Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

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

Pursuant to the Illinois Controlled Substances Act, a '''[p]ractitioner' means a physician licensed to practice medicine in all its branches . . . or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' 720 Ill. Comp. Stat. Ann. 570/102(kk) (West). Illinois law requires that ''[e]very person who manufactures, distributes, or dispenses any controlled substances . . . . must obtain a registration issued by the Department of Financial and Professional Regulation in accordance with its rules.'' *Id.* at 570/302(a).

Further, under Illinois law, the Illinois Controlled Substances Act authorizes the IDFPR to discipline a practitioner holding a controlled substance license. ''A registration under Section 303 to manufacture, distribute, or dispense a controlled substance . . . may be denied, refused renewal, suspended, or revoked by the Department of Financial and Professional Regulation.'' *Id.* at 570/304(a).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to handle controlled substances in Illinois, as his controlled substance license is ''inoperative.'' As already discussed, a practitioner must hold a valid controlled substance license to dispense a controlled substance in Illinois. Thus, because Registrant lacks authority to handle controlled substances in Illinois, Registrant is not eligible to maintain a DEA registration. Accordingly, I 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. AS2410075 issued to Verne A. Schwager, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Verne A. Schwager, M.D. to renew or modify this registration, as well as any pending application of Verne A. Schwager, M.D. for registration in Illinois. This Order is effective December 21, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–25523 Filed 11–18–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jeanne E. Germeil, M.D. Decision and Order

On March 5, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, collectively OSC) to Jeanne E. Germeil, M.D., (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause), at 1. The OSC informed Respondent of the immediate suspension of her Certificate of Registration No. FG0560765 pursuant to 21 U.S.C. 824(d), because her continued registration constituted an imminent danger to the public health and safety. *Id.* The OSC also proposed the revocation of Respondent's Certificate of Registration (hereinafter, registration) pursuant to 21 U.S.C. 824(a)(4), ''because [her] continued registration is inconsistent with the public interest . . . .'' *Id.* (citing 21 U.S.C. 823(f)).

I. Procedural History

Specifically, the OSC alleged that Respondent ''prescribed controlled substances to [two] DEA confidential source[s], Patient Y.H. [and Patient L.G.], that [she] knew or should have known were not for a legitimate medical purpose, in violation of 21 U.S.C. 841(a) and 842(a), 21 CFR 1306.04(a), and Fla. Admin. Code r. 64B8–9.013.'' OSC, at 2; *see also id.* at 6. The OSC alleged that Respondent ''[was] aware that at least a portion of the controlled substances [she was] prescribing to Y.H. [and to L.G.] were being sold, given to third parties, or otherwise diverted, because Y.H. [and L.G.] told [her] so.'' OSC, at 2; *see also id.* at 6. Additionally, the OSC alleged that Respondent ''had been falsifying [her] medical records.'' *Id.* at 9. The OSC alleged that Respondent's ''falsification of the[ ] records violated state law, *see* Fla. Stat. § 458.331(1)(m), and further demonstrate[d] that [Respondent] issued prescriptions for controlled substances to Patients Y.H. and L.G. outside the usual course of professional practice and that these prescriptions were beneath the standard of care for the State of Florida, violating both 21 CFR [1306.04(a)[1]] and Fla. Admin. Code r. 64B8–9.013.'' *Id.*

On March 5, 2018, the former Acting Administrator made a preliminary finding ''that [Respondent had] issued prescriptions for controlled substances that [she] knew were without a legitimate medical purpose and outside the usual course of professional practice, which is inconsistent with the public interest . . . .'' *Id.* And that ''in light of the rampant and deadly problem of prescription controlled substance abuse, that [Respondent's] continued registration . . . would constitute an imminent danger to the public health or safety because of the substantial likelihood that [she would] continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances unless [her] DEA [registration was] suspended.'' *Id.* The former Acting Administrator concluded that Respondent's ''continued registration . . . [would] constitute[ ] an imminent danger to the public health and safety.'' *Id.*

[1] The citation to 21 CFR 1604(a) throughout the OSC appears to be a typographical error (as no such regulation exists). It is clear from the surrounding text, that where the government typed 21 CFR 1604(a), it was referring to 21 CFR 1306.04(a). The Government also specifically notified Respondent that was alleging violations of 21 CFR 1306.04(a). OSC, at 2.

