substance in North Carolina. Thus, because Registrant lacks authority to practice as a nurse practitioner in North Carolina and, therefore, is not authorized to handle controlled substances in North Carolina, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MJ7465289 issued to Lisa Jones, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Lisa Jones N.P., to renew or modify this registration, as well as any other pending application of Lisa Jones N.P., for additional registration in North Carolina. This Order is effective July 29, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 21, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–14200 Filed 6–27–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–29]

Jeffrey Pollock, P.A.; Decision and Order

On February 6, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Jeffrey Pollock, P.A., (Respondent) of Midvale, Utah. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, Control No. MP2900935, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '''an imminent danger to the public health or safety.''' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on July 28, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 54. Following the ALJ's Recommended Decision, Respondent filed Exceptions. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[1] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD.

I. Findings of Fact

1. Utah Standard of Care

Dr. Phillip Engen, M.D., testified for the Government as an expert in the area of pain management and the standard of care in the prescribing of controlled substances, specifically oxycodone. RD, at 9; Tr. 86–87. Dr. Engen is an anesthesiologist licensed to practice medicine in Colorado since 1993 and is Board certified in anesthesia, pain medicine, and hospice and palliative medicine.[2] RD, at 8; Tr. 75; Government Exhibit (GX) 14, at 2–3.[3] Dr. Engen testified that he has direct experience prescribing opioids for pain, including to patients with addiction issues, and is familiar with the risks associated with prescribing opioids. RD, at 8; Tr. 77, 79, 95.[4]

Regarding the Utah standard of care for a patient inherited from another provider, Dr. Engen testified that the inheriting provider must first evaluate the patient and determine if the patient is within the scope of his or her practice, including by obtaining informed consent and conducting a physical exam. RD, at 21; Tr. 139–40. If the patient is not within the scope of the provider's practice, then the provider must refer the patient out to a qualified specialist. RD, at 21; Tr.139–140. A physician treating a patient for pain is then required to complete a comprehensive evaluation of the patient. RD, at 10; Tr. 89–90.[5] Further, Dr. Engen testified that the physician must conduct a physical examination of the patient ''directed specifically to the nature of the pain history.'' RD, at 10; Tr. 90. Prior to prescribing opioids, the physician must query the controlled substance database (CSD) as well as attempt to retrieve records from the previous prescriber if the patient was inherited. RD, at 10; Tr. 90. The physician must also enter into an informed consent and opioid agreement

[1] The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment of each of the witnesses' credibility. *See* RD, at 2–31. The Agency agrees with the ALJ that the testimony from the DEA Diversion Investigator (DI), which was primarily focused on the introduction of the Government's documentary evidence, the subpoenas the DI issued to obtain documents, and the DI's involvement with the case, was generally consistent without indication of any animosity towards Respondent and thus was fully credible and warranted substantial weight. RD, at 8. The Agency also agrees with the ALJ that the testimony from the Government's expert witness, Dr. Phillip Engen, M.D., which was focused on the Utah standard of care and Respondent's prescribing to Patient J.M., presented an objective analysis that was internally consistent and logically persuasive and thus was credible, reliable, and warranted significant weight. *Id.* at 21. Finally, the Agency agrees with the ALJ that the testimony from Respondent, which was focused on his background and his treatment of Patient J.M., was genuine and generally consistent. *Id.* at 31. However, as noted by the ALJ, there was minimal evidence offered to corroborate Respondent's testimony and neither the supervising physician nor the pharmacist, both of whom Respondent claims were partners with him in coordinating Patient J.M.'s care, were called as witnesses. *Id.* Further, Respondent has a significant personal interest in the outcome of the proceedings that was also considered when weighing the testimony in relation to other evidence presented during the hearing. *Id.* Overall, however, the ALJ found, and the Agency agrees, that Respondent's testimony was generally credible. *Id.*

[2] For Dr. Engen's full qualifications, *see* GX 14; RD, at 8–9.

[3] Dr. Engen testified that he has not seen patients in a clinical setting since the onset of the coronavirus pandemic in March 2020 and that he currently practices predominately forensic medicine, which he described as ''[n]ot necessarily'' distinct from clinical work; Dr. Engen explained that forensic work ''entails looking at patient data. Patient data with patients that are alive—their records when they [are] alive—patient[ ] data when patients are expired, and clinically evaluating the signs and symptoms of opioid overdose-related deaths, or adverse effects.'' RD, at 8, 9; Tr. 71, 147–48.

[4] Dr. Engen asserted that although he currently practices in Colorado, he familiarized himself with Utah state law in preparation for the current matter, including by visiting the Utah Division of Professional Licensing (DOPL) website where he found links and information relating to the Utah Medical Practice Act, Utah's opioid prescribing guidelines, and other Utah state law relating to prescribing opioids. RD, at 9; Tr.78–83. Dr. Engen also testified that he is familiar with the CDC opioid guidelines, which the Utah opioid prescribing guidelines reference. RD, at 9 n.13; Tr. 83.

[5] Such comprehensive evaluation includes risk assessment, opioid risk assessment, review of history of opioid use, and ''documentation of the character of the pain, onset, location, duration, exacerbating factors, relieving factors[,] and all of the items that identify a specific pain complaint.'' RD, at 10 (quoting Tr. 90); Tr. 89–90.

with the patient establishing the clear functional goals of the opioid therapy and informing the patient of the risks of breaking the agreement. RD, at 10; Tr. 90–91. Dr. Engen testified that after opioid treatment has begun, the patient must be closely monitored, and each follow-up visit with the patient requires the same physical, risk, and functional improvement evaluations as during the initial visit as well as assessment of any adverse effects and aberrant behaviors. RD, at 8 n.12, 10; Tr. 91–92. Dr. Engen testified that signs of aberrant behavior indicative of controlled substance abuse are called ''red flags'' and that if a red flag is noticed, the red flag must be documented and the prescriber must follow up with, consult, or generate a differential diagnosis for the patient, any/all of which must also be documented. RD, at 13–14; Tr. 99–101. Further, any red flags highlighted in an opioid treatment agreement must be addressed and investigated. RD, at 12; Tr. 191. Dr. Engen explained that urine drug screens are required when prescribing opioids for a prolonged period to make sure that the patients are taking the medications as well as not taking any other unprescribed opioids or illicit substances. RD, at 13; Tr. 98. According to Dr. Engen, if a prescriber finds illicit substances or unprescribed opioids in a patient's urine drug screen, the prescriber must immediately call the patient in because ''that's a red flag for misuse and abuse''; during the visit, the prescriber would need to generate a differential diagnosis that either accounts for the improper substance or highlights the suspected abuse. RD, at 13; Tr. 98–99.

