Dr. Kaufman testified that a negative urine screen would be consistent if the patient came back thirty-five days after being issued a thirty-day prescription for oxycodone, because the oxycodone would likely no longer be in the patient's system. Tr. 206-07; 494. Dr. Kaufman further testified that if a prescription for thirty days was filled within thirty-three days of the negative urine screen, it would be inconsistent. *Id.* at 208; 497 ("I would still expect to see that . . . 33 days. 34 days, probably not."); *see also id.* at 652 (confirming that at thirty-three days, Dr. Kaufman would expect to see metabolites for opioids). The ALJ found that Dr. Epstein testified that some individuals metabolize opioids in one-to-two days. RD, at 122 (citing tr. 1501-02). Dr. Epstein's testimony was more focused on the reasons to be concerned about the negative urine screen than on setting a specific timeframe, but he did state that "if it's more than about 33 days since it was filled, then at that point, I'm not concerned." *Id*. at 1501. When pressed, Dr. Epstein testified that "the appropriate measuring stick" for negative urine was the date the prescription was filled but was "not a black and white." *Id*. at 1530. Later, Dr. Epstein testified that he would not be surprised if a patient's urine was clean after a prescription for sixty pills, with a maximum of two per day on day thirty, because "patients are going to sometimes hurt and sometimes not" and "my patients will have a week or two that they don't use any meds." *Id*. at 1552. He further said that "a red flag is someone that never misses," but when asked by the ALJ if what he was stating was that a patient taking medication as prescribed would be concerning, Dr. Epstein said that was not his "intent." *Id*. at 1552, 1553. He stated that he cannot write a prescription for "p.r.n." six times a day and give sixty pills, because the pharmacy will flag it as not enough pills, but that he wants the pills to "average out to no more than twice a day by the end of the month." *Id*. at 1554-55.

Despite Dr. Epstein's testimony about what would "concern"[31] him regarding negative urine screens, he generally testified that when there is "an inconsistent UTOX, your first response is to reevaluate it and to—and to—combine that information with what else you know about the patient and with what their status is, why you're giving the drug, how they're responding to it, and—and—and whether everything else about them seems reasonable." *Id*. at 1590-91.

The ALJ found that the Government "has the burden of proof to establish when a urine screen is inconsistent" and that "[t]he Government chose to meet its burden by offering evidence of an estimate of when the results of a urine screen would be inconsistent." RD, at 122. I agree with the ALJ's statement, but I do not believe that the record supports his finding that the date that was established is "up to and including 32 days prior to providing a urine sample."[32] *Id.* Both Dr. Epstein and Dr. Kaufman testified that if it is *more than* about thirty-three days, they would not be concerned. Tr. 1501 (Epstein); *id*. at 652 (Kaufman).[33] Therefore, I find that the record in this case has established that a urine screen becomes inconsistent with a thirty-day prescription when it is negative for the prescribed controlled substances more than thirty-three days after the fill date.[34]

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[31] Throughout Dr. Epstein testified about when a red flag might be a "concern," but it is unclear what the result of the concern would be. In some cases he appears to be discussing discharge of the patient and sometimes he says "maybe I'm concerned and concerned enough to—to take a good look at it" and "we would not stop prescribing." Tr. 1559. It is difficult to distinguish in his testimony when a practitioner's concern would require counseling, and it is another reason why I find Dr. Kaufman more credible on this matter, because he was clearer about what the concern is and what the concern requires under the applicable standard of care.

[32] Even if I did agree with the ALJ, only two prescriptions are affected by my finding (one to Patient J.C. and one to Patient A.P. (but which I still find was issued beneath the applicable standard of care due to lack of counseling on a positive alcohol test)) and if I were to reverse my finding on the one prescription to J.C., it would in no way affect my overall recommendation of sanction in this case.

[33] Respondent characterizes Dr. Epstein's testimony as a screen taken thity-three days after a thirty-day prescription was filled, but he actually stated that "more than about 33 days," which is also consistent with his one-to-three day estimate. *See* Respondent's Posthearing, at 32.

[34] I find this fact reluctantly and emphasize that I find it only in the context of the evidence presented in this case, because the Government presented its evidence using a bright line rule regarding when to consider a urine screen as triggering the requirement for documentation. When a patient's urine is negative for opioids, even when the amount of the prescription should have reasonably been out of the patient's system, it would still make logical sense that a practitioner should address why the patient did not need the medication, did not go into withdrawal etc. Although bright line rules can be useful, Dr. Kaufman testified that the purpose of the monitoring and documentation

c) Level of Documentation Regarding Inconsistent Urine Screens

The Respondent also posed arguments regarding the level of documentation that is required when there is an inconsistent screen. Respondent argued that the automatic counseling note that she included in combination with the maintenance of the results of the urine tests in the patient's record constitute adequate documentation of the counseling and the fact that the screen was addressed. *Id*. at 1026-1027. She further argued that her documentation system, eClinical, would not permit her to type information into the plan section, but she admitted that she could have typed information into other sections. *Id*. at 914-15; RD, at 45. The regulations require that when there are any breaches of the pain management agreement that demonstrate that the patient is not taking the medication as prescribed, the practitioner must "document within the patient record the plan after that discussion." N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020). It is clear from a plain reading of the regulation that the requirement for documentation is greater than just recording the urine results, and that there needs to be a documented plan as well. *See infra* III(A)(1)(b)(ii) or further discussion. The regulation further bolsters Dr. Kaufman's testimony that Respondent's counseling notes that she selected to autopopulate in eClinical were not adequate under the applicable standard of care. Specifically, he testified regarding the counseling notes that "it was not counseled—I don't see a statement in here, which I've stated before, that there was the medication need to be taken as directed, that you need to not double up on the medications, because that's going to put you at risk for other issues. I don't see that statement here." Tr. 612; *see also id* at 610. Dr. Kaufman clarified that the eClinical automatic entry that appeared in many of Respondent's records and stated "take your medication regularly"

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requirement is to ensure that the patient is taking the medication as prescribed and is not diverting or abusing the medication, and to determine whether continuation of the prescribing is warranted and "to make a justification as to continuation of therapy." Tr. 202.

means only "you take it on a regular basis." *Id*. at 612. These notations do not indicate any plan to address the failure of the patient to take the medication as prescribed, and therefore, I find that these notations are inadequate documentation under the applicable standard of care in New Jersey.[35] I agree with the ALJ's ultimate finding that the applicable standard of care in New Jersey requires "a practitioner to document the cause and resolution of inconsistent urine drug screens, as well as the practitioner's discussion with the patient about the urine drug screens." RD, at 117.

d) Whether a Patient Must be Dismissed for Inconsistent Urine

In this case, I find that Dr. Kaufman and Dr. Epstein were generally in agreement that the matter of what a practitioner is required to do when the urine screen is inconsistent is not "black or white," and where the toxicology screen is negative, the issue is not necessarily whether the practitioner stops prescribing the controlled substance. *Id*. at 1609. Dr. Epstein testified that "[t]he standard of care is to counsel them. The standard of care is to reestablish the norm and to determine if you need to change the dosage, change the treatment, change the medication, do any of those things that you need to do to get them under control if they're not already." *Id*. at 1585. Dr. Kaufman testified that a patient who admitted that he or she "doubled up on a few days during the month" would not disqualify the patient from getting another prescription, but would

[35] In further support of Dr. Kaufman's testimony, the New Jersey Office of Administrative Law has specifically held that "summaries pieced together from memory long after the events sought to be recorded cannot substitute for timely record-keeping." *In the Matter of the Suspension or Revocation of the License of Magdy Elamir, M.D., License No. 25MA41404, to Practice Medicine and Surgery in the State of New Jersey,* OALK Dkt. No. BDS 01663-10 (Decided August 26, 2014). Respondent testified that one could conclude from her records when the prescription was issued despite the inconsistent urine screen that she "had a good, good reason to write the next script;" however, she also testified that she could not remember the results of her discussions. Tr. 1027; 1090-95 (Respondent testified that after L.M. tested positive for Suboxone three times in a row, she thought she had cut her dose, but she had not, and when asked for the reason, she stated, "I don't remember, sir.") Piecing together conclusions *post hoc* is not adequate recordkeeping to be able to understand the reason that she wrote the script or establish a plan moving forward. *See infra* Section III(A)(1)(b)(ii).

instead instigate questions from the practitioner to "elucidate why this increase in pain occurred and treat it appropriately." *Id*. at 643. Overall, I find that the substantial evidence on the record demonstrates that the applicable standard of care in New Jersey, as verified by the regulation, requires that the inconsistent urine screen be addressed, counseled, and documented. *See* N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020).

e) Positive Urine Screen for Non-prescribed Controlled Substances

Dr. Kaufman credibly testified that when the patient tests positive for a non-prescribed controlled substance, the applicable standard of care in New Jersey requires the practitioner to address the urine test with the patient and "to document their conversation in the medical record."[36] Tr. 241, 244 (he would expect to see specific discussion of the other controlled substance in the medical record on the subsequent visit). This concept is further supported by the New Jersey regulation requiring a practitioner to address breaches of pain management agreements and document the plan. *See* N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020). Dr. Epstein testified that when the PMP shows prescriptions for opioids about which he was not aware, it would be a concern, but for certain types of opioids "then that's okay as long as I know that's happening." *Id*. at 1594. Regarding fentanyl, he testified that upon a second test[37] within a limited timeframe demonstrating a non-prescribed controlled substance, "you would speak to

[36] Respondent argued that sometimes the laboratories err in showing positive urine screens and the urine must be retested; however, I saw no evidence in the record of screens being retested shortly after showing positive results for non-prescribed substances. *See* Resp Posthearing, at 43. Additionally, the fact that a screen might be inaccurate does not change the applicable standard of care as Respondent implies, but instead seems to highlight the need for documenting the resolution of the screens to ensure that the patient records are accurate as to what has actually occurred. *See* Resp Posthearing, at 43. I also find this argument unavailing, because if the screens were so inaccurate that they would not help Respondent identify issues with her patients, I do not understand why she ordered them every month at her own expense.

[37] It was unclear from his testimony whether he believed the applicable standard of care would require a conversation with the patient after a first positive test for fentanyl. He seemed to imply that a practitioner could assume that fentanyl was from a surgical procedure upon the first positive test, but the question of whether the practitioner would be required to discuss with the patient was not answered due to a sustained objection. Tr. 1598, 1600.

the patient, you would try to figure out if there was a reason for it, you know, if there was some sort of—you know, they had had other tests . . . ." *Id*. at 1604. Although Dr. Epstein did not explicitly testify that there needed to be a conversation with the patient about the screen, his testimony and findings imply that he would need to know what's "happening." *Id*. at 1594. He also stated that "[he has] to always explore" what is going on. Tr. 1604. The primary difference between the two experts was that Dr. Kaufman testified that the applicable standard of care required the practitioner to document the resolution of the positive screen and Dr. Epstein did not. Dr. Epstein testified, "There's actually no regulation anywhere that I know of in any state that says what needs to be, exactly says how the medical record, how much you have to put in." (Tr. 1630-1631). He also said that documentation is a "best practice. It's really not standard of care. Because it's not care. Okay. It's not care. It's best practice. And it should be done, you know. It should be done." Tr. 1631. New Jersey's regulations contradict Dr. Epstein's testimony.[38] The regulations require that practitioner shall "assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment" and "monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion." N.J. ADMIN. CODE §§ 13:35-7.6(f)(3), (f)(5). As already discussed, I find Dr. Kaufman to be more credible regarding documentation, and supported by New Jersey law.

f) Effect on Prescriptions After an Inconsistent Urine Screen

[38] Additionally, I do not find Dr. Epstein's testimony about the difference between what should be done and what is care to be convincing, because he also testified that "[i]t's about providing the best possible care for the most possible people . . . ." Tr. 718 (Dr. Epstein describing the standard of care).