Pursuant to 21 U.S.C. 824(f) and 21 CFR 1301.36(f), the former Acting Administrator authorized DEA Special Agents (hereinafter, SA) and Diversion Investigators (hereinafter, DI) serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances that Respondent possessed pursuant to the suspended registration. *Id.* The former Acting Administrator also directed those employees to take possession of Respondent's registration No. FG0560765 and any unused prescription forms. *Id.*

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 10 (citing 21 CFR 1301.43). According to the Government's Notice of Service, a member of the DEA Miami Field Division personally served the OSC on Respondent on March 7, 2018. ALJX 2 (Government's Notice of Service of OSC), at 1.

By letter dated April 3, 2018, Respondent timely requested a hearing. ALJX 3 (Request for a Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, the ALJ). On April 6, 2018, the ALJ established a schedule for the filing of prehearing statements. ALJX 4 (Order for Prehearing Statements), at 1. The Government filed its prehearing statement on April 20, 2018. ALJX 6 (Government's Prehearing Statement), at 1. After requesting and receiving additional time, Respondent filed her Prehearing Statement on May 31, 2018. *See* ALJX 7 (Unopposed Motion for Extension of Time to File Prehearing Statement), ALJX 8 (Order Granting Respondent's Motion for Extension of Time to File Prehearing Statement), and ALJX 9 (Respondent's Prehearing Statement). Thereafter, the ALJ issued an Order denying Respondent's motion requesting discovery on the grounds that Respondent failed to establish that the documents she sought were relevant, material, and that the denial of access to the documents was prejudicial. ALJX 18 (Order Denying Respondent's Motion to Compel Discovery), at 4; *see also* ALJX 12 (Motion to Compel Discovery or in the Alternative Issuance of Subpoena), and ALJX 15 (Government's Response in Opposition to Respondent's Motion to Compel and Government's Motion to Quash Subpoena).

On June 6, 2018, the ALJ issued a Prehearing Ruling that, among other things, set out 18 agreed upon stipulations and established schedules for the filing of additional joint stipulations and for the hearing. ALJX 11 (Prehearing Ruling), at 3. Joint Stipulations were filed on June 19, 2018, and on June 26, 2018, the Respondent proposed additional Stipulations to which the Government had no objection. *See* ALJX 16 (Joint Stipulations) and ALJX 19 (Additional Stipulations Proposed by Respondent). The hearing in this matter took place in Miami, Florida and spanned three days. *See generally* Transcript of Proceedings in the Matter of Jeanne E. Germeil, M.D. (hereinafter, Tr.). Both parties filed posthearing briefs. *See* ALJX 27 (Government's Posthearing Brief) and ALJX 28 (Respondent's Posthearing Brief). The ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD) is dated August 31, 2018. Neither party filed exceptions to the RD. Transmittal Letter, at 2. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

Having considered the record in its entirety, I agree with the RD that the record established, by substantial evidence, that Respondent's ''continued registration is inconsistent with the public interest because of her improper prescribing and falsification of medical records.'' RD, at 106. I further agree with the RD that Respondent's ''failure to acknowledge any wrongdoing whatsoever'' and her ''fabrication of documentation to cover her tracks'' shows that she ''cannot be entrusted with the ability to continue prescribing controlled substances.'' *Id.* Moreover, I agree with the RD that revocation is the appropriate sanction. *Id.* I make the following findings of fact.

II. Findings of Fact

A. DEA Registration

The parties stipulated that Respondent is registered with DEA to handle controlled substances in schedules II through V under DEA Certificate of Registration No. FG0560765, at 951 North East 167th Street, North Miami Beach, Florida 33162. ALJX 11, at 1; Tr. 9; and GX 1 (Controlled Substance Registration Certificate). This registration expired on September 30, 2019.[2] GX 1.

[2] The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019).

B. The Investigation

DEA opened its investigation into Respondent after receiving information from the North Miami Beach Police Department that it had responded to Respondent's office several times due to ''altercations between the staff at the office and patients . . . [which] appeared to be over prescriptions for oxycodone.'' Tr. 28.

DEA used two confidential sources (hereinafter, CS), Y.H. and L.G., when conducting the investigation into Respondent. Tr. 28, 150. A DEA SA was the DEA handler for the two confidential sources. Tr. 150. SA would coordinate the undercover operation, meet with the confidential sources, give them direction as to what DEA wanted them to say or do, and provide them with electronic recording devices used to record audio and video of the interaction between the sources and Respondent. Tr. 151. After the undercover operation was finished, SA would obtain the recording devices from the confidential sources, download the information recorded to a DVD, and place the DVD into evidence. Tr. 151–53. SA would also provide a copy of the DVD to a DEA contractor, who would transcribe the DVD. Tr. 154. Thereafter, SA would compare the transcript to the recording for quality control and to make sure the transcript was accurate. Tr. 154–56, 163.