Finally, Dr. Engen testified that completing all of these steps, as well as documenting all of these steps, is necessary to protect the patient, provider, and community from the potentially harmful effects of opioids.[6] RD, at 10–11; Tr. 92–93. Dr. Engen reiterated that a provider in the context of ''chronic opioid therapy'' is required to document the comprehensive evaluation, risk assessment, physical examination, informed consent and opioid agreement, functional goals, assessment of the functional goals, review of the Prescription Drug Monitoring Program (PDMP) or CSD, and a proper diagnosis. RD, at 11; Tr. 93. Dr. Engen testified that in the context of opioid therapy, ''if you don't document it, it did not happen.'' RD, at 11 (quoting Tr. 187).

2. Respondent's Prescribing to Patient J.M.

Dr. Engen reviewed CSD prescribing data, medical records, and prescriptions relating to Respondent's prescribing of oxycodone to Patient J.M. from April 21, 2021, through October 4, 2022. RD, at 14; Tr. 101. Respondent is licensed as a Physician Assistant (P.A.) in the state of Utah and has approximately twenty-five years of experience. RD, at 2 (Stip. 4), 22; Tr. 210. Respondent is a hormone and thyroid specialist who does not regularly prescribe opioids[7] and has worked under a supervising physician, Dr. K.M., since moving to Utah.[8] RD, at 3 (Stip. 5), 22, 23; Tr. 210, 216–17. Between April 21, 2021, and September 6, 2022, Respondent issued at least 140 prescriptions for oxycodone, a schedule II controlled substance, in dosages of 20 mg and 30 mg to Patient J.M. RD, at 3–6 (Stips. 6–7).

Respondent testified that he first met with Patient J.M. in March 2021[9] and initially observed Patient J.M. to be in poor health; Patient J.M. reported back pain and told Respondent that he had been taking opioids to treat his back pain. RD, at 24; Tr. 222–25; 345–46. According to Respondent, the first visit by Patient J.M. involved discussion of a rehabilitative treatment plan not including opioids. RD, at 24; Tr. 225. Respondent testified that during a later visit, Patient J.M. told him that the provider who had been prescribing him opioids was moving and so he was looking for someone else to prescribe him the medication;[10] when Patient J.M. asked if he could continue care and discussed the opioids, Respondent ''turned [Patient J.M.] down.'' RD, at 24; Tr. 226–27, 346. Respondent testified that after ''an emotional plea from [Patient J.M.] who was desperate and talking about how he [felt] so tied to his pain medications,'' Respondent consulted Dr. K.M. RD, at 24; Tr. 228–29.

Respondent testified that he completed a ''full targeted exam on [Patient J.M.]'s back,'' the pain of which was related to an ATV rollover incident; Respondent also testified that he conducted multiple examinations throughout the course of his treatment of Patient J.M. but admitted they were not well-documented. RD, at 25; Tr. 231–34. According to Respondent, he requested Patient J.M.'s records from Patient J.M.'s previous providers, and although Patient J.M. said he would provide these records, he never did. RD, at 25; Tr. 234–35, 247.[11] Respondent also asserted that he would not have gotten to this point if Dr. K.M. had not been ''on board'' with treating Patient J.M. RD, at 25; Tr. 238. According to

[6] Such harmful effects can include sleep disorder breathing, hypogonadism, hypoadrenalism, and osteoporosis with long-term opioid use and death as a potential effect of ingesting a high strength opioid. RD, at 11 n.15; Tr. 95–96.

[7] Respondent testified that after his graduation in 1998, he worked in occupational and sports medicine for the first seven years of his career, during which he prescribed opioids on a near daily basis while working under the supervision of a physician. RD, at 22; Tr. 203–06. According to Respondent, prior to treating Patient J.M., the last time he prescribed opioids was between 2005 and 2006, when he briefly practiced pain management. RD, at 22; Tr. 208–209. Dr. Engen testified that pain management is not within Respondent's usual course of professional practice as he prescribes mostly testosterone, anabolic steroids, and growth hormones, and does not have 4,000 hours of experience treating patients or working with providers who have a chronic pain certification. RD, at 11; Tr. 188–89; *see also* Tr. 336–37. Respondent testified that in his current practice, 99% of the controlled substance prescriptions that he writes are for testosterone; further, aside from initial consultations, he sees most of his hormone therapy patients via telehealth. RD, at 22; Tr. 211–12.

[8] Respondent testified that he and Dr. K.M. entered into a written ''delegation of services of agreement,'' which is a physician supervision agreement that defines the scope of a P.A.'s practice and is required for all P.A.s in Utah until they have completed a certain number of hours of practice experience. RD, at 23; Tr. 217–20; *see also* Respondent Exhibit (RX) 5. According to Respondent, supervising physicians are ''ultimately responsible'' for their P.A.'s practice and P.A.s check everything that they do with their supervising physicians. RD, at 23; Tr. 221. Respondent testified that he consulted Dr. K.M. in all medical decision-making and trusted Dr. K.M.'s judgment; Respondent also testified that Dr. K.M. is directly responsible for Respondent's patients and that treatment decisions are Dr. K.M.'s to make ''because [they] ultimately fall[] on him.'' RD, at 23; Tr. 221–22. On cross-examination, Respondent agreed that the delegation of services agreement that he entered into with Dr. K.M. states that Respondent will mostly prescribe controlled substances related to hormones and weight loss and that Dr. K.M. must cosign ''any medical chart record of a prescription of a Schedule 2 or Schedule 3 controlled substance made by [Respondent].'' RD, at 23; Tr. 341–42; RX 5, at 2. Further, the agreement provides that ''situations or areas outside of [Respondent's] scope of practice will be referred to the appropriate specialist,'' to which Respondent agreed that Dr. K.M. should have signed off on every opioid prescription that Respondent wrote for Patient J.M. and should have referred Patient J.M. to a pain management specialist. RD, at 23; Tr. 342–43; RX 5, at 2.

[9] Respondent testified that Patient J.M. initially sought out hormone therapy and to ''have somebody available to talk to'' and ''order a test if needed'' as Patient J.M. was a ''hypochondriac.'' RD, at 24; Tr. 224, 226.

[10] Respondent testified that Patient J.M. requested help in weaning off of opioids to ''have a better quality or life or at least a more basic dosing.'' RD, at 25; Tr. 229.

[11] The only records from prior treatment that Patient J.M. provided to Respondent were MRI results from 2017. RD, at 25; Tr. 235, 238; *see also* GX 12, at 90–96. Dr. Engen opined that these MRI results were insufficient to substantiate a conclusion that Patient J.M. was experiencing pain and Respondent should have conducted a pain-directed physical examination; however, based on the documentation present in Patient J.M.'s patient file, Dr. Engen could not say definitively whether Respondent had conducted such an exam. RD, at 12; Tr. 165–70, 173; GX 12, at 90–96.