Although the Government originally alleged in the OSC that every prescription after the initial prescription demonstrating an inconsistent urine screen was outside the usual course of the professional practice and beneath the applicable standard of care, Dr. Kaufman contradicted that allegation, stating "[a]ny subsequent ones, if they're having positive urine screens, would be appropriate. The one that was issued directly right after this urine screen would not be because this was not addressed." *Id*. at 250. Therefore, like the ALJ, I am only considering the prescriptions issued directly after an inconsistent urine screen. *See* RD, at 145.

4. Documentation of Alcohol Counseling

Dr. Kaufman testified that in order to meet the applicable standard of care in New Jersey a practitioner who was confronted with a urine screen that was positive for alcohol metabolites would need to "discuss it with the patient and discuss the risks of alcohol with the use of opioids, of opiates, and to tell him to stop drinking" and would need to document that discussion in the record. Tr. 212. Dr. Epstein testified that mixing oxycodone and alcohol is a "very, very bad thing," and a practitioner must counsel his patient, and "the standard of care is that, you know, if you're going to have a drink you shouldn't be doing it at the same time you're taking this pill." *Id*. at 1636. The Respondent does not dispute the ALJ's finding that a doctor must counsel a patient who has been prescribed an opiate and also has alcohol metabolites[39] in his urine about the dangers of concomitant alcohol and opioids. RD, at 120; Resp Exceptions, at 15 ("Respondent does not disagree with this statement.") Dr. Kaufman testified that a prescription

[39] Throughout the hearing, there was discussion about the difference between alcohol and alcohol metabolites on the urine screen and whether the presence of the metabolites indicated less of a concern than the presence of alcohol. *See, e.g.*, tr. 1632. Dr. Epstein testified that an alcoholic's urine would show more than just metabolites, but his testimony seemed to be focused on alcoholics, because alcoholism was relevant to whether or not a practitioner be required under the standard of care to stop prescribing opioids "because it's addictive behavior." Tr. 1634. More importantly, he testified that you have to counsel about the dangers of mixing alcohol and opioids even when the urine shows metabolites. Tr. 1636. I am setting aside the issue of metabolites, because I am only making findings on the counseling and documentation, not the dismissal of the patients, and furthermore, Respondent has conceded that a doctor must counsel when metabolites are present. Resp Exceptions, at 15.

on May 5, 2017, to Patient A.P. was not issued within the usual course of the professional practice in New Jersey, because the "positive alcohol screen . . . was never addressed." Tr. 213. He testified that one time drinking alcohol might not be problematic, but that "you have to explain the dangers of doing that. One drink combined with one opioid can cause an overdose, just once. You may not get a second chance. You can be dead." *Id*. at 482. He also testified numerous times that documentation of the alcohol counseling was essential. *Id*. at 485-86 ("If it's not in the record, it didn't exist, because then you can't substantiate that. That's very important in medicine. That's how we talk to one another.")[40] [41]

Additionally, Respondent testified that when alcohol appears in a drug screen, her usual practice is to counsel the patients and insert the alcohol entry for counseling in e-Clinical. *Id*. at 1013. She admitted that she may sometimes fail to click on the alcohol entry, because she is "not 100 percent." *Id*. at 1013-14. Respondent's own practices demonstrate that she knows that documentation of the alcohol counseling is important, and furthermore, her system includes a shortcut key that permits her to specify that the alcohol-specific counseling occurred. *Id.*

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[40] Dr. Kaufman's testimony was clear about the requirement under the applicable standard of care to counsel regarding alcohol and the requirement to document that counseling. *See* tr. 212. However, he also testified that a practitioner must cease prescribing opioids in the face of urine screens consistently demonstrating alcohol metabolites, and he stated that the standard of care required a practitioner to counsel twice regarding alcohol before terminating the medication. *Id*. at 471-473; RD, at 43. The ALJ found that this testimony "undercuts his own testimony concerning several of the prescriptions to A.D. and S.W." RD, at 119. I agree with the ALJ that Dr. Kaufman's testimony regarding when to terminate a patient was confusing, and because of that confusion, I am not finding any violations on the basis that any of the patients' prescriptions should have been terminated for positive alcohol tests. However, I do not find that he undercut his previous testimony, because Dr. Kaufman was testifying about two different scenarios under the standard of care. In one scenario, he was testifying that a particular prescription "was issued in light of positive urine screen for alcohol, which was not addressed at all." Tr. 251; 251-256; 257 ("in light of an aberrant urine screen, there was no counseling.") In the other scenario, he was responding to Respondent's counsel's question "assuming a person follows the standard of care and counsels against using alcohol or other drugs . . . they can then prescribe maybe another prescription for narcotics, is that right?" Tr. 467.

[41] New Jersey's regulation (d) requires a discussion about risks that shall include "the danger of taking opioid drugs with alcohol" before the initial prescription and prior the third prescription and additionally states, "The practitioner shall include a note in the patient record that the required discussion(s) took place." N.J. ADMIN. CODE 13:35-76(d). Although this regulation does not specifically require that alcohol counseling must occur upon a positive urine screen, and is therefore not being alleged as a regulatory violation in this case, it does very specifically state that the counseling must be documented.

Finding that counseling and its documentation is required when a urine screen shows alcohol metabolites, I also agree with the ALJ's finding that Respondent's selection of alcohol specific counseling is adequate to document the counseling. RD, at 124 n.68. Dr. Kaufman agreed that the "counseling, alcohol and drugs . . . documented in the patient record . . . would [] be an appropriate way to deal with an alcohol screen." Tr. 214. This is further supported by the language in the state regulation regarding alcohol counseling that requires that the record "note" that the discussion took place and not the substance or the plan after that discussion. N.J. ADMIN. CODE 13:35-76(d). In sum, I find that when a urine screen tests positive for alcohol metabolites, the applicable standard of care in New Jersey requires that a practitioner counsel regarding the dangers of alcohol and opioid use and document that counseling, and further that noting that the alcohol-specific counseling occurred is adequate for purposes of this case.

F. Allegations of Issuing Prescriptions Outside of the Usual Course of the Professional Practice and Prescribing Below the Applicable Standard of Care in New Jersey

Having read and analyzed all of the record evidence, I agree with the RD's conclusion and find that the substantial record evidence that Respondent prescribed controlled substances outside of the usual course of the professional practice and below the applicable standard of care in New Jersey. RD, at 139. The ALJ sustained the Government's allegations with regard to the five Vicodin prescriptions Respondent issued to the UC, and twelve of the twenty-one prescriptions that Respondent issued to patients A.P., J.C., L.M., M.W., and S.W. *Id.* In all, the ALJ found, and I agree, that "between April 27, 2016, and March 8, 2018, [Respondent] issued a total of seventeen prescriptions on seventeen different occasions, to a total of six patients, which were issued outside the usual course of the professional practice and beneath the applicable standard of care in the State of New Jersey." *Id.* Although I agree with the ALJ's findings regarding these prescriptions, I make some additional findings as further explained below.

1. UC

The ALJ sustained the Government's allegations that Respondent issued five prescriptions for hydrocodone-acetaminophen (Vicodin), a Schedule II controlled substance, to the UC between November 23, 2016 and April 4, 2017, outside the usual course of the professional practice and beneath the applicable standard of care for the State of New Jersey in violation of 21 C.F.R. § 1306.04(a), because she failed to conduct a physical exam at each of the UC's visits.[42] RD, at 122-23; OSC, at 2. At each appointment, the UC complained of right shoulder pain or tightness. RD, at 46 (citing GX 18, 19, 21, 23, 25, 27; Tr. 46, 51, 56-57, 62, 66, 75, 100). The ALJ found, and I agree, that the allegations were proven through the testimonies of Dr. Kaufman and Dr. Epstein,[43] and to a lesser extent through Respondent and Dr. Gutheil based on the applicable standard of care in New Jersey. RD, at 122-23. Dr. Kaufman credibly testified that the applicable standard of care in New Jersey required a physical exam prior to prescribing controlled substances, and that Respondent should have "examine[d] the shoulder where the primary complaint was, other than observing the patient." Tr. 391. He further explained that a minimal physical examination of the shoulder is "certain maneuvers such as a Neer's test, a Hawkins' test, an Apley's test, an O'Brien's test, a reduction of the shoulder,

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[42] The Respondent's treatment notes for each visit with the UC indicate that physical examinations were performed on each visit; however, the UC testified that they did not and the video recordings did not demonstrate palpation or otherwise adequate physical examination. Tr. 176; GX 29.

[43] As the ALJ noted, Dr. Epstein initially testified that prescriptions to the UC met the standard of care; however, in formulating his opinion, it was clear through his testimony that he had relied on the treatment record for UC, which had detailed a physical exam, which the Government proved through video evidence and testimony did not occur. *See* RD, at 122 (citing tr. 1435; tr. 1614; GX-6). "Dr. Epstein testified that his opinion would change . . . if [Respondent] had not conducted a physical examination." RD, at 123 (citing tr. 1527). *See also supra* II(E)(2).

intrinsic rotation of the shoulder, palpation of the AC joint, palpation of the bursa, palpation of the muscle; basic shoulder exam."[44] *Id*. at 378.

During the hearing, Respondent admitted that she did not palpate the UC's shoulder or touch the UC. RD, at 122 (citing tr. 878-79).[45] Additionally, the UC credibly testified that Respondent did not give her a physical exam or touch her on any of the visits. Tr. 45, 51, 57, 62, 66, 75. Respondent argued that observation of the patient, his or her presentation, speech, and carriage was part of the physical exam, which Dr. Kaufman conceded may be a "small component," but is "woefully inadequate and below standards." *Id*. at 386, 390. Dr. Kaufman further testified that a physical exam is required each time controlled substances are issued based on the applicable standard of care and the regulation, which "stipulates that an appropriate physical exam must be conducted." *Id*. at 399. When asked if a physical examination was still necessary if a physician had a recent MRI showing a problem, Dr. Kaufman testified that "[i]t's still necessary." *Id*. at 397.

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[44] Respondent argued that "Dr. Kaufman could not explain the minimum examination required for a shoulder complaint." Resp Exceptions, at 13. Respondent's argument taken in context of the transcript is not convincing. When pressed by Respondent's attorney to quantify how many of those nine tests would constitute and minimal shoulder examination, Dr. Kaufman stated, "There is no strict number, whether you need to do two or three or four, but you need to do something" and then stated, "You need to do something to elucidate what the problem is." Tr. 379. Respondent's attorney then asked, "Maybe one thing?" Dr. Kaufman responded, "One thing is not enough. If you do one thing, you're only checking one aspect of the shoulder." *Id.* Respondent's attorney continued to push to try to find out "what [Respondent] needed to do to meet the threshold where you would say, No, this was okay." *Id*. at 380. Dr. Kaufman answered, "She didn't do anything." *Id.* The facts demonstrate that Dr. Kaufman specifically testified to the components of a standard shoulder examination and he credibly testified that the number of tests that would need to be included in an examination of the shoulder to meet minimal standards is not essential in this instance, because Respondent did not conduct *any* of these tests on the UC. The argument that Respondent conducted part of a physical examination does not change Dr. Kaufman's credible testimony that any such examination was beneath the applicable standard of care in New Jersey.

[45] Respondent's testimony directly contradicted a portion of the video that her attorney attempted to argue that she may have briefly touched the UC. Tr. 868. Later, it is noted that the attorney asked Respondent about her inconsistent statements with regard to whether she touched A.P. and she stated, "I saw her in 2016, so my memory is not that great." *Id*. at 1017. Upon reviewing the video, I agree with the ALJ's statement in the hearing that this movement is "pretty insignificant given the fact that there was a desk between the two of them." *Id.*; GX 6, 0320.010, at 9:53-9:57.