In November 2017, DEA executed a search warrant on Practice Fusion, an electronic medical record software company, to obtain Respondent's patient files. Tr. 29–30. DEA compared the obtained patient files for Y.H. and L.G. with the recordings made by Y.H. and L.G. and determined that there were inaccuracies in the medical records. Tr. 30. Thereafter, DEA retained a medical expert to review the patient files and recorded videos. *Id.*

C. Government's Case

The Government's documentary evidence consists primarily of video recordings [3] and transcripts of two confidential sources' visits with Respondent, and prescription records for the two confidential sources. *See* GX 1–19, 22. Additionally, the Government called five witnesses: A DI, confidential source Y.H., confidential source L.G., SA and an expert, Dr. Reuben Hoch, M.D.

DI testified about his investigation-related actions, including his role in

[3] Respondent's counsel conceded that ''there can be [no] question that the video evidence is always going to be good evidence.'' Tr. 485.

executing a search warrant to obtain Respondent's patient files. Tr. 26–42; RD, at 5. Having read and analyzed all of the record evidence, I agree with the RD that DI ''presented his testimony in a professional, candid, and straightforward manner.'' RD, at 5. I also agree that DI's testimony is ''sufficiently objective, detailed, plausible, and internally consistent'' to be given full credibility. *Id.*

Y.H. testified about her role as a confidential source [4] during DEA's investigation into Respondent, identified the recordings she made while meeting with Respondent, and identified the prescriptions Respondent issued to her. Tr. 42–95. Y.H. also testified regarding her non-recorded interactions with the staff at Respondent's practice. Tr. 45–46, 52, 57. Y.H. is a felon; however, her last conviction occurred in 1996, and I agree with the ALJ that it is too distant to impact her credibility. RD, at 6; Tr. 43. Having read and analyzed all of the record evidence, I agree with the RD that Y.H. ''presented her testimony in a candid and straightforward manner.'' RD, at 6. I also agree that ''Y.H.'s testimony was sufficiently objective, detailed, plausible, and internally consistent with other evidence of record . . . [to] merit it as credible.'' [5] RD, at 6.

L.G. testified about his role as a confidential source [6] during DEA's investigation into Respondent, identified the recordings he made while meeting with Respondent, and identified the prescriptions Respondent issued to him. Tr. 96–145. Y.H. also testified regarding his non-recorded interactions with the staff at Respondent's practice. *Id.* at 98, 106–07, 113–14. On this topic (which I find is irrelevant, *see supra* n.5), the ALJ found that L.G.'s testimony was briefly evasive when he did not acknowledge on cross examination that hypothetical video evidence of his interactions with Respondent's staff would have been better evidence than L.G.'s live testimony. RD, at 7; Tr. 133–35. The RD found that this was relevant to L.G.'s credibility. RD, at 7. L.G. also testified that he was convicted of a felony in 2010 for impersonating a police officer and was released from confinement for that offense in 2015. Tr. 96, 119; RD, at 6. The ALJ found the felony conviction was relevant to L.G.'s credibility. RD, at 7. However, the ALJ found, and I agree, that the two items relevant to L.G.'s credibility, ultimately ''do not diminish L.G.'s overall credibility.'' RD, at 7. Having read and analyzed all of the record evidence, I agree with the RD that L.G. ''presented his testimony in a candid and straightforward manner.'' *Id.* I also agree that ''L.G.'s testimony was sufficiently objective, detailed, plausible, and internally consistent with other evidence of record . . . [to] merit it as credible.'' *Id.*

SA testified about the investigative work he did regarding Respondent, including his work as the handler for both Y.H. and L.G. Tr. 150–52. SA also testified regarding the integrity and authentication of the video evidence and the accompanying transcripts. *Id.* at 152–63. Having read and analyzed all of the record evidence, I agree with the RD that SA presented his testimony ''in a professional, candid, and straightforward manner.'' RD, at 8. I also agree that SA's testimony is ''sufficiently objective, detailed, plausible, and internally consistent'' to be given full credibility. *Id.*

Dr. Hoch, is Board-certified in anesthesiology and pain medicine. Tr. 193; GX 22 (Resume of Dr. Hoch); RD, at 8. He is the chief anesthesiologist at the Aventura Hospital, where he is involved in the administration of surgical anesthesia and the management of pain. *Id.* Dr. Hoch has been involved in pain management for at least 25 years, including managing his own pain medicine practice, working as an interventional pain specialist at the JFK Medical Center in Palm Beach, Florida, and working as the Chief of the Division of Pain Medicine at Brooklyn Hospital. Tr. 194–95; RD, at 8. Dr. Hoch is licensed in Florida and was accepted in this matter (and he has been accepted in other DEA matters) ''as an expert in pain management and prescribing controlled substances with respect to the standard of care for pain management in the State of Florida.'' RD, at 9; *see also* Tr. 198, 202. Having read and analyzed all of the record evidence, I agree with the RD that Dr. Hoch's testimony ''was sufficiently objective, detailed, plausible, and internally consistent . . . [to] merit it as fully credible.'' RD, at 10–11. Moreover, Dr. Hoch's expert testimony was unrebutted. *Id.* at 11.