Respondent, he conducted an examination of Patient J.M. with Dr. K.M. and had a ''larger visit'' that involved Patient J.M., Dr. K.M., and a pharmacist (none of whom were pain specialists). RD, at 25–26, 26 n.26; Tr. 229–30, 239–40, 350. Respondent testified that during the meeting, he checked the CSD database to confirm that Patient J.M. was getting the prescriptions at the dosages and frequencies that he was reporting and to look for red flags. RD, at 26; Tr. 240–42.[12]

According to Dr. Engen, there was no ''proper'' diagnosis noted in Patient J.M.'s medical records during the first four months of his treatment by Respondent.[13] RD, at 14; Tr. 102. Nonetheless, Patient J.M. received weekly prescriptions for 150 tablets of oxycodone 20 mg and 200 tablets of oxycodone 30 mg, a dosage of ''almost twice the [morphine milligram equivalent (MMS)] of the previous prescriber.'' [14] RD, at 14; Tr. 103; GX 12, at 53–62. Further, in Dr. Engen's opinion, this frequency and dosage was inappropriate for the conditions noted in Patient J.M.'s medical file. RD, at 14; Tr. 103–04. Dr. Engen noted that the opioid treatment agreement signed by Respondent and Patient J.M. included some of the risks associated with opioid use such as addiction, physical dependence, and potential for withdrawal symptoms.[15] RD, at 11; Tr. 156–60; 174–75; GX 12, at 51. Further, Dr. Engen noted that he observed indicators that were suggestive of addiction in Patient J.M.'s patient file.[16] RD, at 12; Tr. 175. More than a year into treatment, Respondent began tapering the opioids for Patient J.M. which Dr. Engen agreed was appropriate; however, Dr. Engen opined that the tapering should have begun earlier than it did as tapering had been an initial goal of the treatment. RD, at 12; Tr. 178.[17]

Respondent testified that the amount of medication he prescribed to Patient J.M. was related to a discussion with the pharmacist about Patient J.M.'s tolerance to opioids; further, Dr. K.M. was ''on board'' with the amounts prescribed. RD, at 26; Tr. 244–45. Respondent testified that the goal of treatment was to wean Patient J.M. off of opioids but after the ATV accident, they ''decided to just not wean, but to give him some pain relief . . . ''; Respondent also testified that his attempts to wean Patient J.M. off of opioids were ''met with a lot of resistance.'' RD, at 27; Tr. 245–46, 253.[18] RD, at 27; Tr. 245–46. Further, Respondent testified that Dr. K.M. ''played a big part'' in his continuing to prescribe opioids to Patient J.M. and that he would ''just kind of do what [Dr. K.M.] ask[ed] for the most part.'' RD, at 27; Tr. 249–50.[19]

3. Improper Documentation

Dr. Engen noted that although the opioid agreement signed by Respondent and Patient J.M. was dated April 21, 2021, and the first opioid prescription Respondent wrote for Patient J.M. was dated April 21, 2021, the first documented visit from Patient J.M. was nearly four months later on August 2, 2021. RD, at 14–15; Tr. 104–05; GX 12, at 49, 51. Notably, Patient J.M. had been prescribed approximately 5,000 oxycodone tablets without proper documentation in the medical record. RD, at 15; Tr. 105; GX 11, at 1; GX 13, at 1. Further, Dr. Engen opined that the medical records for Patient J.M.'s August 2, 2021 visit do not contain sufficient information to support any medical diagnoses and were entirely inadequate for either an initial or follow-up visit. RD, at 15; Tr. 106–08.[20] Specifically, Dr. Engen observed that no history, physical exam, assessment, functional evaluation, or attempts to assess aberrant behavior or adverse effects of medications were documented

[12] Respondent also testified that the pharmacist sent Respondent a copy of the prescription fill history for Patient J.M. at that pharmacy, and these records gave Respondent a ''level of comfort'' because there was no indication of opioid abuse. RD, at 26, 26 n.27; Tr. 242–44; *see also* GX 12, at 53–75.

[13] Dr. Engen testified that he noticed general notes in the ''history of present illness'' section of Patient J.M.'s medical records after four months of treatment; however, Dr. Engen did not find any ''proper assessment[s] [or] planned diagnoses'' in the ''assessment and plan'' section nor anywhere else in Patient J.M.'s medical file and had to assume diagnoses based on the notes that he saw in the ''history of present illness'' section. RD, at 14; Tr. 102–03. Dr. Engen also noticed an ICD–10 code for cancer written on the prescriptions at issue in the current matter, but found no substantive documentation noting or supporting this diagnosis. RD, at 14; Tr. 103; GX 11, at 2, 4, 6. Regarding the cancer diagnosis code, Respondent testified that during his meeting with Dr. K.M. and the pharmacist, the pharmacist told Respondent that he needed a diagnosis code for all controlled substance prescriptions; Respondent testified that the pharmacist provided him with the cancer diagnosis code ''that the previous provider used.'' RD, at 30; Tr. 316; *see, e.g.,* GX 11, at 2, 4, 6. Respondent testified that because he thought the diagnosis codes were ''just for insurance billing purposes'' and he knew that Patient J.M. was not using insurance, he ''didn't look into it'' and ''just documented . . . the ones that he gave me.'' RD, at 30; Tr. 316–17.

[14] Dr. Engen testified that Patient J.M. had previously been prescribed approximately 683 MMEs of opioids per day. RD, at 11; Tr. 160–62; GX 12, at 67. Dr. Engen explained that MMEs—morphine milligram equivalents—are a uniform measurement of the strength of opioids and are utilized to determine opioid-related overdose or death; the higher the MMEs of an opioid dosage, the more likely it is to be associated with an opioid overdose or related death. RD, at 13; Tr. 96. According to Dr. Engen, the CDC opioid prescribing guidelines recommend limiting MME to 50 mg a day and having ''extensive conversations with the patient if you want to go to 90 MME.'' RD, at 13; Tr. 96–97. Dr. Engen opined that if a patient is being prescribed over 90 MME per day, the provider should have ''specific discussions regarding the increased risk of opioid overdose and death'' with the patient. RD, at 13; Tr. 97. Further, Dr. Engen testified that the Utah opioid guidelines specifically state that patients taking more than 80 mg of oxycodone a day should be referred to a pain specialist. RD, at 13; Tr. 97.

[15] Dr. Engen opined, however, that although withdrawal would have been an important consideration for Respondent if Patient J.M. had been an established patient receiving a high dose of opioids, because Patient J.M. was inherited from another provider, Respondent should have referred Patient J.M. to a specialist. RD, at 11–12; Tr. 163–64. Regarding the opioid treatment agreement signed by Respondent and Patient J.M., *see* GX 12, at 51–52, Respondent testified that he and Dr. K.M. had discussed its contents and Dr. K.M. had reviewed the final draft. RD, at 28; Tr. 252–53. On cross-examination, Respondent agreed that violation of the opioid treatment agreement should have resulted in the safe discontinuation of his care of Patient J.M. RD, at 29; Tr. 351.