Respondent argued that she had required the UC to obtain a new MRI before prescribing controlled substances, and she testified that when she reviewed the second MRI, she was able to make a diagnosis that the UC had arthritis. *Id*. at 823-24; GX 29, at 24; Tr. 865 (Respondent testified that because pain is subjective, she relies on results of MRIs "about 90 percent of the time"). However, Respondent did not include her alleged diagnosis of arthritis in the UC's treatment notes. RD, at 57 (citing GX 19[46]). Instead, the assessment section lists "pain in right shoulder" and "chronic pain syndrome." GX 29, at 13; tr. 1057-58; RD, at 57. Further, Respondent's own recorded statements at the UC's third appointment undermine her testimony that she had made a diagnosis based on the second MRI.[47] Tr. 824. In the recorded conversation, the UC reminded Respondent that she received a new (second) MRI, "[c]ause I got—from the first time to the second time, I got a different—I got uh, updated MRI," and Respondent replied, "Right. And [it] still didn't show anything, sweetheart." GX 14, at 11; *see also* RD, at 59.[48] This statement clearly undermines Respondent's testimony that she had a clear diagnosis from the MRI to justify prescribing to the UC.[49]

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[46] GX 19 is a one page extract of the UC's second visit. The same record is also found in GX 29, at 13.

[47] Despite this claim, Respondent responded affirmatively to the question, "Couldn't you have learned more from a physical examination?" Tr. 824-25.

[48] Further, in defending the lack of physical examination, Respondent stated, "[I]n my clinical judgment, the way I observed [UC], even second time, third time, fourth time, [UC's] arm, the range of motion was good. And, I prescribed her the little amount that I thought was sufficient." Tr. 1067. It is unclear to me even from Respondent's testimony what her justification was for the prescriptions she issued to the UC. Additionally, this statement undermines her argument that she performed the physical examination by watching the UC, because the UC patient records list under Physical Examination, "Right Shoulder Tenderness," which would imply that Respondent saw something indicating tenderness during her observation. *See, e.g.,* GX 18, at 1.

[49] Respondent did mention arthritis in some of the UC transcripts, which she appeared to base on the MRI. *See, e.g.*, GX 13, at 7. However, on several subsequent visits, during which she prescribed controlled substances, she did not seem to have access to the MRI before she made any of the prescribing decisions. On December 22, 2016, she asked, "[T]he reason we were giving you narcotic, we discussed that before, right? It was for what reason, sweetheart?" And then, "I mean, what was your diagnosis with the other doctor? I got me some records, right, before?" GX 14, at 11. On the same visit, Respondent said she could not increase the dosage without x-rays showing something and she never seemed to find the MRI. *Id.* She stated, "If it's just bursitis, I can't do it." *Id.* at 13. On January 19, 2017, she asked, "[W]ere you able to give me the MRI of the ankle, right from the place?" UC asked, "Ankle? No, that wasn't me." Respondent said, "Soft tissue injury, you had…sorry, not ankle, the shoulder." GX 15, at 5. Again, on March 7, 2017, Respondent asked the UC, "I didn't have any MRI's, nothing

After reviewing the record evidence, including the video and audio recordings of the UC's visits with Respondent, I agree with the ALJ's finding that, Respondent did not perform an adequate physical examination of the UC at any of the UC's appointments. RD, at 46.

Based on the fact that Respondent did not perform an adequate physical examination, as required by the applicable standard of care in New Jersey, the ALJ found, and I agree, that the prescription for Vicodin issued to the UC at her second appointment on November 23, 2016, was issued outside the usual course of the professional practice of medicine. RD, at 58 (citing Tr. 179-80, 878-79, 1442; GX 20). Additionally, I agree with the ALJ that the prescriptions Respondent issued to the UC for: Vicodin on December 22, 2016; Vicodin on January, 19, 2017; Vicodin[50] on March 7, 2017; and Vicodin on April 4, 2017, did not meet the applicable standard of care in New Jersey and were issued outside the usual course of the professional practice of medicine, because Respondent never performed a competent physical examination of the UC. RD, at 62, 64, 68, 71 (citing GX 22, 24, 26, 28; tr. 191-93, 195, 878-79, 1442).

The ALJ did not sustain the alleged violation of the applicable standard of care that Respondent recorded the results of a complete physical in the UC's medical record, even though

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from you, right?" GX 16, at 9. These statements further contradict Respondent's testimony that she relied on the UC's MRI in lieu of a physical examination as a basis for her prescriptions.

[50] Although the ALJ found that on March 7, 2017, the Respondent's issuance of the prescription for tramadol (brand-name Ultram) did not meet the applicable standard of care in New Jersey, the ALJ ultimately did not sustain a violation related to tramadol, because the Government failed to allege the violation associated with this prescription in the OSC or either of its prehearing statements. RD, at 101 n.49. I agree with the ALJ that the Government did not mention the prescription for tramadol or Ultram in any of its prehearing documents, nor did it count this prescription in the number of violations related to UC. The Government argued that it raised the Ultram prescription specifically during the hearing, in which Dr. Kaufman testified that the prescription was issued below the applicable standard of care, and therefore it was litigated by consent. Govt. Exceptions, at 8, n.3 (citing Tr. 191-192); *see also* Govt Post Hearing, at 4. The analysis of litigation by consent is fact specific. *See Farmacia Yani,* 80 Fed. Reg. at 29,059. "'An agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.'" *Id.* (quoting *Yellow Freight System, Inc. v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992)). The Government had ample opportunity to include this prescription to its own undercover agent and, in this case, Respondent's counsel did not indicate any sort of consent other than failing to object, so I am not sustaining this allegation. *See* tr. 191-191.

the exam did not occur. RD, at 139. He reasoned that he could not find a recordkeeping violation "because it was not alleged as a separate violation in the OSC, and the Government did not detail in either of its prehearing statements how this false entry was a separate violation." *Id.* The Government did not take exception specifically to this finding, but urged that the false recordkeeping demonstrated that "Respondent's medical records grossly overstate the care provided." Govt Exceptions, at 20. The Government laid out numerous inconsistencies in the records, related to when Respondent's records for the UC reflect that counseling occurred, when the transcripts demonstrate that it did not. *Id.* at 21-22; *e.g.*, tr. 52 (UC confirming no counseling occurred); GX 18, at 2 (Respondent's medical record for UC noting that counseling about medication and smoking occurred). I agree with the ALJ that there was no specific violation alleged with regard to falsely documenting the physical examination, and therefore, I concur with the ALJ and sustain no violation on that account. I also agree with the Government that the fact that the UC's medical records reflect a detailed physical exam that was not, in fact, conducted, and counseling that never occurred,[51] casts serious doubt upon the other records Respondent maintained and is relevant to the Respondent's overall credibility.

2. Patient A.P. Alcohol Allegations

The stipulated facts demonstrate that between and including June 6, 2016, and April 5, 2018, Respondent issued prescriptions for controlled substances to A.P. on twenty-three occasions. *See* Stipulations 4(a)-(v). In this time period, A.P. submitted a total of nineteen urine samples for screening. RD, at 73-74. The ALJ found, and I agree, that A.P.'s urine screens were positive for alcohol metabolites on May 5, 2017; July 8, 2017; August 10, 2017; September 7, 2017; October 5, 2017; and February 8, 2018. RD, at 75 (citing Stipulations 5(a), (c)-(f), (h);

[51] *See, e.g.*, GX 18, at 2 (smoking counseling noted that never occurred); GX 18, 19, 21, 23, 25 (physical examination never occurred).

GX 54, 60, 63, 69, 79). The ALJ found that on August 10, 2017, (following the July 8, 2017 alcohol metabolite positive urine test) and September 7, 2017,[52] (following the August 10, 2017 alcohol metabolite positive urine test), Respondent's patient records for A.P. indicate that she provided expanded and alcohol specific drug counseling. GX 61, 64. On direct examination at the hearing, Dr. Kaufman testified that A.P.'s patient notes for these visits demonstrate that specific discussions about alcohol counseling occurred on these two occasions. Tr. 214-15. Therefore, the ALJ found that the two prescriptions issued on these dates did not violate the applicable standard of care related to alcohol counseling. RD, at 75. I do not believe that Dr. Kaufman provided sufficient evidence to rebut the Respondent's arguments that this level of documentation with regard to alcohol screening was adequate under the applicable standard of care, and even though I have serious doubts regarding the credibility of Respondent's testimony and records in this case, I will concur with the ALJ and weigh alcohol-specific counseling documentation in her favor. However, the ALJ found, and I agree, that counseling occurred only when the patient records specifically indicated that alcohol counseling was provided. RD, at 124 n.68. Therefore, the prescriptions[53] resulting from the visits on October 5, 2017, (following the

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[52] Dr. Kaufman testified that the discussion on September 7, 2017, was appropriate for someone who had tested positive for alcohol two times in a row, but then testified that the prescription dated September 7, 2017, was not issued within the usual course of the professional practice, because Respondent "in her notes, clearly stated to the patient twice, do not use alcohol with drugs, do not use alcohol with drugs." Tr. 216. Respondent had issued the second warning to the patient on the date of this prescription. *See* GX 64, 65. At this point, although A.P. had tested positive three times for alcohol (May 5, 2017, July 8, 2017, and August 10, 2017), Respondent had only *documented* counseling the patient twice (one of which was on the day of the prescription in question). The ALJ pointed out what he described as an inconsistency, that in accordance with Dr. Kaufman's later testimony, the applicable standard of care does not require a practitioner to terminate the controlled substances on the third visit following two inconsistent urine screens. RD, at 125-26 (citing Tr. 472). The ALJ is correct about the substance of Dr. Kaufman's testimony, but I do not believe that this part of his testimony was inconsistent. The confusing matter in this instance is that this was, in fact, the *fourth* visit, not the *third* and there had been *three* urine screens demonstrating alcohol, not *two*. The discussion related to the first positive urine screen had simply not been documented or had not occurred. I note this merely to clear up what the ALJ considered to be an inconsistency with the Government expert's testimony; however, as stated previously, I am only finding violations for alcohol where counseling was not documented, not on the basis of dismissal. *See supra* note 39; *see also* RD, at 120.

[53] Respondent pointed out that there was an additional unalleged positive test for alcohol on October 5, 2017, but the prescription issued on November 3, 2017, was not addressed by the Government. Resp Posthearing, at 26 n.15; GX

September 7, 2017) and March 8, 2018,[54] (following the February 8, 2018 alcohol positive urine screen) were not issued within the applicable standard of care for New Jersey, because there was no documentation of the alcohol counseling. RD, at 126-127; *see also*, tr. 219-20 (Dr. Kaufman testified that "continued permissive alcohol use and continuance of opioids puts a patient in a dangerous situation. Therefore, it should not have been issued.") The ALJ did not sustain the allegations related to the June 8, 2017, prescription following the alcohol positive urine screen that occurred on May 5, 2017, despite the fact that Respondent did not document her alcohol counseling, because the ALJ did not believe it would be appropriate to terminate the prescriptions after the first screen demonstrating alcohol use. RD, at 124 (citing RD 117-20). I respectfully disagree with the ALJ's determination regarding this prescription. Dr. Kaufman testified that this particular prescription was not issued within the usual course of the professional practice for New Jersey because, the "positive alcohol screen . . . was never addressed." Tr. 213. As discussed previously, the ALJ had found the prescription on March 8, 2018, to be issued below the applicable standard of care in New Jersey, because Respondent "did not document what she told him about consuming alcohol while also taking a prescription opiate," which would be the same rationale for the June 8, 2017 prescription. RD, at 127. I find that Government has proven by substantial evidence that a prescription issued after a positive urine screen for alcohol with no documentation of alcohol counseling does not meet the applicable standard of care in New Jersey, and therefore, I find that the prescription issued on June 8, 2017, was also issued beneath the applicable standard of care. *See infra* Section II(E)(4).

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59. I agree that this was not appropriately alleged and will not include any findings on the November 3, 2017 prescription. The RD did not address this prescription either.

[54] Respondent alleged that the March 8, 2018 prescription was not alleged in the OSC; however, the prescription following the February 8, 2018 urine screen was noticed in the Government's Supplemental Prehearing statement. Resp Posthearing, at 26, n.15; Govt Supp Prehearing, at 5-6.