D. Respondent's Case

The Respondent's documentary evidence consists primarily of medical and criminal records for the two confidential sources, photos of the Germeil clinic, employee resumes,[7] a list of continuing education courses Respondent attended,[8] discharge letters for various patients [9] (not including Y.H. or L.G.), and documents related to an Administrative Complaint filed by the State of Florida Department of Health against Respondent. *See* RX 1–8, 11. As for live testimony, Respondent called two witnesses: J.F. and J.W. The main arguments Respondent attempted to establish through the witness testimony were: (1) That Respondent's positive dispensing experience should be considered; (2) that the Germeil clinic's procedures were to conduct a physical exam at the first visit and that medical assistants conducted pain assessments as part of taking a patient's vitals and discussed the vitals (including the pain assessment) with Respondent; and (3) that Respondent demonstrated her acceptance of responsibility by instituting remedial measures. ALJX 28, at 12–15. Notably, Respondent did not testify in this matter.

[4] Y.H. has worked for DEA as a paid confidential source since 2002. Tr. 43.

[5] The Respondent requested that the ALJ treat the testimony of both Y.H. and L.G. as not credible and afford their testimony no weight. RD, at 58; Tr. 487; ALJX 28, at 13–14. In support, Respondent argued that Y.H. and L.G. were both convicted felons who were paid to serve as confidential sources and, as such, they had ''every incentive to . . . help the government.'' Tr. 486. I agree with the ALJ's thorough assessment of the credibility of Y.H. and L.G. RD, at 94–95. In short, the relevant testimony of Y.H. and L.G. with regard to their encounters with Respondent is fully supported by the video evidence which, as Respondent notes, ''speaks for itself.'' ALJX 28, at 13; *see also* Tr. 485; RD, at 94. I also agree with the ALJ that the unrecorded interactions that Y.H. and L.G. had with Respondent's office staff and medical assistants are irrelevant to what Respondent herself did or did not do. *See* RD, at 94. As Dr. Hoch testified, it is the physician's responsibility to examine the patient, to draw his or her own conclusions, and to maintain medical records. Tr. 326, 354; RD, at 94. As such, it is the physician's recorded interactions with the patients that are relevant to this case. I fully agree with the ALJ's determination that Y.H. and L.G. are credible witnesses. RD, at 95.

[6] L.G. has worked as a confidential source for DEA for about two and a half years. Tr. 96.

[7] Respondent's resume indicates that Respondent has been a licensed physician in the State of Florida since October 2007. RX 5 (Resume of Jeanne Esther Germeil), at 1. She has had her own medical practice, Germeil Medical, Inc., since September 2011. *Id.*

[8] Among other things, the CLE records show that on October 7, 2017, Respondent completed 5 credits in the educational activity titled ''Legal & Ethical Implications in Medicine: A physician's Survival Guide—Laws & Rules.'' RX 6 (List of Respondent's Completed Continuing Education Courses), at 7. On October 1, 2017, Respondent completed 8 credits in the live educational activity titled, ''Quality Medical Record Keeping for Health Care Professionals.'' *Id.* at 9. On December 27, 2017, the Florida Medical Association notified Respondent that her record keeping mentor ''noted that [Respondent's] follow-up records showed improvement and that the recommendations made during Phase I, for the most part, were successfully implemented.'' *Id.* at 8 (emphasis in original). The Florida Medical Association mentioned that there were additional suggestions for further improvements, but that documentation was not included in the record. *Id.* The CLE records also show that Respondent took courses in prescribing for pain in 2013. *Id.* at 2.

[9] I note, that there are 47 pages of discharge letters including 38 unique letters and 9 duplicates. *See* RX 8 (Discharge Letters), at 14, 16, 19, 21, 24–25, 26–27, 32).