[16] Dr. Engen also opined that it is ''medically probable'' that the erectile dysfunction, low testosterone, and delirium experienced by Patient J.M. as noted in his patient file were caused by long-term opioid use at an ''egregiously large,'' ''toxic'' dosage. RD, at 12; Tr. 175–78. Respondent testified that erectile dysfunction had been a longstanding issue for Patient J.M. and was only included in the notes because Patient J.M. expressed interest in trying a new ''shockwave therapy'' treatment. RD, at 29; Tr. 259, 261; *see also* GX 12, at 40.

[17] Dr. Engen noted that the tapering of opioids for Patient J.M. did not begin until nearly eight months after a delirium incident in September 2021 that resulted in Patient J.M. visiting an emergency room. RD, at 12 n.17; Tr. 189–90; GX 12, at 41. Regarding this incident, Respondent testified that the episode was not opioid-related and so he decided to not ''follow through with much.'' RD, at 29; Tr. 256–67. Even so, Respondent acknowledged and agreed with Dr. Engen that his documentation was ''way subpar, especially for this.'' RD, at 29; Tr. 258.

[18] Regarding steps he took to refer Patient J.M. to a specialist, Respondent testified that he told Patient J.M. that he did not feel qualified or comfortable continuing prescribing him opioids; further, Respondent testified that he documented this conversation and Patient J.M. agreed to look for another provider. RD, at 27; Tr. 369–70. Respondent testified that he never issued an official written referral, but did provide names of suggested practitioners; these practitioners were pain management specialists, not addiction specialists. RD, at 27; Tr. 370–71.

[19] Respondent testified that he had in-person visits with Patient J.M. every two weeks and was not concerned about Patient J.M. diverting his medication because Patient J.M. was wealthy; moreover, Respondent witnessed Patient J.M. take his medication when his watch timer went off, as well as concluded that someone taking so much medication would not give his or her medication away. RD, at 26–27; Tr. 233, 246–47, 250–51.

[20] Dr. Engen testified that if this had been a first office visit by Patient J.M., there should have been documentation of a comprehensive evaluation, a pain-directed physical examination, a ''proper diagnosis,'' and a diagnosis and functional goals assessment plan; if this had been a follow-up visit, there should have been documentation of a proper diagnosis, a pain-directed physical examination and diagnosis, and an assessment of adverse effects, aberrant behaviors, and progress towards therapeutic goals. RD, at 15; Tr. 107–08.

from this visit. RD, at 15; Tr. 105; GX 12, at 49. The records for the August 25, 2021 visit were similarly inadequate [21] and insufficient to justify the high amount of oxycodone prescribed (350 tablets a week). RD, at 16; Tr.111.[22]

Moreover, the records for all of the following visits were inadequate and insufficient to justify the high amount of oxycodone prescribed: 1) Patient J.M.'s September 7, 2021 visit, in which Dr. Engen observed no notes at all despite CSD data showing that Respondent wrote a prescription for 150 tablets of oxycodone 20 mg for Patient J.M. and Patient J.M. filled the prescription; 2) Patient J.M.'s March 16, 2022 visit, in which Dr. Engen observed no notes other than an indication that Respondent again wrote prescriptions for Patient J.M. for 200 tablets of oxycodone 30 mg and 150 tablets of oxycodone 20 mg; and 3) Patient J.M's April 21, 2022 visit, in which Dr. Engen noted that while Respondent included notes indicative of a physical examination, the documentation was still insufficient to justify the opioid prescriptions as the notes were not thorough enough, the notes lacked a plan or assessment, and the type of pain noted (muscle pain) was not an indication for opioid treatment. RD, at 16, 19, 20; Tr. 112, 127–28, 133; GX 12, at 20, 25, 45; GX 13, at 1.[23] Respondent also admitted that he had made after-hours visits to Patient J.M.'s home to conduct medical evaluations, though Respondent neither created nor kept medical records for these visits. RD, at 26 n.28; Tr. 361, 363–64.[24]

4. Failure To Properly Address Red Flags of Abuse/Diversion

Dr. Engen highlighted a note from the August 2, 2021 visit that indicated that Patient J.M. had lost prescriptions and was given replacement prescriptions during this visit; Dr. Engen opined that the loss and replacement of opioid prescriptions caused him concern for two reasons. RD, at 15; Tr. 105, 108; GX 12, at 49. One reason was that Patient J.M., who has an opioid use disorder, could have been taking more opioids than prescribed. RD, at 15; Tr. 108. The second reason was that the authorities were not notified of a high-dose, large quantity oxycodone prescription that might be found and filled by someone else. RD, at 15; Tr. 109. Dr. Engen opined that this red flag of a lost prescription was not properly addressed because there was no documented differential diagnosis, no documentation that local authorities were contacted, and no documented urine drug screen ordered to determine the medications present in Patient J.M.'s system. RD, at 15–16; Tr. 109.[25] Similarly, with regard to the February 9, 2022 visit, Dr. Engen said the record indicated that Patient J.M. was in the process of moving and had misplaced prescriptions. RD, at 17; Tr. 122; GX 12, at 28. On this occasion, Respondent reissued prescriptions for oxycodone 20 mg and 30 mg, noting that he ''checked CSD and last fill was [February] 3.'' RD, at 17–18; Tr. 122–23; GX 12, at 28.[26]

In addition to Patient J.M.'s instances of missing prescriptions, Dr. Engen also highlighted that notes from Patient J.M.'s March 3, 2022, and April 21, 2022 visits indicated that urine drug screens of Patient J.M. had tested positive for hydrocodone, a non-prescribed opioid. RD, at 18, 19; Tr. 124–25, 130; GX 12, at 20, 26. Dr. Engen explained that a non-prescribed opioid present in a urine drug screen is a red flag that needed to be addressed; specifically, Respondent should have created a differential diagnosis and discussed medication-assisted addiction treatment with Patient J.M. as well as documented this resolution. RD, at 18, 19; Tr. 125, 130–31. Instead, Respondent in both instances prescribed Patient J.M. 200 tablets of oxycodone 30 mg and 150 tablets of oxycodone 20 mg without documenting that any such action had been taken. RD, at 18, 20; Tr. 125–26, 132–33; GX 12, at 20, 26.[27]

Finally, Dr. Engen opined that an early refill given to Patient J.M. during his August 15, 2022 visit due to travel was a red flag that was not properly addressed or documented by Respondent. RD, at 20; Tr. 134–136; GX 12, at 5.