3. Patient A.P. Inconsistent Urine Screening

The ALJ found, and I agree, that Patient A.P. tested negative for opioids[55] on June 8, 2017, and January 8, 2018.[56] RD, at 73-74; GX 57, 73. The ALJ conducted a thorough evaluation of the New Jersey Prescription Monitoring Program (hereinafter, PMP)[57] records to determine the number of days between the date that the PMP indicated that A.P. filled the prescription[58] and the date that his urine tested negative for oxycodone. RD, at 73-74 (citing ALJX 45 (PMP), at 6). The ALJ analyzed these dates in a chart with the amount of tablets in the prior prescription to determine whether it was reasonable for Respondent not to have documented the inconsistent urine screen.

Dr. Kaufman testified that a January 8, 2018 urine screen that tested negative for opiates following a prescription that was issued on December 7, 2017, thirty-three days prior to the drug screen, was inconsistent, and therefore the prescription issued on February 8, 2018, following Respondent's knowledge of the results of that drug screen was issued outside the usual course of practice for the State of New Jersey. Tr. at 210. Dr. Kaufman reasoned that it was outside the usual course of the professional practice because "[t]hat urine screen was never addressed, it's

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[55] In the OSC, the Government "incorrectly alleged that A.P.'s urine screen of May 5, 2017, tested negative for oxycodone." RD, at 124 (citing ALJX 1, at 2-3). The Government's Supplemental Prehearing Statement concedes that this was incorrect. G's Supplemental Prehearing, at 2. The OSC does allege that all prescriptions after November 3, 2016, were issued outside the usual course of the professional practice without giving a rationale for this finding, so it appears that the Government might have mixed up the May 5, 2017 date with November 3, 2016 (*see infra* note 55), but I am not including findings on November 3, 2016, either because it was not adequately noticed. ALJX 1, at 3.

[56] The ALJ also included in his chart two other dates where A.P. tested negative for opiates, November 3, 2016, and April 5, 2018. RD, at 73-74 (citing GX 84, at 98 and 123). The Government did not allege any violations related to these two tests in the OSC, nor in either the Prehearing Statement or Supplemental Prehearing Statement or the Posthearing Brief. The ALJ does not address these two inconsistent urine screens in his final findings on the allegations, and I agree that this was appropriate, so I will not consider them.

[57] The Government introduced the PMP records in GX 2 and 3, and the ALJ presented an excerpt of the 6 patients' records to the parties for comment at the conclusion of the hearings, upon which he relied in his RD. Tr. 1646.

[58] It appears that on almost every negative urine screen in this case, the prescription was filled on the same date it was issued; therefore, I am only distinguishing the fill date where relevant, and I incorporate the RD's charts in this decision.

almost as if it didn't happen." *Id.* at 210-11. The ALJ found that because this urine screen was within thirty-three days of the fill date, there was no requirement for documentation of the screen, because he had found that the Government's evidence had only established the requirement at thirty-two days. RD, at 126. As explained above in *supra* Section II(E)(3)(b), I found that the Government established that the threshold for counseling and documentation of an inconsistent urine screen was more than thirty-three days; and therefore, I sustain the allegation that this prescription was issued beneath the applicable standard of care, because the Respondent should have documented a discussion with the patient about the inconsistent results and the plan to address it.

Dr. Kaufman testified that the urine screen on June 8, 2017, was inconsistent with the prescribed opioids; however, the ALJ found that the allegation regarding the prescription could not be sustained because it had been thirty-five days since A.P. had filled the prescription on May 5, 2017. RD, at 76. Due to the fact that the Government's expert testified that a negative urine screen would not be concerning thirty-three days after the prescription was filled, I agree with the ALJ that the Government has not proven that the prescription on July 6, 2017, after the results of the negative urine screen on June 8, 2017, was issued outside of the usual course of the professional practice and below the applicable standard of care in New Jersey, based on the negative urine screen.[59] RD, at 124-25.

Overall, with respect to Patient A.P, I find that the prescriptions issued on October 5, 2017; June 8, 2017; March 8, 2018 were issued below the applicable standard of care in the State of New Jersey, because there was no documented alcohol counseling, and the prescription on

[59] However, I find below that this prescription was issued beneath the applicable standard of care and outside the usual course of the professional practice because of the undocumented alcohol counseling.

February 8, 2018, was issued below the applicable standard of care in the State of New Jersey, because there was no documented discussion related to the inconsistent urine screens.

4. Patient J.C.

The stipulated facts demonstrate that between and including August 22, 2016, and April 10, 2018, Respondent issued prescriptions for controlled substances to J.C. on twenty-one occasions. *See* Stip. 6(a)-(t); *see also* RD, at 77-78. In this time period, J.C. submitted a total of sixteen urine samples for screening. RD, at 78. The ALJ found, and I agree, that J.C.'s urine screens were negative for oxycodone on October 19, 2016, June 20, 2017, July 25, 2017. RD, at 78-79 (citing GX 88; GX 130, at 63; GX 130, at 53; GX 130, at 51; Stip. 7(a), 7(b) and 7(c)).

The ALJ conducted a thorough evaluation of the PMP records to determine the number of days between the date that the PMP indicated that J.C. filled the prescription and the date that his urine tested negative for oxycodone. RD, at 78-79 (citing ALJX 45, at 2-3 (PMP)). The ALJ analyzed these dates in a chart with the amount of tablets in the prior prescription to determine whether it was reasonable for Respondent not to document the inconsistent urine screen. *Id.*

Dr. Kaufman testified that a October 19, 2016, urine screen that tested negative for opiates following a prescription that was issued on September 21, 2016 (seventeen days prior to the drug screen) was inconsistent, and therefore the prescription issued on November 17, 2016 following Respondent's knowledge of the results of that drug screen was issued outside the usual course of the professional practice in the State of New Jersey. Tr. 223. J.C. testified that Respondent always counseled him on the negative test results and asked him why he was not taking his medication and J.C. further testified that he told Respondent that his pain was too intense, so he used all of the medication. RD, at 80 (citing tr. 853, 935, 974-75, 978-79, 993-94, 1046, 1343-45, 1354). Although Respondent testified that she always counseled J.C. following

the inconsistent urine screens, the patient notes for J.C. do not reflect additional counseling or what was discussed and what the plan was moving forward with treatment. *Id.*; *see also,* RD, at 80 (citing GX 92, 109, 112). Due to the Respondent's lack of documentation regarding the counseling that she asserts occurred, I agree with the ALJ that the prescription issued on November 17, 2016, was issued outside the usual course of the professional practice and below the applicable standard of care in the State of New Jersey. RD, at 128.

On June 20, 2017, J.C. tested negative for opiates despite the fact that he had been prescribed thirty days of Roxicodone thirty days prior to the urine test on May 11, 2017. Dr. Kaufman testified that the prescription issued to J.C. on July 25, 2017, was "not issued within the usual course of practice, because it 'was issued after the negative urine screen, without counseling of the urine drug screen as to why it was negative…' for opiates." RD, at 81 (citing tr. 227, GX 109, 110). Due to the Respondent's lack of documentation regarding the counseling that she asserts occurred, I agree with the ALJ that the prescription issued on July 25, 2017, was issued outside of the usual course of the professional practice and below the applicable standard of care in the State of New Jersey. RD, at 129.

On July 25, 2017, J.C. tested negative for opiates despite the fact that he had been prescribed thirty days of Roxicodone thirty-four days prior to the urine test on June 20, 2017. The ALJ applied the measuring unit of thirty-two days to determine when the applicable standard of care would require counseling and found that the subsequent prescription on August 22, 2017, was issued within the usual course of the professional practice. RD, at 129. Although I believe the appropriate test is 33 days, I agree with the ALJ that the Government has not proven by substantial evidence that this prescription was beneath the applicable standard of care in New Jersey. RD, at 129.

Overall, with respect to Patient J.C., I find that the prescriptions issued on November 17, 2016, and July 25, 2017, were issued below the applicable standard of care in the State of New Jersey, because there was no documented discussion related to the inconsistent urine screens.

5. Patient L.M.

The stipulated facts demonstrate that between and including September 28, 2015, and May 24, 2017, Respondent issued prescriptions for controlled substances to L.M. on twenty-three occasions. *See* Stip. 8(a)-(u); *see also* RD, at 82-83. In this time period, L.M. submitted a total of fourteen urine samples for screening. RD, at 84. The ALJ found, and I agree, that L.M.'s urine screens showed inconsistent results on May 17, 2016;[60] June 13, 2016; July 12, 2016;[61] January 31, 2017; and April 26, 2017. RD, at 84-85; GX 175, at 144; GX 175, at 141; GX 175, at 139; GX 175, at 131; GX 175, at 123; Stip. 9(a), 9(b) and 9(c)).

Respondent testified that when L.M. tested positive for Suboxone, she had called the lab and the lab had said to recheck the urine "[a]nd I tested her again; she didn't come back positive the next time." Tr. 857. This description of the events is undermined by the evidence on the record that shows that L.M. tested positive three times in a row for Suboxone and Respondent's own later testimony. *See infra* note 60; tr. 1092-95. Dr. Kaufman testified that on June 13, 2016, L.M.'s urine screen tested positive for norbuphrenorpine or Suboxone, which is "generally

[60] Despite that the prescription on June 13, 2016, was issued after testing positive for Suboxone and fentanyl on May 17, 2016, the Government did not address this in any of its filings nor its testimony, so I am not including a violation for this date. GX 175, at 144.

[61] On July 12, 2016, for the third time in a row, the records demonstrate that Patient L.M. tested positive for Suboxone, but the Government did not reference this date in its OSC or prehearing statements or in the presentation of its case at the hearing. That being said, the Respondent raised the fact that L.M. had tested positive for Suboxone three times in a row. Tr. 1092-95. I will not include a specific finding regarding the prescription following this screen on August 18, 2016; however, I believe that the record adequately demonstrates that L.M. tested positive three times in a row for Suboxone—a fact which enhances the egregiousness of Respondent's overall prescribing to this patient. GX 147; Tr. 1092-95; *see also* (Govt Posthearing, at 10 n.3 (admitting that the Government did not charge this prescription, but proposing that it demonstrates that the buprenorphine/Suboxone "was not an isolated incident.")

used for controlled substance withdrawal" and in order to meet the minimum standard of care in New Jersey a practitioner would need to address why the patient tested positive for Suboxone. Tr. 258-59. Dr. Kaufman testified that he would "expect to see a note such as I discussed with the patient the positive urine screen for metabolite of Suboxone. I questioned the patient as to where they were getting this, why were they getting this? . . . . [a]nd could they be inadvertently hurting themselves because they're now taking two controlled substances?" Tr. 260. Dr. Kaufman testified that he was particularly concerned that the PMP did not reflect that this medication was prescribed, which indicates that the patient could be receiving it illicitly and that the patient needed to know about safety issues of taking two controlled substances. *Id.* at 262-63. Respondent[62] testified that she counseled L.M. about the Suboxone in her urine and she realized by the third visit when L.M. had tested positive three times in a row that the counseling was not successful, but she could not explain why she had not subsequently reduced the dose of Percocet for L.M. Tr. 1092-95. She believed that Suboxone was not "a street drug" and that the patient had likely received it from a hospital for withdrawal. *Id.* The fact that Respondent cannot remember why she continued to issue prescriptions for L.M. after she tested positive for Suboxone underscores the importance of maintaining adequate records resolving the inconsistent urine screen. The ALJ found, and I agree, that the prescriptions on the date following urine screen demonstrating Suboxone were not issued within the usual course of the professional

[62] The ALJ stated that Respondent credibly testified that she had counseled the patient here. *See* RD, at 130. However, earlier he had found Respondent's credibility regarding the Suboxone prescriptions to be problematic, because her explanation that the patient ran out of the oxycodone that she had prescribed and then went to a clinic or hospital to get Suboxone for withdrawal were not plausible. RD, at 23; *see* Tr. 1099-1101. On June 13, 2016, and July 12, 2016, Patient L.M.'s urine testified positive for BOTH Suboxone and Oxycodone. GX 175, at 139; GX 175, at 131. If she had received Suboxone for withdrawal symptoms, then it does not make sense that she would still have tested positive for the oxycodone, unless she had received it illicitly. *See also* RD, at 23. I do not find Respondent to be credible that she counseled the patient about this test, because her explanation based on that counseling is implausible; however, as stated earlier, I am not resting my finding of a violation on the existence of counseling, but instead upon the non-existence of its documentation.

practice in New Jersey "because [Respondent]'s records for L.M. on July 12, 2016, following the June 13th urine test, did not document how she resolved the fact that L.M.'s urine screen was positive for Suboxone." RD, at 130 (citing his Finding of Facts (hereinafter, FF) 34, 79, 189).