J.F. is Respondent's husband and the general manager of the Germeil Medical Clinic. Tr. 362, 390. J.F. testified regarding his roll maintaining the clinic's records and regarding the Clinic's procedures. *Id.* at 362. Concerning records, J.F. testified that, since 2011, medical records were contained in the Practice Fusion system and that, early on, the Clinic had problems with the system losing medical records.[10] *Id.* at 368. He also testified that L.G. was ordered to have a urine test performed, and that Respondent would no longer see him as a patient when L.G. did not comply with the order. Tr. 376–78; RX 3 (Lab Order for L.G. dated October 4, 2017). On this issue, the ALJ found ''[J.F.'s] reasons why the Clinic had not issued termination letters to Y.H. and L.G. for failing to take urine tests to be less than credible.'' RD, at 12. J.F. stated that the Clinic's procedure for vitals included taking blood pressure, weight, height, and conducting a pain assessment. Tr. 372. Further, J.F. testified that he was not present when vitals were taken, but he made sure that the information was entered into Practice Fusion. *Id.* at 372–73. The ALJ found that J.F. lacked credibility when he testified that he had personal knowledge of what vitals were taken with Y.H. and L.G., when really, J.F. simply had to trust that the recorded information was accurate. RD, at 12–13; Tr. 392, 419–20. J.F. also testified regarding the general procedures Respondent used when seeing patients and regarding improvements that the Germeil Clinic had instituted in the year prior to the hearing. Tr. 385, 387–88; RD, at 12.

Having read and analyzed all of the record evidence, I agree with the RD that J.F.'s testimony was not presented in a straightforward and candid manner. RD, at 13. Still, the RD found, and I agree, that J.F. was generally a credible witness. *Id.* The RD went on to find that much of J.F.'s testimony was irrelevant because he had little personal knowledge of how Y.H. and L.G. were treated as patients and because Respondent did not accept responsibility for her actions. *Id.* I agree.

J.W. is the office manager of the Germeil Clinic and, in that role, he supervises the medical assistants. Tr. 433–34, 437; *see also* RX 7 (Resume of J.W.). J.W. testified concerning the office procedures for taking a patient's vitals (which J.W. occasionally did himself). Tr. 442–47. In taking vitals, a medical assistant obtains a patient's blood pressure, weight, height, and conducts a preliminary pain assessment. *Id.* at 443. The vitals are then provided to Respondent who occasionally asks questions about a patient's pain. Tr. 445, 447, 453. Diminishing J.W.'s credibility, the ALJ found that J.W. painted a picture of being able to consistently monitor (hear and observe) the medical assistants, while they took vitals, when he obviously had other responsibilities as the office manager to which he had to attend. Tr. 434, 459, 471–74. Moreover, while J.W. testified credibly as to the clinic's procedures for taking a patient's vitals, he provided no testimony that he observed the taking of Y.H. or L.G.'s vitals. RD, at 14. Thus, the RD found, and I agree, that J.W.'s testimony does not outweigh the direct testimony of both Y.H. and L.G. concerning how their vitals were taken and whether or not they were asked about their pain.[11]

The ALJ found the remainder of J.W.'s testimony to be generally credible. RD, at 14. He testified that if Respondent suspected that a patient was diverting drugs, she would send the patient for a urine drug test. Tr. 448. If the patient did not take the urine drug test, the patient would not be seen again until the test is taken. *Id.* If the patient refuses to take the test, the patient would be discharged. *Id.* J.W. testified that since he started in December 2016, the Germeil Clinic had worked to reduce patients' wait times, spend more time with patients, use a pain questionnaire, and give more attention to taking vitals. Tr. 449–50.

Having read and analyzed all of the record evidence, I agree with the RD that J.W.'s testimony was presented in a straightforward and candid manner. RD, at 14. The RD went on to find that, like J.F.'s testimony and for the same reasons, much of J.W.'s testimony was irrelevant to the issues in this case. *Id.* Again, I agree.

E. The Standard of Care in the State of Florida

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

During the prehearing conference on June 6, 2018, the parties stipulated that Respondent ''is presently'' licensed in the State of Florida as a Medical Doctor. Dr. Hoch presented unrebutted testimony regarding the usual course of professional practice and the applicable standard of care for a Florida physician when prescribing controlled substances.

Dr. Hoch explained that Florida Administrative Code, Rule 64B8–9.013, Standards for the Use of Controlled Substances for the Treatment of Pain, lays out a physician's responsibilities when prescribing controlled substances for pain management.[12] RD, at 9; Tr. 203–05. Dr. Hoch acknowledged that Florida Administrative Code § 64B8–9.013 [13] provides guidelines rather than black-and-white rules, but he further acknowledged that those guidelines are authoritative regarding a physician's standard of care in Florida. RD, at 9; Tr. 272, 280–81. The Florida Code states that ''[t]he Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation.'' Fla. Admin. Code r. 64B8–9.013(1)(f) (West 2020).