5. Failure To Address Signs of Adverse Effects

Dr. Engen highlighted a note from Patient J.M.'s September 27, 2021 visit that indicated Patient J.M. had been feeling ''groggy''—which Dr. Engen explained can be indicative of delirium, an ''acute toxic effect'' of opioids—and had visited the emergency room. RD, at 16–17; Tr. 113; GX 12, at 41. Dr. Engen opined that this instance of delirium was particularly concerning to him because the opioid doses prescribed to Patient J.M. were ''clearly'' in the range that could cause death. RD, at 17; Tr. 113. According to Dr. Engen, this incident should have resulted in a differential diagnosis and face-to-face physical examination to determine if it was related to the prescribed opioids. RD, at 17; Tr. 113–14. Dr. Engen testified that following this incident, Patient J.M. should have been referred to a pain medicine and/or addiction medicine specialist to consider medication-assisted treatment or a switch away from opioids, but instead, Respondent wrote Patient J.M. two more

[21] Dr. Engen testified that the only notes present for the August 25, 2021 visit indicate that Patient J.M. was ''doing ok, no new problems . . . [s]ome increased pain recently due to extra effort put into opening new store''; further, Respondent wrote Patient J.M. an early refill because he would be on vacation. RD, at 16; Tr. 110; GX 12, at 46.

[22] Respondent repeatedly wrote Patient J.M. a prescription for oxycodone 30 mg, four to five tablets every four hours, 200 tablets per week, and a prescription for oxycodone 20 mg, three to four tablets every four hours, 150 tablets per week. RD, at 16; Tr. 110; GX 12, at 46.

[23] Regarding blank patient notes in Patient J.M.'s medical records, Respondent testified that there had been occasions when he opened a note during a visit but found that ''there was really nothing that needed to be documented . . . .'' RD, at 28–29; Tr. 254–55; *see, e.g.,* GX 12, at 45.

[24] Respondent testified that despite visiting Patient J.M.'s house numerous times and sharing his personal cell phone number with Patient J.M., he did not have a personal relationship with Patient J.M. RD, at 26 n.28; Tr. 328, 347–48.

[25] Regarding the issue of lost prescriptions, Respondent testified that Patient J.M. lost his prescriptions on two or three separate occasions; Respondent testified that Patient J.M. was able to locate the missing prescriptions and return them to Respondent for disposal on one occasion, and on another occasion, Patient J.M. destroyed a missing prescription over video call with Respondent. RD, at 29–30; Tr. 260, 358, 360; *see also* GX 12, at 28, 49. Respondent also testified that he monitored the CSD to ensure that the missing prescriptions ''didn't surface'' and were not filled. RD, at 30; Tr. 359. On cross-examination, Respondent testified that he never conducted a pill count of Patient J.M. despite the lost prescriptions and early refill requests by Patient J.M. RD, at 30; Tr. 353–54.

[26] Dr. Engen noted that during the August 2, 2021 visit, Respondent noted in the medical file that he would no longer offer replacement prescriptions. RD, at 18; Tr. 123; GX 12, at 49. Dr. Engen reiterated that missing prescriptions warranted a differential diagnosis and Respondent should have contacted local authorities to track the prescriptions; moreover, all of these required actions needed to be documented. RD, at 18; Tr. 123; GX 12, at 28.

[27] Respondent testified that he used urine drug screens in his treatment of Patient J.M. because Patient J.M. was receiving a high dose of medication and he wanted to make sure that Patient J.M. was not getting additional medication elsewhere that could elevate risks; Respondent testified that he ordered urine drug screens for Patient J.M. ''pretty regularly'' and Patient J.M. always complied. RD, at 29; Tr. 258–59. Regarding the note reporting hydrocodone in Patient J.M.'s urine drug screen, Respondent testified that the note was a typo and that the tests he used for Patient J.M. did not test for hydrocodone. RD, at 29; Tr. 266–67, 354–55; *see also* GX 12, at 20. Dr. Engen opined that Respondent's actions were insufficient and opined that the positive result on this test should have resulted in Respondent ordering a more precise ''confirmatory'' test. RD, at 19 n.19; Tr.131–32; *see also* GX 12, at 20. Even so, based on Patient J.M.'s patient file note from the April 21, 2022 visit indicating a positive result for ''opiates/hydrocodone,'' Dr. Engen testified that he would assume that the test that Respondent used was sensitive enough to detect and differentiate oxycodone (as an opiate) and hydrocodone. RD, at 19 n.19; Tr. 131–32; *see also* GX 12, at 20.

prescriptions for oxycodone. RD, at 17; Tr. 114–15; GX 12, at 41.[28]

Regarding Patient J.M.'s March 3, 2022 visit, Dr. Engen highlighted notes that Patient J.M. visited the ER once more for gastrointestinal issues such as vomiting blood and inability to swallow[29] and a lab result indicated low testosterone. RD, at 18; Tr. 124; GX 12, at 26. Dr. Engen explained that opioids can cause such effects and again opined that a differential diagnosis to account for these adverse effects should have been considered and documented. RD, at 18; Tr. 124–25; GX 12, at 26. Finally, during Patient J.M.'s August 15, 2022 visit, Patient J.M. reported various adverse effects such as stomach problems, brain fog, and memory issues, but Respondent again failed to properly address and document these adverse effects. RD, at 20; Tr. 134–36; GX 12, at 5.

6. Weaning Off Patient J.M. From Opioids

In the medical file for Patient J.M.'s April 25, 2022 visit, Respondent's notes indicate that he and Patient J.M. discussed the long-term risks of opioid treatment and Patient J.M. stated that he wished to wean off in a safe manner; the initial goal was to lower Patient J.M.'s opioid dosage below 90 MME. RD, at 19; Tr. 128; GX 12, at 22.[30] Dr. Engen pointed out that Patient J.M.'s opioid therapy had begun nearly a year before this visit and opined that this discussion should have taken place on the first day. RD, at 19; Tr. 128–29*; see* GX 12, at 51; GX 13, at 1. However, Dr. Engen credited Respondent for recognizing the importance of lowering the dose from the ''massive'' 1900 MME per day that it had reached, and noted that Respondent did taper the dose by approximately 10% about one month after the April 5, 2022 visit. RD, at 19; Tr. 129. Even with the reduction, Dr. Engen noted that there was still insufficient documentation of a proper diagnosis, treatment plan, assessment, or functional evaluation to justify the dosage. RD, at 19; Tr. 129–30. Respondent continued to lower Patient J.M.'s dose by about 10% during each of Patient J.M.'s visits on July 6, 2022,[31] August 15, 2022, and September 13, 2022. RD, at 20, 28; Tr. 133–35, 270–71, 329; GX 12, at 2, 5, 11.