On January 31, 2017, L.M.'s urine sample tested positive for fentanyl, which was not prescribed by Respondent. GX 175, at 129. Respondent stated that she "called the primary care and [she] asked for their note" and they "told [her] over the phone that they ordered a colonoscopy"; however, if such a call occurred, it was not documented in the patient record. Tr. 856. The ALJ determined, and I agree, that the prescription issued on February 28, 2017, following the January 31st inconsistent test, "was not issued within the usual course of practice of medicine in New Jersey because [Respondent] did not document that she resolved the 'clearly aberrant urine screen . . . for [] [f]entanyl." RD, at 131 (citing tr. 265; FF 79, 192).

On April 26, 2017, Patient L.M.'s urine sample tested positive for 6-MAM, a heroin metabolite. RD, at 131; GX 175, at 126. On L.M.'s subsequent appointment with Respondent on May 24, 2017, L.M.'s patient records demonstrate that Respondent discharged the patient for heroin; however, she also issued L.M. a prescription for 90 Percocet 5/325 milligrams. RD, at 131; *see also* tr. 550; GX 173 ("D/C UDS positive for heroin"); GX 174 (prescription). Dr. Kaufman testified that the only information in the patient record was that the patient was discharged for heroin. There was no additional explanation of counseling. Tr. 551. Dr. Kaufman testified that the applicable standard of care upon a urine screen positive for heroin would be "to stop [prescribing opioids] and treat any withdrawal symptomology." Tr. 557. He testified that it would be within the applicable standard of care to prescribe a small amount of medication "with a very specific weaning schedule for that patient." *Id.* at 562. Respondent did

reduce[63] the amount of her prescription to L.M., which she characterized as a "weaning script." Tr. 1061.

Dr. Kaufman testified that Respondent did address the positive heroin test, because "she discharged [L.M.] from the practice." Tr. 564; *accord id.* at 566. He also answered affirmatively to Respondent's counsel's question that it *could* be within the standard of care to issue a weaning dose upon the discharge. Tr. 565 (emphasis added). The ALJ concluded that on cross examination, Dr. Kaufman had testified that Respondent's reduction of the dose of L.M.'s prescription on her last visit was within the applicable standard of care. RD, at 132 (citing tr. 562-63). I agree that both the questions and the answers during this part of the hearing were confusing, but I do not agree with that conclusion. Dr. Kaufman answered, "That's correct" after a lengthy question containing a double negative and ending with "it's your conclusion that this [presumably L.M.'s chart] doesn't indicate that this was outside the standard of care, is that right?" Tr. 562-63. From my reading of the testimony, this response was not necessarily inconsistent, because Dr. Kaufman testified several times that the chart does not state anything about the reason for the prescription, so it does not make logical sense that a chart with no explanation could indicate whether or not the prescription was intended for weaning.[64] In fact, the chart does not indicate one way or another that it was a weaning prescription, and that is the ultimate reason why I find that this prescription was issued beneath the applicable standard of care. [65]

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[63] During the two preceding visits on March 30, 2017, and April 26, 2017, Respondent had prescribed L.M. two prescriptions for Percocet. GX 175, at 64 (prescription for 90 tablets of Percocet 5/325); RX 9, at 2 (prescription for 30 Percocet 10 miligrams).; Tr. 560. The ALJ noted that the PMP confirmed the two prescriptions. RD, at 131 (citing ALJX 45, at 5).

[64] This response makes more sense when read along with Respondent Counsel's preceding question, "So do you have any reason to believe that Doctor, from this chart, that [Respondent] didn't provide a weaning schedule?" to which Dr. Kaufman responded, "I don't." Tr. 562.

[65] It is noted that despite this characterization, Respondent's Pain Management Agreement with L.M. states that if she breaks the agreement, "my doctor will taper off the medicine over a period of several days, as necessary to avoid

Furthermore, when the Government followed up with Dr. Kaufman on this issue, he clarified that weaning a patient would require documentation in the record, and also would include directions "written on the prescription to give the patient the proper directions on how to do it"; therefore, the prescription was "not necessarily" a weaning prescription. Tr. 654-55. Dr. Kaurman also affirmed that the prescription was outside the applicable standard of care. *Id.* Even though Respondent had followed the applicable standard of care in discharging the patient after the heroin was discovered, I believe that the Government has established by substantial evidence that, the prescription issued on May 24, 2017, was issued outside the usual course of the professional practice and beneath the applicable standard of care in New Jersey, because Dr. Kaufman credibly testified that the applicable standard of care required that a weaning prescription be documented as such and provide weaning instructions to the patient. *See id*. Without adequate recordkeeping, there is no indication of the intent of the prescription or the fact that counseling occurred.[66]

6. Patient M.W.

The stipulated facts demonstrate that between and including January 30, 2015, and August 25, 2017, Respondent issued prescriptions for controlled substances to M.W. on thirty-two occasions. *See* Stip. 10(a)-(ff); *see also* RD, at 87-89. In this time period, M.W. submitted a total of nineteen urine samples for screening. RD, at 89, 133. The ALJ found, and I agree, that

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withdrawal symptoms." *See e.g.*, GX 175, at 2. Respondent's own Pain Management Agreement appears to dictate a much more specific and shorter period of prescription for discharged patients than what she prescribed for L.M. Although I am not sustaining an allegation regarding this prescription on whether the weaning prescription was appropriate, but instead on a lack of documentation, Respondent's Pain Management Agreement supports Dr. Kaufman's testimony that in order to meet the applicable standard of care, the prescription should have contained a weaning schedule or instructions to "taper off the medicine."

[66] This finding is further supported by the regulation's mandate to "document the plan" after a breach of the pain management agreement, which was in effect at the time of this prescription. N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020). Even though Respondent documented the discharge, she did not explain the weaning prescription in any way and she provided no instructions to the patient. *See* GX 174 (prescription for 90 Percocet to L.M. on May 24, 2017).

M.W.'s urine screens showed inconsistent results for someone who has been prescribed opioids on May 3, 2016 (thirty days since filled), July 8, 2016 (fifteen days since filled), and July 28, 2017 (thirty days since filled). RD, at 89-90; GX 207, 242; Stip. 11(a), 11(b) and 11(d).[67] There was no documented counseling that specifically addressed any of the inconsistent urine screens. RD, at 87-92; GX 259, at 60-61, 62-63, 92-93; Stip. 10(m), 10(ee), 10(ff). Therefore, the ALJ found, and I agree, that the Government has proven by substantial evidence that the prescriptions issued on May 27, 2016, August 5, 2016, and August 25, 2017, following the inconsistent urine screens were issued beneath the applicable standard of care and outside of the usual course of the professional practice in New Jersey. *See* RD, at 91-92; GX 209, 216, 244.

7. Patient S.W.

The stipulated facts demonstrate that between and including March 16, 2015, and April 6, 2018, Respondent issued prescriptions for controlled substances to S.W. on thirty-nine occasions. *See* RD, at 92-94. In this time period, S.W. submitted a total of eighteen urine samples for screening. RD, at 94-96.

Patient S.W.'s urine tested positive for alcohol metabolites on March 30, May 25, June 22, July 20, and August 23, 2016. RD, at 95-96 (citing GX 288, 293, 296, 299, 302; Stip. 13(a), 13(b), 13(c), 13(d), 13(e)). The patients' records for the prescriptions issued on the visit following the results of these urine screens did not document any specific counseling with regard alcohol.[68] RD, at 93 (citing GX 289, 291, 294, 297, 300, 303). Therefore, I find that the

[67] The OSC alleged a total of six inconsistent urine screens for M.W., but the Government did not present evidence about three of these dates through testimony and additionally did not include them in the Prehearing statement or in the Posthearing Brief; and therefore, the ALJ disregarded the inconsistent urine screens on June 1, 2015, November 3, 2015, and April 28, 2017. OSC, at 4; Govt Posthearing, at 11-12; RD, at 90; GX 235; GX 259, ar 116, 154, 158. Although I believe that the record evidence establishes that two of the screens were inconsistent and therefore required documented counseling that did not occur, I will not include them in my findings, because they appear to have been dropped by the Government and I do not find them necessary to my ultimate finding in this case.

[68] Respondent testified that she was told by a lab that a patient's diabetes could cause a urine screen to be positive for alcohol, and S.W. was diabetic. Tr. 851, 927. Dr. Kaufman agreed that diabetes may cause a positive alcohol

prescriptions for controlled substances issued on April 27, 2016;[69] June 22, 2016; July 20, 2016;August 24, 2016; and September 21, 2016, were not issued within the usual course of practice of medicine and did not meet the applicable standard of care for New Jersey because there was no documented counseling regarding the patient's use of alcohol in her records, nor other explanation of the positive screens. RD, at 96-99, 135-137.

On April 5, 2017, S.W.'s urine screen tested positive for fentanyl. *Id*. at 95 (citing GX 319; Stip. 13(f)). Dr. Kaufman testified that the prescription Respondent issued on May 3, 2017, after the positive fentanyl urine screen did not meet the applicable standard of care in New Jersey and was issued outside the usual course of the professional practice of medicine in New Jersey, because Respondent did not address the fentanyl with S.W. Tr. 249. Respondent testified that S.W. had a history of breast cancer[70] and had told her that the fentanyl was the result of a port being inserted for chemotherapy. RD, at 99 (citing tr. 849). However, the patient records do not reflect this discussion, nor any counseling regarding the fentanyl. *Id.* (citing GX 320, 321). Therefore, the ALJ found, and I agree, that the prescription issued on May 3, 2017, did not meet

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screen, but "she has to document that there's an average urine screen. It's shown that it's the metabolites of alcohol, and there's a comment that given the light of the patient's diabetes, one would expect a positive urine screen for alcohol[]." Tr. 463. Therefore, despite the possible explanation of why alcohol might have been present, I find that these prescriptions were issued beneath the applicable standard of care, because Respondent did not document her counseling regarding the alcohol in the urine screens or her rationale for not counseling.

[69] The ALJ did not sustain the allegations related to the prescriptions on April 27, 2016, June 22, 2016, July 20, 2016, due to the fact that Dr. Kaufman had testified that the applicable standard of care required the practitioner to discharge a patient who has had alcohol counseling three times and continues to consume alcohol while taking opioids. RD, at 136. As explained herein, I agree with the ALJ that Dr. Kaufman's testimony was confusing on the issue of when to cease prescriptions in the face of an alcohol test; however, I find that Dr. Kaufman also credibly testified that the applicable standard of care in New Jersey required that the Respondent counsel the patient about the alcohol use on each occasion and document that counseling, and there is no such documentation; therefore, I disagree with the ALJ and sustain violations on these dates. *See* Tr. 212.

[70] Respondent argued that S.W.'s records reflect that she had a history of breast cancer and that she was actively being treated for breast cancer because they noted that she was receiving "Herceptin IV once a week." Tr. 630. Therefore, Respondent argued that it was reasonable given her history and ongoing treatment to continue prescribing after the fentanyl. Dr. Kaufman testified that he did not see any documentation in the record explaining the rationale for prescribing and stated, "It all goes to the crux of the matter. If it's not written here, how can I assume all of that, what you just said, took place? I can't." *Id.* at 632. I agree with Dr. Kaufman that the applicable standard of care and State regulation in effect at this time in New Jersey required documentation. *See infra* III(A)(1)(b).

the applicable standard of care and was issued outside the usual course of the professional practice in New Jersey. *Id*. at 138.