According to Dr. Hoch, that regulation requires that a doctor: Take a complete medical history and conduct a physical examination [14] before issuing a prescription for a controlled substance; develop a written treatment plan; discuss the risks and benefits of controlled substances with a patient;

[10] DI testified that he has investigated at least three clinics that used the Practice Fusion program and he has not found that the program deletes or omits things. Tr. 32–33.

[11] Moreover, this testimony is irrelevant as this matter involves Respondent's failure to conduct physical examinations, not her failure to collect vitals. And as Dr. Hoch explains, Respondent's responsibility to conduct a physical exam cannot be satisfied by her medical assistants. *See infra* n.33; Tr. 307, 326.

[12] Moreover, the parties stipulated that ''a Florida licensed physician must follow the standards and rules set forth by the Florida Department of Health, Standards of Practice of Medical Doctors. ALJX 16, at 1; Tr. 10. The parties further stipulated that ''Florida Administrative Code, Rule 64B8–9.013, Standards for the Use of Controlled Substances for the Treatment of Pain, applies to a Florida licensed [p]hysician dispensing controlled substances.'' *Id.*

[13] The relevant portions of Florida Administrative Code § 64B8–9.013 have not been amended at any time during the relevant time period in this matter.

[14] The Florida Code does not define what constitutes a physical exam and does not necessarily require that a physician conduct a physical examination of a patient each time the patient presents for an appointment. RD, at 50; Tr. 289. However, Dr. Hoch opined that the standard of care requires a physician to perform a physical examination in certain circumstances including before first prescribing a controlled substance, when the patient requests a higher dose of controlled substances, presents with new symptoms or complaints, has a new diagnosis, or has not been seen for a period of months. *See* Tr. 290, 341–42, 345–46.

and maintain complete and accurate records with respect to a patient. RD, at 9; Tr. 205–06, 338. Additionally, a physician is required to conduct a periodic review of the course of treatment provided to a patient. RD, at 50; Tr. 337–38.

Further, a physician's medical records must also meet the standards set forth in Florida Administrative Code Rule 64B8–9.003 [15] and Florida Statute § 458.331(1)(m).[16] Under the Florida Administrative Code, ''[a] licensed physician shall maintain patient medical records . . . with sufficient detail to clearly demonstrate why the course of treatment was undertaken.'' Fla. Admin. Code r. 64B8–9.003(2) (West 2020). The regulation also states that physician's ''medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed . . . .'' *Id.* at 9.003(3). The Florida Statute provides that the ''following acts constitute grounds for denial of a license or disciplinary action . . .: [f]ailing to keep legible . . . medical records . . . that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.'' Fla. Stat. Ann. § 458.331(1)(m) (West 2020).

The Florida Administrative Code provides the following standards and record keeping requirements, *see* Fla. Admin. Code r. 64B8–9.013 (West 2020):

—''A complete medical history and physical examination must be conducted and documented in the medical record.'' Fla. Admin. Code r. 64B8–9.013(3)(a) (West 2020). A Florida physician ''is required to keep accurate and complete records to include . . . [t]he complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(1) (West 2020).

—''The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function . . . .'' Fla. Admin. Code r. 64B8–9.013(3)(b) (West 2020). A Florida physician ''is required to keep accurate and complete records . . . [on t]reatment objectives.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(4) (West 2020).

—''The physician shall discuss the risks and benefits of the use of controlled substances with the patient.'' Fla. Admin. Code r. 64B8–9.013(3)(c) (West 2020). A Florida physician ''is required to keep accurate and complete records to include . . . [d]iscussion of risks and benefits.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(5) (West 2020).

—''[T]he physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment.'' Fla. Admin. Code r. 64B8–9.013(3)(d) (West 2020). A Florida physician ''is required to keep accurate and complete records to include . . . [p]eriodic reviews. Records must remain current, maintained in an accessible manner, readily available for review . . . .'' Fla. Admin. Code r. 64B8–9.013(3)(f)(10) (West 2020).

Dr. Hoch explained that the basic rule of thumb for medical documentation is a ''SOAP'' note. RD, at 51; Tr. 212. The ''S'' is a patient's subjective complaint; the ''O'' is the doctor's objective findings based on a physical examination; ''A'' is the doctor's assessment or impression or the diagnosis of the condition the doctor is treating; and the ''P'' is the plan where a doctor explains why a particular treatment has been selected. RD, at 51; Tr. 212. He testified that the plan is the most important part of the documentation because it allows a doctor to explain ''why [she's] doing what [she's] doing . . . [and] detail [her] decision-making.'' Tr. 212. Dr. Hoch explained that it is a doctor's responsibility to maintain patients' records. RD, at 50; Tr. 354.