7. Respondent's Prescribing to Patient J.M. Was Beneath the Standard of Care

Dr. Engen concluded that each of the prescriptions issued by Respondent to Patient J.M. from April 2021 to at least September 2022 was issued outside the usual course of professional practice. RD, at 21; Tr. 142. Specifically, Dr. Engen opined that the amount of opioids prescribed to Patient J.M. was ''egregiously excessive,'' and that there was no clinical justification for the ''nearly 1,000 MME per day increase'' from April 21, 2021, to April 28, 2021, and from a previous dose that was already ''extremely high.'' RD, at 21; Tr. 143. Moreover, Dr. Engen again highlighted that there was insufficient documentation to support a diagnosis that would justify Respondent's prescribing of an ''egregious, massive dose'' of opioids to Patient J.M. RD, at 21; Tr. 143, 193–94. Dr. Engen opined that Respondent needed to conduct a comprehensive evaluation and develop a comprehensive treatment plan for Patient J.M. that, in light of the documented instances of likely opioid misuse, should have resulted in referral of Patient J.M. to medication-assisted addiction treatment. RD, at 21; Tr. 141–42. Dr. Engen ultimately emphasized that Patient J.M. was likely in a toxic range of oxycodone and oxycodone metabolites, that Respondent's care of Patient J.M. was ''grossly negligent'' and caused Patient J.M. harm, and that Respondent's care was outside the scope of Respondent's practice and fell below the Utah standard of care. RD, at 21; Tr. 143–44.[32]

Ultimately, the ALJ found, and the Agency agrees, that Respondent's prescribing was outside the usual course of professional practice and in violation of the Utah standard of care. RD, at 43. As described above, Respondent repeatedly failed to conduct and document proper physical examinations of Patient J.M.; repeatedly failed to document diagnoses justifying his continued prescribing of controlled substances to Patient J.M.; repeatedly failed to adequately address and document the risks of Patient J.M.'s continued use of controlled substances; and repeatedly failed to establish and document a proper treatment plan while continually writing Patient J.M. prescriptions for controlled substances at dangerously high dosages. *Id.*

II. Discussion

A. The Five Public Interest Factors

Under the Controlled Substances Act (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 under such section.'' 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

[28] Dr. Engen noted the sleep disordered breathing mentioned throughout Patient J.M.'s medical file and opined that Patient J.M.'s oxygenation was likely affected by the opioids that he was prescribed; Dr. Engen testified that a safety net needed to be created to prevent unintended overdose. RD, at 17; Tr. 113. Dr. Engen also testified that erectile dysfunction was an additional adverse effect of opioids noted during the September 27, 2021 visit; Dr. Engen explained that long-term opioid use can cause low testosterone and can affect the parasympathetic nervous system, either of which could result in erectile dysfunction, and opined that soundwave therapy, which Respondent noted as his recommended treatment, is not appropriate and does not address the opioid-related causes of erectile dysfunction. RD, at 17; Tr. 115–16; GX 12, at 40.

[29] Regarding this ER visit, Respondent testified that this occurrence did not cause him concern because Patient J.M. ''overreacts sometimes to certain things''; according to Respondent, the cause turned out to be gastroesophageal reflux that was ''corrected by acid lowering medications.'' RD, at 29; Tr. 260–61.

[30] According to Respondent, this discussion was inspired by Patient J.M.'s reluctance to wean off of opioids and the fact that Patient J.M. had ''been on pain meds for so long.'' RD, at 27–28; Tr. 264. Respondent testified that after his discussion with Dr. K.M. and realizing that he had been prescribing opioids to Patient J.M. for a year, he was tired of ''excuses'' to delay Patient J.M.'s weaning off; Respondent felt he needed to ''make it happen'' because he ''just was kind of done with it.'' RD, at 28; Tr. 264–65. According to Respondent, he told Dr. K.M. that he felt ''locked in'' to which Dr. K.M. told Respondent to ''make a demand'' and start lowering the dosage to Patient J.M. by 10% per month until it reached a ''more manageable dose.'' RD, at 28; Tr. 265. Respondent noted that he ''learned a lot about . . . how this works'' and agreed that Patient J.M. should have been referred to a specialist. RD, at 28 n.30; Tr. 266.

[31] Regarding this visit, Respondent testified that this was the point at which he believed he was beginning to make progress with Patient J.M. because Patient J.M. was being more compliant and the decrease in dosage did not result in increased pain; Respondent believed that Patient J.M. responded positively to their ''frank discussion'' and there were no more excuses to delay decreasing the dosage. RD, at 28; Tr. 269–70. Though recognizing progress had been made, Dr. Engen opined that Respondent still failed to include sufficient documentation in the patient file to support the still ''massive'' doses. RD, at 20; Tr. 134.

[32] Following an investigation by the Utah DOPL regarding Respondent's care of Patient J.M., Respondent entered into a stipulation with the DOPL that puts Respondent on probation for a period of five years, requires Respondent to have a supervising physician that is in good standing with the DOPL, and prohibits Respondent from prescribing opioids. RD, at 28; Tr. 318–320, 322–324; RX 7. In the stipulation, Respondent admits to making insufficient notations or diagnoses in the medical record to justify his prescribing of oxycodone to Patient J.M. and admits that his treatment of Patient J.M. constituted ''unprofessional'' conduct under Utah law. RD, at 28; Tr. 356–357; RX 7. Ultimately, Respondent wishes to relinquish his ability to prescribe opioids in the future; Respondent stated that he only needs to be able to handle and prescribe testosterone to be able to keep his practice open. RD, at 31; Tr. 335, 371–372.

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

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

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

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

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D.[33] RD, at 34; *see also id.* at 34 n.34 (finding that for Factor A, while there was an indirect recommendation from the Division of Professional Licensing of the Department of Commerce of the State of Utah, in the form of a stipulation and order related to Respondent's state license to practice as a physician assistant and to administer and prescribe controlled substances, such a recommendation has not historically been a case-dispositive issue under the Agency's precedent, and that Factors C and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts the ALJ's analysis, and finds that the Government's evidence 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); RD, at 31–48.

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.,* 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Respondent violated numerous federal and state laws regulating controlled substances. OSC/ISO, at 1–3. Specifically, federal law requires that ''[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). As for state law, Utah regulations prohibit issuing a prescription for a controlled substance ''without first obtaining information in the usual course of professional practice, that is sufficient to establish a diagnosis, to identify conditions, and to identify contraindications to the proposed treatment.'' Utah Code Ann. section 58–1–501(2)(m)(i);[34] *see also id.* section 58–37–6(7)(i) (a practitioner may not prescribe controlled substances in excess of medically recognized quantities necessary to treat the ailment, malady, or condition). Further, Utah regulations require that prior to issuing a prescription for opiates, a practitioner must discuss with the patient: ''(a) the risks of addiction and overdose associated with opiate drugs; (b) the dangers of taking opiates with alcohol, benzodiazepines, and other central nervous system depressants; (c) the reasons why the prescription is necessary; (d) alternative treatments that may be available; and (e) other risks associated with the use of drugs being prescribed.'' *Id.* section 58–37–19(2)(a)-(e). Finally, Utah regulations require that prescribing practitioners keep accurate records for each patient reflecting examination, evaluation, and treatment. Utah Admin. Code r. 156–37–602(b). Patient medical records shall: ''(i) accurately reflect the prescription or administration of controlled substances in the treatment of the patient; (ii) the purpose for which the controlled substance is utilized; and (iii) information upon which the diagnosis is based.'' Utah Admin. Code r. 156–37–602(c).[35]