In sum, I find that the record evidence demonstrates that Respondent issued twenty-three prescriptions for controlled substances beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey (five occasions to UC, four occasions to A.P., two occasions to J.C., three occasions to L.M., three occasions to M.W., and six occasions to S.W.). Additionally, I find that the Government has presented substantial evidence that Respondent: failed to conduct a physical examination of the UC in violation of N.J. ADMIN. CODE § 13:35-7.1A, and failed to document the discussion of the plan and assess the risk of abuse, addiction or diversion after inconsistent urine screens in violation of N.J. ADMIN. CODE § 13:35-7.6(e) and (f), as further explained in *infra* III(A)(1)(b) for the following prescriptions issued after the regulation's effective date of March 1, 2017: July 25, 2017, to J.C.; February 8, 2018, to A.P.; May 24, 2017, to L.M.; August 25, 2017, to M.W.; and April 5, 2017, to S.W.. Additionally, four of these prescriptions violated N.J. STAT. ANN. § 24:21-15.2, which became effective May 16, 2017.

III. DISCUSSION

A. Allegation that Respondent's Registration Is Inconsistent with the Public Interest

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

directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing . . . controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 Fed. Reg. 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

Fed. Reg. 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 C.F.R. § 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[71] I find that the Government's evidence with respect to Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors Two and/or Four – The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

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

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 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

[71]I agree with the ALJ that Factors One and Three do not weigh for or against revocation in this case, nor does Factor Five weigh in favor of revocation. RD, at 146. Without referencing Factor One, Respondent mentions that the State of New Jersey has not brought any action against her state license. Resp Posthearing, at 1. However, Agency decisions have long found that in considering Factor One, a state entity's inactions does not weigh for or against revocation. *See Ajay S. Ahuja, M.D.*, 84 Fed. Reg. 5479, 5490 (2019) (finding that "where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.")

patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006).

Respondent engaged a skillful attorney to defend herself against the allegations. I read and analyzed every aspect of Respondent's defense including all of the evidence she put in the record. Respondent's arguments regarding the allegations are not persuasive.

I acknowledge the complexity of this case. The OSC/ISO contained errors, what appeared to be a very adversarial hearing led to confusion relating to testimony on both sides, and the ALJ's statements in the lengthy RD were at times inconsistent with each other.[72] Because of the complexity of this case, I have parsed out only the allegations against that were clearly presented. The end result remains that Respondent issued numerous prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in New Jersey. DEA decisions have found that "just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . ." *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.*, 80 Fed. Reg. 28,643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 Fed. Reg. 51,592, 51,601 (1998). In fact, in this case it seems that two out of the six patients presenting were successful in purposefully exploiting Respondent's carelessness (the UC and L.M.).

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[72] *See, e.g.,* RD, at 155 (stating that if Respondent had violated New Jersey law, her "conduct would have been far more egregious than it actually was); *but c.f.*, RD, at 101, n.49 ("even if N.J. ADMIN. CODE § 13.35-7.1A were considered, such consideration would not change my recommended sanction in this Recommended Decision.").

Respondent contended that the OSC alleged over 150 unlawful prescriptions and the Government only presented evidence about twenty-six and highlights the ALJ's characterization of the OSC as "error-filled and overzealous."[73] Resp Exceptions, at 1. She further alleged that "[i]t effectively destroyed [r]espondent's practice built up over ten years." *Id.* The OSC alleged that Respondent continued to prescribe after she had not documented the resolutions of a multitude of red flags in violation of the applicable standard of care in, and state law of, New Jersey and therefore that every subsequent prescription issued after the first violation to each patient was issued beneath the applicable standard of care and outside the usual course of practice in New Jersey.[74] Although the Government did not litigate the broader allegations that subsequent prescriptions were also in violation, in actuality the majority of the underlying facts alleged in the OSC were, in fact, sustained. I have sustained a few more violations than the ALJ based on the reasons stated herein, but it is truly not the mere number of violations that tip the public interest against Respondent.

Respondent additionally contended that the number of alleged violations only represents a small subset of the 2,800 patient visits that DEA reviewed. *See* Resp Posthearing, at 2. Respondent argued that she has a very busy practice and that the Government presented

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[73] I disagree with this characterization of the OSC/ISO. Due to the ALJ's perceived errors in the OSC/ISO, the ALJ also made a statement that was misleading and incorrect. He stated, "All of these allegations painted a picture of a practitioner whose actions were inconsistent with the public interest. All of those allegations were wrong!" RD, at 155. In making this statement, the ALJ differentiated between the number of violations presented at hearing and a number that was not quantified in the OSC; incorrectly found that DEA did not prove violations of New Jersey law as alleged in the OSC; differentiated between alcohol and alcohol metabolites, which even Respondent admits is inconsequential to the requirement to counsel about alcohol risks; and highlighted one instance of an incorrect date in the OSC for a negative urine screen (however, the Government omitted two other negative urine screens for this patient that were never addressed and likely would have been found to be violations). RD, at 154-155; *see supra* notes 54, 55. The OSC did contain errors, as described throughout this decision, but several of the instances that the ALJ included here were incorrect and not as egregious as they seemed, and the errors that were made cannot justify a lesser sanction for someone who has not demonstrated that she can be entrusted with a DEA registration. *See infra* note 86.

[74] The ALJ characterized this as over one hundred and fifty prescriptions, but the OSC did not quantify how many prescriptions it was purporting to encompass.

allegations in only a subset of the prescriptions she wrote, but the violations I have found demonstrate that she repeatedly violated the applicable standard of care and state law and that her conduct was not an isolated occurrence, but occurred with multiple patients and in multiple contexts over a period of years. *See Wesley Pope*, *M.D.*, 82 Fed. Reg. 42,961, 42,986 (2017).

The Respondent asserted that no one "died or overdosed or diverted any medication." Resp Posthearing, at 1. She does not, however, cite legal authority for the proposition that I must find death, an overdose or controlled substance diversion before I may suspend or revoke a registration. I agree with the ALJ that a decision of revocation does not need to be based on specific evidence of death or overdose. *See* RD, at 141. As the ALJ noted, Agency decisions have found that "diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .'" *Id.* (citing *Roy S. Schwartz*, 79 Fed. Reg. 34,360, 34,363 (2014)). In this case, I have found that Respondent issued prescriptions without complying with her obligations under the CSA and New Jersey law. *See George Mathew, M.D.*, 75 Fed. Reg. 66,138, 66,148 (2010)).

Respondent further argued that the UC failed in obtaining opiates without any ailment, because the "agent was only able to obtain a minimal prescription of a low-dose opiate after presenting an MRI report demonstrating disease." Resp Posthearing, at 2. Respondent did require that the UC obtain a clearer MRI before prescribing her controlled substances, she did recommend alternative therapies, she did conduct urine screens, but she also never conducted a physical examination of the UC required by law.[75] Dr. Kaufman credibly testified that Respondent's opioid prescriptions to the UC were beneath the applicable standard of care and

[75] I note that this Agency has consistently relied on expert testimony stating that a component of an adequate physical examination is palpation. *See, e.g.*, *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882 (2018); *Randall L. Wolff, M.D.*, 77 Fed. Reg. 5106 (2012). N.J. ADMIN. CODE § 13:35-7.1A (West 2020); Govt Supp Prehearing, at 4.

outside of the usual course of the professional practice in the State of New Jersey. As discussed below, the New Jersey regulations concur. It is possible that had Respondent required the new MRI and conducted a physical examination as required by law, in order to make her diagnosis, the investigation might have ceased. However, she did not conduct the requisite physical examination. Therefore, I cannot credit her efforts to characterize herself as a victim or attempts to compare this investigation to a "second Katrina," when she was clearly responsible for an undocumented decision to not conduct the physical examination required by New Jersey. Resp Exceptions, at 1 (quoting tr. 789).

I found Respondent's credibility to be dubious and her counseling on the record to be insufficient, but the record was clear that, whether or not Respondent actually counseled patients with inconsistent urine screens or alcohol metabolites, she did not adequately document that counseling to demonstrate that she was actively resolving the issues. The ALJ cited to numerous DEA cases that demonstrate that "requiring patients to take a drug test serves little purpose, if any, if the registrant ignores the test results." RD, at 112 (citing *U.S. v. Moore*, 423 U.S. 122, 142-143 (1975); *see also Dreszer, M.D.*, 76 Fed. Reg. at 19,388.)[76] Respondent argued that the "caselaw cited by the ALJ in support of the documentation requirement seems to stand for the proposition that the documentation is needed to demonstrate that an act occurred, not that the

[76] Agency decisions relying on expert testimony have found that documenting the results of inconsistent urine screens is part of the applicable standard of care. In *Jacobo Dreszer, M.D.*, a case arising in Florida, inconsistent urine screens not only "should have inspired additional diligence or inquiry on the part of the [r]espondent," but they should have also "raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file." 76 Fed. Reg. at 19,394; *see also Cynthia Cadet, M.D.*, 76 Fed. Reg. 19,450, 19,457 (2011) (noting the patient's urine screen produced abnormal results and the respondent "made no effort to resolve the conflict as best as can be divined from the patient file"). Even though these Agency decisions are not essential or controlling in determining the standard of care in New Jersey that applies to this case, the fact that other medical experts in other states have testified regarding the importance of documenting inconsistent urine screens to their applicable standard of care and that DEA has long highlighted the importance of this aspect of the standard of care in those states to maintaining registrations under the CSA lends further support to the findings herein.

documentation is a prerequisite for the proper practice of medicine." Resp Exceptions, at 24 (citing *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006)). The cases to which the ALJ cited were decided based on expert testimony and state standards regarding the applicable standard of care and were not, as Respondent implies, medical judgments of the DEA. In this case, the applicable standard of care requiring documentation of the inconsistent urine screens was established by New Jersey laws that have explicitly addressed his issue and credible expert testimony. In fact, in exercising my authority under the CSA, I am instructed to consider "the registrant's compliance with state and local drug laws." *Gonzales v. Oregon*, 546 U.S. 243, at 270 (citing 21 U.S.C. § 823(f)(4)). Furthermore, Agency decisions highlight the Agency's interpretation that "[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.'" *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19,450, 19,464 (2011). DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.

Respondent paints herself as an "appropriate steward of her controlled-substance license." Resp Posthearing, at 2. Further, she argued that "with her lack of venality and her cautious approach to her practice, it is submitted that [R]espondent is exactly the kind of practitioner who should be encouraged." *Id.* at 58. I disagree. Respondent's practice incorporated some safeguards to prevent the diversion of opioids, such as, monthly urine screens, diagnostic testing, and recommending alternative treatments, but the safeguards were not fully implemented in a meaningful way, because she never documented their resolution, if they were

in fact resolved. In balancing the public interest, I weigh in Respondent's favor that the record evidence shows that she attempted to implement controls, such as monthly urine screens to prevent diversion. However, the record contains numerous instances where these controls fell short and lacked substance. When she continued to prescribe to Patient L.M. in the face of a multitude of inconsistent urine screens showing three tests for Suboxone in a row, fentanyl, and finally heroin, her justifications were inconsistent and not credible and they were not otherwise documented. *See supra* II(F)(5). When she prescribed to the UC, she claimed that she was basing the five prescriptions on the results of the MRI in lieu of a physical examination, but her diagnosis was inconsistent and the transcript of the recorded video, which shows that she could not appear to recall or find the MRI on some of the subsequent visits. *See supra* II(F)(1). Partially implementing safeguards against diversion is not the same as actually implementing them and is not an excuse for prescribing controlled substances beneath the applicable standard of care and outside the usual course of the professional practice. I therefore find that Factors Two and Four weigh in favor of revocation.

b) Allegations of Violation of Federal and New Jersey Law

I find that in issuing twenty-three prescriptions beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey, Respondent violated 21 C.F.R. § 1306.04(a).

i. New Jersey Administrative Code § 13:35-7.1A

I also find that the Government has proven by substantial evidence that Respondent's failure to conduct an adequate physical examination of the UC constitutes a violation of N.J. ADMIN. CODE § 13:35-7.1A (West 2020) (effective September 15, 2003) (practitioners shall not issue prescriptions "without first having conducted an examination, which shall be appropriately documented in the patient record" to include "an appropriate history and physical

examination."). Respondent characterizes the regulation to require an "appropriate physical examination," but in fact, the regulation requires "an appropriate history" and "physical examination." Resp Posthearing, at 10. She did not support a reading in New Jersey law that re-arranges the clear order of the regulation's provisions.[77] Even if the word "appropriate" in the regulation were to apply only to the physical examination, any practitioner discretion[78] would still be bound by the objective, applicable standard of care in New Jersey, which, as clearly established by Dr. Kaufman, Respondent's treatment of the UC fell below. Additionally, Respondent did not adequately document her justification for why a physical examination was inappropriate or unnecessary under the circumstances. I find that Respondent violated the New Jersey regulation when she prescribed a controlled substance to the UC without having performed an appropriate physical examination.