The Florida Administrative Code provides that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes.'' Fla. Admin. Code r. 64B8–9.013(1)(d) (West 2020). Dr. Hoch explained that, in Florida, ''it is a very big responsibility for prescribing physicians to be concerned about diversion.'' Tr. 224. When a patient tells a doctor that he or she is diverting his or her controlled substances that statement ''is a very big red flag that has to be addressed at that moment.'' RD, at 51; Tr. 224–25. In fact, Dr. Hoch stated that if a patient tells a doctor that he or she is selling or giving away controlled substances, ''that's sort of a deal breaker . . . .'' [17] Tr. 351. Therefore, in accordance with Dr. Hoch's testimony and the record as a whole, I find that the standard of care in Florida requires that a physician stop writing prescriptions for a patient following statements from the patient that are consistent with diversion. *See* Tr. 256–57.

F. The Florida Department of Health Complaint

The parties stipulated that Respondent's license to practice medicine has never been suspended or revoked by the State of Florida, Board of Medicine. ALJX 19 (Additional Joint Stipulations Proposed by Respondent), at 1.

On January 20, 2017, the Florida Department of Health issued an Administrative Complaint (hereinafter, Complaint) against Respondent. Respondent's Exhibit (RX) 11 (Records from the Florida Administrative Complaint against Respondent), at 16–24. The Complaint alleged, among other things, that Respondent's medical treatment of a patient M.N.,[18] between July 2013, and August 2015, ''fell below the prevailing professional standard of care,'' that she ''prescribed controlled substances inappropriately . . . , '' and that she ''failed to adequately create or maintain medical records that justified [the] amount and/or type of controlled substances she prescribed'' in violation of Florida Statute Section 458.331(1)(m) and Florida Administrative Code Rule 64B8–9.003. *Id.* at 20, 22–23. The facts alleged in support of the Complaint are that Respondent: Continued prescribing controlled substances to her patient upon learning that the patient was sharing another person's pain medication; failed to obtain a medical history; failed to list a chief complaint or history of present illness; recorded the patient's vitals only one time; and did not have the patient sign a pain medication contract. *Id.* at 17–18, 21. Based on the alleged violations, the Complaint sought ''permanent

[15] The relevant portions of Florida Administrative Code § 64B8–9.003 have not been amended at any time during the relevant time period in this matter.

[16] Florida Statute § 458.331(1)(m) has not been amended at any time during the relevant time period in this matter.

[17] Dr. Hoch's meaning by ''deal breaker'' is clarified by the totality of his testimony. Tr. 351. He testified that if he had a patient that admitted to diversion, he would not write another prescription for that patient. Tr. 256–57. Similarly, the Florida Administrative Complaint makes clear that the Florida Department of Health's position is that practitioners should ''discontinue prescribing scheduled medications after learning that the patient [engaged in diversion].'' RX 11, at 19. I also note that Respondent's Posthearing states, ''[Respondent] knows that she should not have issued the prescription for Y.H. and L.G. after they made statements consistent with diversion . . . she had a duty to investigate . . . [and] should have refused to give the prescription[s] and sent them for drug testing immediately.'' ALJX 28, at 15.

[18] There are no allegations of improper prescribing in this proceeding relevant to patient M.N.; however, this Complaint is relevant for other reasons as described herein.

revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand'' and/or other lesser penalties against Respondent. RX 11, at 24.

On February 8, 2017, Respondent signed a Settlement Agreement to settle the matters alleged in the Complaint. *Id.* at 6–15. Although Respondent neither admitted nor denied the allegations in the Complaint, she did admit that if the allegations were proven, they ''would constitute violations of Chapter 458, Florida Statutes.'' *Id.* at 7. The Settlement Agreement (as amended by the Florida Board of Medicine (hereinafter, State Board) pursuant to the Final Order, dated April 21, 2017) required Respondent to pay a fine of $10,000, reimburse $2,895.21 in costs, take four classes within a year, have a risk manager evaluate her medical practice, and comply with the risk manager's recommendations for improvements. *Id.* at 1–2, 6–15. Additionally the Settlement Agreement stated that ''[i]n the future, Respondent shall not violate Chapter 456, 458 or 893, Florida Statutes, or the rules promulgated pursuant thereto, or any other state or federal law, rule, or regulation relating to the practice or the ability to practice medicine . . . .'' *Id.* at 12.