In the current matter, the Agency agrees with the ALJ's analysis that Respondent repeatedly issued controlled substance prescriptions to Patient J.M. in violation of the Utah standard of care—and thus outside of the usual course of professional practice—because, as detailed above, Respondent repeatedly failed to conduct and document proper physical examinations of Patient J.M., repeatedly failed to document a diagnosis justifying the prescribing of controlled substances to Patient J.M., repeatedly failed to adequately address and document the risks of prolonged use of controlled substances with Patient J.M., and repeatedly prescribed dangerously high dosages of opioids to Patient J.M. without establishing and documenting a proper treatment plan; further, Respondent lacked the requisite training and experience to issue the prescriptions that he issued to Patient J.M. RD, at 43–48.[36]

As Respondent's conduct displays clear violations of the federal and state regulations described above, *see supra* I.7, the Agency agrees with the ALJ and hereby finds that Respondent repeatedly violated federal and state law relating to controlled substances. *Id.* at 48. Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). *Id.*

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62339 (2012). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance

[33] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the CSA and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f) as 21 U.S.C. 823(g)(1). When discussing the public interest factors, the RD refers to their former numerical designations (*i.e.,* 1–5) under 21 U.S.C. 823(f).

[34] Since the issuance of the OSC/ISO, this statute has been redesignated (with the language unchanged) as Utah Code Ann. section 58–1–501(2)(xiii)(A). *See* RD, at 36 n.35.

[35] Utah regulations also require that a ''physician assistant who wishes to change specialties to another specialty . . . shall engage in collaboration for a minimum of 4,000 hours with a physician who is trained and experienced in the specialty to which the physician assistant is changing.'' Utah Code Ann. section 58–70a-307(4).

[36] The Agency also agrees with the ALJ's conclusion that none of Respondent's arguments to the contrary, as detailed above, refute this analysis. *Id.*

of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

Here, and as noted by the ALJ, Respondent did admit some fault and accept some responsibility for his misconduct such as admitting and accepting his documentation failures. RD, at 50; Tr. 258. However, as noted by the ALJ, Respondent repeatedly shifted the blame for his misconduct to others. RD, at 51. In particular, Respondent blamed his supervising physician, Dr. K.M., who Respondent testified was ''ultimately responsible'' for the P.A.'s practice; Respondent also emphasized that he would ''just kind of do what [Dr. K.M.] ask[ed] for the most part.'' RD, at 50–51; Tr. 221–22, 238, 224–50, 334–35. Therefore, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for his actions.[37] RD, at 51 (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79188, 79201–02 (2016)).[38]

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74810. In this case, the Agency agrees with the ALJ that given that Respondent was the sole prescriber that issued all of the prescriptions at issue in the current matter, the interests of specific deterrence weigh in favor of revocation of Respondent's registration. RD, at 53; Tr. 227–238; GX 11–13. Further, the Agency agrees with the ALJ that the interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that failure ''to complete and document even the most basic treatment-related evaluations and examinations, or document any information related to treatment decisions'' can be overlooked or excused. RD, at 53.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Id.* at 51–53. As stated by the ALJ, ''Respondent issued many controlled substance[ ] prescriptions over a one-year period without any regard for his obligations to conduct and document adequate examination and evaluation to justify treatment.'' RD, at 51–52.[39] The ALJ also highlighted that ''Respondent's heavy reliance on, and deferral to, Dr. K.M., the pharmacist, and even Patient J.M. himself,[40] appears to have resulted in an almost complete abdication of Respondent's own role and responsibilities for the proper medical treatment of Patient J.M.'' RD, at 52.[41]

In sum, Respondent has not offered any credible evidence on the record to rebut the Government's case for revocation of his registration and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. RD, at 54. Accordingly, the Agency will order that Respondent's registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MP2900935 issued to Jeffrey Pollock, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Jeffrey Pollock, P.A., to renew or modify this registration, as well as any other pending application of Jeffrey Pollock, P.A., for additional registration in Utah. This Order is effective July 29, 2024.

[37] In his Exceptions, Respondent argues that other statements he made demonstrate that he ''clearly accepted responsibility for his actions.'' Exceptions, at 2–4. For example, Respondent stated: ''I wrote the prescriptions, and I'm totally responsible for that. It's not [Dr. K.M.]'s fault. It's not [Patient J.M.]'s fault. It's mine;'' and ''[t]here's a lot of regrets there. I realize the mistakes I made.'' Exceptions, at 2–3; Tr. 334, 362–63. In the case cited by Respondent in his Exceptions, the practitioner explained his misconduct, but ultimately took full responsibility and did not shift any of the blame or responsibility to others for his own actions and decisions. Exceptions, at 5 (citing *Wesley G. Harline, M.D., Continuation of Registration With Restrictions,* 65 5665, 5669 (2000)). In contrast, in the current matter, Respondent has made various statements essentially arguing that he was just doing what he was told to do by his supervising physician, as described above, and in contradiction to his other statements expressing a total acceptance of responsibility. RD, at 50–51; Tr. 221–22, 238, 224–50, 334–35. Therefore, the Agency does not find Respondent's acceptance of responsibility to be fully sincere and unequivocal; Respondent continually shifted between taking total responsibility himself and assigning blame to others.

[38] In his Exceptions, Respondent argues that he will change his behavior and that ''his stipulation with the Utah [DOPL] provides a structure for him to avoid making similar mistakes in the future.'' Exceptions, at 2, 5–7. When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy,* 81 FR 79202–03); *Daniel A. Glick, D.D.S.,* 80 74800, 74801, 74810 (2015). Even so, in the current matter, the ALJ noted, and the Agency has considered, that Respondent testified that he will not ''prescribe an opioid again or anything of a real addictive nature of any sort,'' as well as that he is less ''willing to go along with what people want'' and has ''tightened up everything'' going forward, though Respondent did not offer any further explanation of the latter statement. RD, at 51 n.44; Tr. 373–74. Notably, the stipulation order that Respondent entered into with the Utah DOPL puts Respondent on probation for five years, requires Respondent to have a supervising physician that is in good standing with the Utah DOPL, and prohibits Respondent from prescribing opioids. RD, at 51; Tr. 318–20; 322–24; RX 7. In light of Respondent's failure to unequivocally accept responsibility and due to the egregiousness of his actions and need for deterrence, the Agency does not find that the offered remedial measures are sufficient for it to trust the Respondent with his registration.