Respondent further argued both that the patient's MRI gave her a diagnosis and that she had conducted enough of an examination by observing the patient "to derive a proper etiology of

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[77] Respondent argued that N.J.S.A. 24:21-15.2 requires a physical exam prior to an initial opioid prescription "as appropriate." Resp Exceptions, at 8. Respondent noted that this provision was not in effect during the treatment in question, but that it "does give insight into the State's standards." *Id.* at n.9. I agree with the Respondent that the New Jersey statutes and regulations give insight into the standard of care in New Jersey, which is one of the reasons why I am including them herein as evidence of the applicable standard of care as contradicting Dr. Epstein's testimony. Although not controlling law on this issue, this statute is not explicit about what the term "appropriate" means; however, its implementing regulation states that a practitioner must "conduct a physical examination appropriate to the practitioner's specialty, including an assessment of physical and psychological function, and an evaluation of underlying or coexisting diseases or conditions." N.J. ADMIN. CODE § 13:35-7.6(b)(2) (West 2020). From the regulation, it appears that the term "appropriate" in the statute, as interpreted by the New Jersey Attorney General refers to the practitioner's specialty, which would correlate directly to the patient's medical condition, and not to the practitioner's discretion. Further, as noted, Dr. Kaufman credibly testified that Respondent's examination of the UC was not adequate under the standard of care in New Jersey.

[78] To further demonstrate this discretion, Respondent cites to the exceptions to the examination requirement in N.J. ADMIN. CODE § 13:35-7.1A(b) arguing that they list "circumstances all relate[d] to, other than emergencies, those situations where a patient already has a diagnosis for their pain." Resp Posthearing, at 8 n.2. In fact, the provisions unrelated to emergencies are either because the physician is assuming the care of the patient for another practitioner who has performed a physical (b)(2) and (b)(5); or for "an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription." N.J. ADMIN. CODE § 13:35-7.1A(b)(4) (West 2020). As the ALJ notes, there is no evidence on the record to support Dr. Epstein's claim that the UC was Respondent's "established patient" at the time of her second visit. RD, at 15. Additionally, even if she were considered an established patient, the term "new" examination necessarily implies that there was a previous examination, and there was not.

a patient's subjective pain complaints and come up with a plan . . . ." *Id*. at 10-11. In interpreting the requirements of N.J. ADMIN. CODE § 13:35-7.1A, the New Jersey Office of Administrative Law determined that a physician, who listened to the patient's breathing and "visually observed her while she was in the examination room" had "failed to perform any competent physical examination of her back or spine," the place of the patient's complaint. *In the Matter of the Suspension or Revocation of the License of John G. Costino, Jr., D.O. to Practice Medicine and Surgery in New Jersey,* 2009 WL 1396180, at 5. (N.J. Adm.) (May 14, 2009). Respondent's observation of the UC was not a "competent physical examination" of the place of the patient's complaint under New Jersey law, her "diagnosis" was undercut by her own recordkeeping and statements, and therefore, I find that her treatment of the UC violated this New Jersey regulation. *See supra* (II)(F)(1).

ii. New Jersey Administrative Code § 13:35-7.6(f)(2), (5)

I further find that Respondent violated N.J. ADMIN. CODE § 13:35-7.6(f)(2) and (5) for five prescriptions issued after its effective date of March 1, 2017, where the patients' records demonstrate no documentation of the resolution or "plan" after breaches to the pain management agreement due to patients not taking controlled substances as prescribed and no documented assessment of their risk of dependence before issuing additional prescriptions.[79]

Respondent argued that she complied with the requirement to document a "plan," because of what she described as her "decision-tree analysis" based on Dr. Gutheil's testimony that the end result shows the judgment that goes before it. Resp Posthearing, at 20 (citing Tr.

[79] I am considering Section 13:35-7.6(f)(2), because although there was limited specific discussion of this Section in the record, together Sections (f)(2) and (f)(5) demonstrate the requirement to document the rationale for continuing to prescribe after inconsistent urine screens—whether it is to develop a plan or assess the risk of the individual patient. The finding of violations of these sections individually has not been given any additional weight in my decision to revoke. Dr. Kaufman clearly testified that "within the State of New Jersey, each time the patient comes in, you're supposed to assess the patient, to make sure that, A, that they're taking it. B, that it is efficacious, are there any side effects? And then, make a justification as to continuation of therapy." Tr. 201-202

1220). "For [Respondent], whenever there was an inconsistent urine reported, but a prescription was issued, it indicated to her that appropriate counseling was done and all safety concerns were resolved."[80] *Id.* (citing tr. 1024-1025, 1027). She further argued that the requirement to document the "plan" does not include the counseling or the discussion or the reasons for the breach. *Id.* at 18-19. Respondent offered no New Jersey caselaw, valid regulatory interpretations, or expert testimony related to what constitutes a plan in the context of this regulation under the applicable standard of care and the usual course of the professional practice to support this reading, and legal analysis of the regulation's purpose and history do not support this limited reading.

The plain meaning of the term "plan" cannot be, as Respondent suggests, merely identifying the breach and documenting the end result after a discussion. Respondent's own testimony demonstrates why it cannot. With regard to Patient L.M., who tested positive three times in a row for un-prescribed Suboxone, Respondent could not remember why she had not cut L.M.'s dosage even though she testified that after the third positive test, she realized that the "counseling wasn't successful." Tr. 1092-95. The unchanged prescriptions following these visits could not be adequate documentation of a plan to address counseling about a breach of her pain management agreement that Respondent herself knew at that point was not being successful, because Respondent cannot remember why she issued the full prescription or why she resolved the unsuccessful counseling in that manner.[81]

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[80] Dr. Gutheil testified at most that documentation of the result "does minimally" document what occurred in terms of the physician-patient interaction. Tr. 1220. However, in no way did Dr. Gutheil's testimony address the statutory requirement to discuss breaches and document the plan and how a decision tree analysis would meet that requirement.

[81] I am using this as an example to demonstrate why the prescription alone cannot demonstrate the "plan." The regulation was not in effect until the prescription issued after Patient L.M. tested positive for heroin and was discharged in April of 2017.

Furthermore, in other sections of the regulation, the State of New Jersey used very different terminology. For example, Section (d) states, "The practitioner shall include a note in the patient record that the required discussion(s) took place." N.J. ADMIN. CODE 13:35-76(d). As discussed earlier, this provision requires that the practitioner note the fact that the discussions took place. The inclusion of the word "plan" in the Section at issue indicates that the regulations require more documentation than only a conclusory assertion.

In interpreting the meaning of a regulation, "agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments . . . ." *Hillsborough County, Fla. v. Automated Medical Labs., Inc.* 471 U.S. 707, 718 (1985). The New Jersey regulation requiring a "plan" was adopted through emergency amendments "because of the imminent peril created by the epidemic of prescription opioid and heroin abuse in New Jersey." New Jersey Division of Consumer Affairs, Rule Proposal, Volume 49, Issue 6, (March 20, 2017) *available at*: https://www.njconsumeraffairs.gov/proposals/pages/03202017-bme-proposal.aspx (hereinafter, the Preamble).[82] Further, the Preamble to the regulation states that a statute was signed into law—P.L. 2017, c. 28, codified at N.J. Stat. § 24:21-15.2; however because it "does not become effective until May 16, 2017, the Attorney General has determined that this rulemaking is necessary because the state of New Jersey is confronting a staggering public health crisis brought about by prescription opioid and heroin abuse." *Id.* One reason for the public health emergency is "the prevalence of opioid prescribing." *Id.*

There are two affirmative obligations in the regulation that are applicable to this record—"[w]hen controlled dangerous substances are continuously prescribed for management of chronic

[82] The online version of the Preamble does not contain pagination; therefore, the page references are based on a printed copy of the online document.

pain[83]" (defined as pain continuing for three months), the practitioner shall "assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment" and "monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion." N.J. ADMIN. CODE §§ 13:35-7.6(f)(2), (f)(5). The preamble to the regulation states that (f)(2) "contains an affirmative obligation to assess the patient prior to the issuance of each prescription for a controlled dangerous substance." The Preamble, at 7. "Overall the amendments to this subsection are designed to increase practitioner involvement and vigilance when prescribing for the treatment of chronic pain, and to ensure that the patient record reflects active pain management procedures." *Id.*

The Preamble is very clear that the State of New Jersey's purpose in enacting emergency controls on prescribing controlled dangerous substances for chronic pain is to ensure not only vigilance and involvement but that these "active pain management procedures" are also reflected in the patient record. Additionally, reading the two paragraphs together, it is apparent that the practitioner must assess the risks before every prescription and where there is a breach to the pain management agreement that demonstrates a potential risk of dependence, the plan and the assessment must be documented. Therefore, I find that five prescriptions with unresolved inconsistent urine screens issued after the effective date of March 1, 2017, violated N.J. ADMIN. CODE § 13:35-7.6(f)(2) and (5).

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[83] "'Chronic pain' means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically." N.J. ADMIN. CODE 13:35-7.6(a) (West 2020). Due to the fact that the patients in this case were prescribed opioids for more than three months prior to this regulation, I believe that they fall under this definition.

iii. New Jersey Statute § 24:21-15.2[84]

In its Posthearing Brief and Exceptions, the Government alleged that "when issuing prescriptions for opioids practitioners must determine 'that the issuance of the subsequent prescription does not present an undue risk of abuse, addiction or diversion and [must] document[] that determination.'" Govt Posthearing, at 15-16 (citing N.J. STAT. ANN. § 24:21-15.2(c)(3)). The Section of the statute that the Government cited appears to apply only when issuing a subsequent prescription "no less than four days after issuing the initial prescription." N.J. STAT. ANN. § 24:21-15.2(c). It is not clear from the plain language of the subsection that the risk assessment would be required for *every* subsequent prescription, and the Government ignored the issue in its briefs. A reading of subsection (c) that applied to every subsequent prescription could also be in conflict with subsection (f)(2), which requires that *after three months* of prescribing a Schedule II controlled dangerous substance or any opioid drug for chronic pain the physician must "assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment." N.J. STAT. ANN. § 24:21-15.2(f)(2). Despite the Government's error in citing to subsection (c) in its Posthearing filings, it did not so limit itself in its Supplemental Prehearing Statement or Posthearing Brief. The Supplemental Prehearing Statement stated that N.J. STAT. ANN. § 24:21-15.2 requires "that a doctor prescribing opioids enters into a pain management agreement with patients; and that patients receiving opioids are monitored for compliance with the pain management through various measures such as drug

[84] Regarding N.J. STAT. ANN. § 24:21-15.2, the ALJ found that the statute "by its terms, applies to 'initial prescriptions' and "the Government presented no evidence to show that the prescription [Respondent] issued to [UC] was her first prescription for an opioid." RD, at 111 (citing N.J. Stat. § 24:21-15.2(b)). The statute also was not in existence at the time that the alleged violations related to UC had occurred, as the relevant portions came into effect on May 16, 2017, and therefore I am disregarding his conclusions on that issue.

screens" and further that a physician's compliance with the statute "must be documented in a patient's medical records." Govt Supp Prehearing, at 4. Although not specifically noted, the Government was clearly implicating Sections N.J. STAT. ANN. § 24:21-15.2 Sections (e) and (f) pertaining to chronic pain, because the pain management agreement is not required under the subsequent prescription in Section (c) and Respondent and the Government presented arguments during the hearing implicating these sections; therefore, I find that, despite the Government's Posthearing briefings, Respondent was on adequate notice of the allegations of these violations and they are appropriately considered.

Respondent argued that the statute does not specify the requirement to document noncompliance with the pain management agreement. *See* Resp Supp Prehearing, at 3. Respondent further argued that, because the statute was enacted after the regulation and the documentation was "intentionally absent" in the statute, a narrow reading of the term "plan" in the regulation is more appropriate, because if New Jersey had intended a broader interpretation, it would have required this by statute. Resp Posthearing, at 19. The history of the statute and the regulation refutes Respondent's contention. P.L. 2017, c. 28 was signed into law on February 15, 2017, prior to the emergency adoption of N.J. ADMIN. CODE § 13:35-7.6 on March 1, 2017. The stated purpose of the emergency regulation was because "P.L. 2017, c.28, does not become effective until May 16, 2017." Preamble, at 2. The Attorney General of New Jersey believed that the "staggering public health crisis brought about by prescription opioid and heroin abuse" could not wait for even another three months to become effective. *Id.* Further, because the "standards set forth in this rulemaking will provide a basis to seek emergent action to suspend or limit licenses pending a plenary hearing, pursuant to N.J.S.A. 45:1-22, and/or for disciplinary

sanctions pursuant to N.J.S.A. 45:1-21," I find that New Jersey intended that the regulatory violations found above also constitute statutory violations. *Id.*

Therefore, I find sufficient evidence to sustain violations of N.J. STAT. ANN. § 24:21-15.2 for the three prescriptions occurring after it was effective on May 16, 2017. I further find that these provisions support Dr. Kaufman's testimony regarding the importance under the New Jersey standard of care of documenting not only the fact that counseling occurred, but also the resolution of such counseling.

The laws that New Jersey has implemented clearly demonstrate the extent to which the applicable standard of care in New Jersey relies on, not just checking for compliance with the pain management agreement, but that breaches, such as inconsistent urine screens are discussed and "the plan after that discussion" is documented in the patient record. N.J. ADMIN. CODE § 13:35-7.6(f)(5) (West 2020). These laws require more than lip service to safeguards, but actual rational, thoughtfulness on the part of the practitioner in making the decision to reissue a prescription to someone who is presenting red flags or danger AND the memorialization of that decision. To preserve the value of New Jersey law, I cannot agree with the ALJ here that this is "not the sort of recordkeeping violation that would defeat the purpose of the Controlled Substances Act." RD, at 150.[85] Documentation of a practitioner's decision-making is essential to the practitioner's accountability for that decision—it ensures that the practitioner is actually processing the information in front of her and applying it to her care of the patient and marking it with permanence.

[85] 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." *Gonzales v. Oregon*, 546 U.S. at 274.

c) Summary of Factors Two and Four and Imminent Danger

As found above, the Government's case establishes by substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice. I, therefore, conclude that Respondent engaged in misconduct which supports the revocation of her registration. *See Wesley Pope*, 82 Fed. Reg. 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. 213, 482 (the opinion of the Government's expert, Dr. Kaufman, that mixing alcohol and opioids could result in death); tr. 1494 (opinion of Dr. Epstein that "people who use fentanyl as an abuse drug die.).[86]" In particular, Respondent did not dismiss Patient L.M. after she had tested positive for fentanyl, Suboxone, and heroin, while still testing positive for prescribed oxycodone several times, and she did not document any explanation or discussions with Patient L.M. regarding breaches of her pain management agreement, which is particularly egregious in the face of the danger that her urine samples demonstrated. Although Respondent presented evidence to mitigate the egregiousness of her prescribing to patient S.W., she was required to maintain adequate records describing the mitigating circumstances under the applicable standard of care in

[86] Although Dr. Epstein's testimony about fentanyl was aimed at concluding that L.M.'s multiple urine tests showing fentanyl must have been incorrect or a result of surgery, the evidence in the record demonstrates that L.M. was, in fact, also abusing heroin, so it seems likely that she was abusing fentanyl that was not legitimately prescribed, thus this danger that he is describing is applicable in this case.

New Jersey and by New Jersey law; and therefore, the Government could not have known about these mitigations at the time of issuing the ISO. Although I agree that the OSC/ISO contained errors,[87] I do not agree with the ALJ's statement that it was overzealous.[88] *See* RD, at 154. At the time the Government issued the OSC/ISO, the Government had clear evidence of violations of law through an undercover who had been unlawfully prescribed controlled substances and records that appeared to demonstrate a practitioner who was prescribing with no explanation to individuals whose urine screens were demonstrating dangerous combinations of unprescribed controlled substances and alcohol or consistently showing no evidence of the controlled substances that she had prescribed.

IV. SANCTION

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to her violations pertaining to controlled substance prescribing and non-compliance with federal and State law, the burden shifts to the Respondent to show why she can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 Fed. Reg. 18,882, 18,910 (2018) (collecting cases).

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b). This authority

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[87] It is noted that although the OSC included some errors, such as that it alleged that on May 5, 2017, A.P.'s urine screen was negative for prescribed controlled substances, it also contained errors that omitted evidence which would have likely resulted in additional findings of violations, so the fact that the OSC included errors also benefitted Respondent. *See, e.g.*, *supra* notes 49, 52, 55, 59, 60, 66. Additionally, I would not have altered my decision on the Immediate Suspension Order due to these errors. There was enough evidence without them to justify the suspension of Respondent's registration.

[88] In making this statement, the ALJ highlighted the fact that the OSC argued that all prescriptions after the date of the first prescription were unlawful, which would have encompassed over 150 unlawful prescriptions. RD, at 154. Although I agree with the ALJ on the legal matter that the Government did not prove this allegation, as stated previously, the OSC did not quantify how many prescriptions it was attempting to encompass; therefore, the impact of that number was not as strong as the ALJ implies.

specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." *Gonzales v. Oregon*, 546 U.S. at 259. A clear purpose of this authority is to "bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking." *Id*. at 270. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondent submitted to determine whether or not she has presented "sufficient mitigating evidence to assure the Administrator that [she] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). "'Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 463 (2009) (quoting *Medicine Shoppe*, 73 Fed. Reg. 364, 387 (2008)); *see also Jackson*, 72 Fed. Reg. at 23,853; *John H. Kennnedy*, *M.D.*, 71 Fed. Reg. 35,705, 35,709 (2006); *Prince George Daniels*, *D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016).

In evaluating the degree of a respondent's acceptance of responsibility required to entrust her with a registration, in *Mohammed Asgar, M.D.*, 83 Fed. Reg. 29,569, 29,572 (2018), the Agency looked for "unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct." *Id.* (citing *Lon F. Alexander, M.D.*, 82 Fed. Reg. 49,704, 49,728 (2017)). The ALJ found, and I agree, that "Respondent has not accepted responsibility, other than to concede that she 'should have written more.'" RD, at 152 (citing tr. 1071). Respondent's assertion that she "should have written more" barely scrapes the surface of these issues, and seems to be an attempt to minimize the severity of her actions by so lightly characterizing a substantive documentation requirement. Tr. 1071; *see Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,973 (2019) (finding that a registrant's minimization in describing his crime weighed against a finding of acceptance of responsibility). Respondent argued that she did accept responsibility for the prescriptions to the UC, when she stated that "yes, she wrote it, she wrote the scripts." Tr. 874; *see* Resp Exceptions, at 33. But when asked whether the prescriptions were issued outside the usual course of the professional practice, she answered no. Tr. 875. Accepting responsibility for writing the prescriptions does not equate to admitting fault. *See Hoxie v. Drug Enf't Admin.*, 419 F.3d at 483 ("The DEA properly considers the candor of the physician" and "admitting fault" is an "important factor[] in determining whether the physician's registration should be revoked"). Additionally, Respondent compared the DEA case to her "second Katrina," which ultimately demonstrates that she takes no responsibility for her violations of law, but instead views herself entirely as a victim of forces beyond her control. Tr. 789.

Respondent's mitigating evidence and the Government's mistakes have whittled down or softened some of the violations in this case; however, I see no evidence from Respondent that

demonstrates that she will "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.* 75 Fed. Reg. 8194, 8236 (2010). Acceptance of responsibility is an important part of that demonstration. *Id.* Although the evidence of her struggles with her software system is relatable at a basic level to every human being who has experienced technological frustrations, it again shows a passing of blame and an unwillingness to accept responsibility for a legal requirement and a requirement of the applicable standard of care and the usual course of the professional practice in her field to document her prescribing practices and decisions. Documentation of the discretion that Respondent had been implementing in her prescribing practices in the face of inconsistent urine screens is similar to accepting responsibility for her actions, because it memorializes her decisions with permanence. None of the recordkeeping in the Government's evidence demonstrates the rationale behind her prescribing decisions and she demonstrated through her testimony that her memory is not reliable to fill in the gaps.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,095 (2009); *Singh,* 81 Fed. Reg. at 8248. With regard to specific and general deterrence, it is my responsibility under the CSA to encourage the good practices of preventing diversion that Respondent had implemented, including but not limited to, increasing urine screens to detect abnormalities, requiring an MRI to obtain more information about the source of pain, and encouraging alternative treatments; however, those additional measures are of no value to their stated purpose if the results of the urine screens are ignored. The cavalier attitude with which Respondent treated her documentation responsibilities and the fact that she did not undertake this responsibility with seriousness in any of these instances, weigh against my ability to entrust her with a registration.

See Singh, M.D., 81 Fed. Reg. at 8248 ("until . . . [a] Respondent can convincingly show he [or she] accepts the authority of the law and those bodies charged with enforcing it and regulating his [or her] activities, granting [] a DEA registration will gravely endanger the public."). Therefore, I disagree with the ALJ that "specific and general deterrence do not weigh in favor of revocation in this case." RD, at 153. The interests of general deterrence in discouraging practitioners from ignoring their legal obligations and not genuinely complying with important recordkeeping provisions, and the interests of specific deterrence in preventing Respondent from hiding behind rote diversion controls without legitimately attending to and documenting red flags weigh in favor of a sanction of revocation.

Although the ALJ ultimately recommended a sanction short of revocation, I cannot agree, because there is insufficient evidence in the record to demonstrate that Respondent can be entrusted with a registration. *See Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988) (describing revocation as a remedial measure "based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration."). The ALJ's recommended mitigations might have helped Respondent understand better the legal requirements and might have permitted DEA to monitor her progress more easily, but they do not solve the underlying issue of trust.[89] If I did not appropriately consider whether Respondent had accepted responsibility such that I could entrust her with this responsibility, I would be

[89] In fact, the ALJ does not address the issue of whether I can trust the Respondent at all in his Recommended Decision. Most of the statements in the RD do not demonstrate that I can trust her, such as his qualified finding of her credibility. RD, at 22-24. It seemed from the ALJ's diction and punctuation that it was his frustration with the Government's case that led him to recommend a sanction less than revocation. *See id.* at 155. However, I cannot exclude from a final determination on this case consideration of the issue of trust in the face of violations, even where there are fewer violations found than initially alleged.

minimizing Registrant's violations of state and federal law, undermining the public interest by not attempting to address those violations, and then placing the burden on the Agency whose trust she broke to monitor her compliance. Although such measures may be appropriate in some cases, here, Respondent has not given me a reason to extend them to her.

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

ORDER

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a), I hereby revoke DEA Certificate of Registration BK9710939 issued to Kaniz F. Khan-Jaffery, M.D. Further, pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I hereby deny any pending application of Kaniz F. Khan-Jaffery, M.D., to renew or modify this registration, as well as any other applications of Kaniz F. Khan-Jaffery, M.D. for additional registration in New Jersey. This Order is effective [insert Date Thirty Days From the Date of Publication in the Federal Register].

Timothy J. Shea,
Acting Administrator.

[FR Doc. 2020-16387 Filed: 7/28/2020 8:45 am; Publication Date: 7/29/2020]