[39] In his Exceptions, Respondent argues that his prescribing did not cause Patient J.M. harm. Exceptions, at 12. Agency precedent is clear that proof of actual, subsequent harm is not required when a registrant has acted inconsistently with the public interest. *Melanie Baker, N.P.,* 86 FR 23998, 24009 (2021); *Larry C. Daniels, M.D.,* 86 FR 61630, 61660–61 (2021); *Jeanne E. Germeil, M.D.,* 85 FR 73786, 73799 n.32 (2020). Even so, the Agency gives substantial weight to the opinion of the Government's expert witness that Respondent's prescribing did cause harm to Patient J.M., with the amount of opioids prescribed to Patient J.M. being ''egregiously excessive'' and lacking documented clinical justification. Tr. 142–44; *see also* RD, at 52.

[40] The ALJ was particularly concerned ''by the instances of notes in Respondent's patient file that were entirely self-reported by Patient J.M., as well as the instances of Patient J.M. essentially treating himself with the capitulation of Respondent.'' RD, at 52.

[41] In his Exceptions, Respondent argues for a limited revocation of his registration, asserting that there is no ''rational connection'' between his wrongful conduct and a full revocation of his registration because he primarily practices hormone therapy, for which he is fully qualified, and he has never had any issues with respect to prescribing testosterone. Exceptions, at 7–8 (emphasis omitted) (quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005)) (citing 21 U.S.C. 824(b); 21 CFR 1301.36(c); Tr. 210–13, 215). Respondent also emphasized that he has treated thousands of patients and has never previously been the subject of any other complaints regarding controlled substances. Exceptions, at 8–9 (citing *Krishna-Iyer* v. *Drug Enf't Admin.,* 249 Fed. Appx. 159, 160 (11th Cir. 2007)); Tr. 211, 215. However, in *Jayam Krishna-Iyer, M.D.,* 74 FR 459 (2009), the Agency stated that ''even where the Government proves only a few instances of illegal prescribing in the 'entire corpus' of a practitioner's experience, the Government has nonetheless made out a *prima facie* case and thus shifted the burden to the registrant to show why he should be entrusted with a [new or continued] registration.'' *Jayam Krishna-Iyer,* 74 FR 464. In the current matter, given the particular egregiousness of Respondent's misconduct as well as Respondent's lack of unequivocal acceptance of responsibility, the Agency finds that considerations of the rest of Respondent's positive experience as a practitioner do not sway the Agency's findings that the Government has made a *prima facie* case for revocation of Respondent's registration and Respondent has failed to unequivocally accept responsibility for his actions. As for Respondent's argument of a lack of rational connection between his actions and his primary practice of prescribing testosterone such that full revocation of his registration is unwarranted, the Agency finds that Respondent's misconduct—such as his continuous documentation failures and his continuing to treat a patient while lacking the requisite qualifications and experience—does not speak only to his prescribing of opioids but to his prescribing practices as a whole. Accordingly, the Agency finds that there is undoubtedly a rational connection such that full revocation of his registration is warranted.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 21, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24–18]

Abdul Naushad, M.D.; Decision and Order

I. Introduction

On November 8, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Abdul Naushad, M.D. (Respondent) of Poplar Bluff, Missouri. OSC, at 1. The OSC proposes the revocation of Respondent's DEA Certificate of Registration (registration) No. BN7853864 on the ground that he has ''no state authority to handle controlled substances.'' [1] *Id.* (citing 21 U.S.C. 824(a)(3)).

By letter dated November 30, 2023, Respondent requested a hearing. The Government requested summary disposition in its ''Submission of Evidence and Motion for Summary Disposition'' dated December 7, 2023 (Government Summary Disposition Motion). Respondent opposed summary disposition arguing, among other things, that Respondent's registration expired before the OSC was filed, Respondent ''has not attempted to renew'' it, and, ''[s]ince there is nothing to revoke,'' summary disposition should be denied and the OSC should be dismissed. (Respondent Opposition), at 1–6. The Chief Administrative Law Judge, John J. Mulrooney II, denied the Government's Motion, ''*sua sponte*'' granted summary disposition for Respondent, and recommended that the OSC ''be dismissed based on the Agency's lack of jurisdiction over the registration.'' Order Denying the Government's Motion for Summary Disposition, Granting a Summary Disposition on Behalf of the Respondent, and Recommending Dismissal of the Order to Show Cause dated January 4, 2024 (RD), at 6.

After considering the entirety of the record, the Agency revokes Respondent's registration because of his undisputed loss of authority to dispense controlled substances in Missouri, the state where he is registered. 21 U.S.C. 824(a)(3); *infra* section III; Respondent Opposition, at 1; Government Motion, at 4; RD, at 2.

II. The Agency's Jurisdiction [2]

To effectuate the goals of combating the international and interstate traffic in illicit drugs, conquering drug abuse, and controlling the legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to . . . dispense . . . any controlled substance except in a manner authorized by the C[ontrolled] S[ubstances] A[ct]'' (CSA). *Gonzales* v. *Raich,* 545 U.S. 1, 12–13 (2005). Among the responsibilities and prerogatives that the CSA assigns to the Attorney General are to register practitioners to dispense controlled substances, and to de-register them. *E.g.,* 21 U.S.C. 823(g)(1) and 824(a). The Attorney General delegated these responsibilities to the DEA Administrator. 28 CFR 0.100.

The CSA provides that the Administrator ''shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). In 21 U.S.C. 824(a), the CSA also provides that the Administrator may suspend or revoke a registration for several reasons, including upon a finding that the registrant ''has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' 21 U.S.C. 824(a)(3). The CSA does not place a time restriction or constraint on the Administrator's administrative law enforcement investigations, findings, or actions regarding a registrant that may culminate in the suspension or revocation of the registrant's registration, nor is there anything in the record transmitted to the Agency that posits that it does.[3] *Id.*

[1] ''A jury found . . . [Respondent] guilty of health care fraud in 2022. . . . He is currently serving a prison sentence in connection with the crime. Since he cannot practice medicine before his release, he let his Missouri controlled substance license expire on August 31, 2023, and he let his . . . [registration] expire on October 31, 2023.'' Respondent's Memorandum of Law in Opposition to the Government's Motion for Summary Disposition and to the Order to Show Cause dated December 18, 2023 (Respondent Opposition), at 2.

[2] RD, at 6 (''[I]t is herein recommended that the Order to Show Cause dated November 8, 2023, be dismissed based on the Agency's lack of jurisdiction over the registration.'').

[3] Respondent argues that, as Respondent's registration ''expired before the DEA filed an Order to Show Cause, seeking to revoke,'' the ''Tribunal should deny the [revocation] request . . . [s]ince there is nothing to revoke.'' Respondent Opposition, at 1. The RD relies heavily on 21 CFR 1306.36(i) which concerns registrants' options for renewing their DEA registrations. The terms of subsection (i) do not resolve this matter.