G. Allegation of Improper Prescribing to Y.H.

Having read and analyzed all of the record evidence, I agree with the RD and find that the record contains substantial evidence that Respondent improperly prescribed controlled substances to Y.H. without a legitimate medical purpose, beneath the standard of care and outside the usual course of professional practice. RD, at 68, 71, and 73. Y.H. visited in the capacity as a confidential source for DEA a total of eight times between March 3, 2016, and January 25, 2017. Tr. 43–44; RX 1.[19] Y.H.'s first encounter with Respondent was on March 22, 2016. RX 1, at 30. According to the patient records, Y.H.'s chief complaint during the first visit was, ''I just came to hav[e] some pain meds. I am not function [sic.] w/o pain meds. . . . I share oxycodone 30 mg. I had 2 MVA and a bad slip[ ] about 2 years ago. I'd like flexeril as well.'' RX 1, at 30. Y.H.'s last three visits with Respondent, and the prescriptions resulting therefrom, presented as evidence in this case—September 8, 2016, October 12, 2016, and January 25, 2017.

1. Y.H.'s September 8, 2016 Visit

On September 8, 2016, Y.H. visited Respondent in her capacity as a confidential source and pursuant to the instructions given to her by her DEA handler. Tr. 43–44. During the visit, Y.H. wore a recording device that provided both audio and visual recordings of the office visit and she activated the device when she began interactions with Respondent. *Id.* at 44. As is evident from the records, Respondent spent approximately ten minutes with Y.H. GX 2 (Video Recording from September 8, Encounter). The vast majority of that time was spent discussing Y.H.'s sexuality and upcoming wedding. GX 3 (Transcript of Recording from September 8, Encounter), at 4–14.

During the visit, there was no discussion regarding the amount of Y.H.'s pain. *See generally* GX 3. Further, Y.H. testified that she was not asked to describe her pain levels by any member of Respondent's staff. Tr. 45, 87–88. The only discussion that occurred regarding pain occurred when Y.H. seemingly could not remember the location of her pain. GX 3, at 3

CS: I don't know. It's hurting my back.
Germeil: Uh—![20]
CS: Oh! I forgot. It's not my back—it's my neck.
Germeil: Uh
CS: It's my back and my neck. Yeah, 'cause [VOICES OVERLAP][21]
Germeil: So, it's not on your shoulder but [U/I]
CS: No. Not at all [U/I].

Id. After seemingly not knowing the location of her pain, Y.H. requested additional pills. ''Doc, remember last month you were going to give me one twenty (120)—for the Oxy's, but you didn't, and you told Josh to tell me this month you'd give me one forty (140).'' *Id.* at 10. After requesting additional pills, Y.H. informed Respondent that she had been giving, even selling, some of her pills to her brother. *Id.* at 17, 19.

CS: Okay, [my brother] is coming and he has to get pills because last month
Germeil: Uh-huh.
CS: when you didn't get—uh—you did not give him enough, and again, he wanted to borrow from me—and I was like ''No, I'm selling them to you this time''
Germeil: [U/I]
CS: ''You are going to give me money''
. . . .
CS: Last month he ran out—he's drinking three (3), four (4) pills a day—I said, ''Bro, you are not going [to] bum anything of me, you are going to give me money for these pills'' and he has to pay me first [U/I] because I'm not going to give them to him for free. I'm tired of him! I'm tired of him, doc!''

Id. Respondent's only response to Y.H.'s admission to diverting her controlled substances was ''Okay.'' *Id.* at 19.

Despite Y.H. not knowing the location of her own pain, requesting an increase in the number of pills prescribed, and admitting to diversion, Respondent wrote Y.H. prescriptions for controlled substances during the visit. GX 14 (Prescriptions issued to Y.H. on September 8), at 1. The parties stipulated that on September 8, 2016, Respondent prescribed Y.H. one hundred and forty[22] dosage units of oxycodone HCL 30 mg.[23] and sixty dosage units of alprazolam 2 mg.[24] ALJX 11, at 2; Tr. 9.

Y.H. testified that during this visit, Respondent did not conduct a physical exam, did not discuss other medical conditions Y.H. might have, did not discuss the medications that Y.H. was taking, did not discuss Y.H.'s diet or exercise. Tr. 48–49. Y.H. testified that the person who took her vitals on September 8, 2016, did not conduct a physical exam, discuss Y.H.'s medical condition, or ask about controlled substances Y.H. was taking. Tr. 45.

According to the patient records for that visit, Y.H.'s chief complaint was ''I need a little bit more of my pills, I ran out so fast. I really need them. I am getting married soon and I need a little bit more.'' RX 1, at 22. The patient records ''Plan'' stated that Respondent, among other things, explained the side effects of the medication, advised regarding adverse reactions, discussed lifestyle modifications to control weight and blood pressure, and that a

[19] No videos or transcripts of Y.H.'s earlier visits with Respondent were introduced in this matter. However, based on Y.H.'s credible testimony and the opinion of Dr. Hoch, I find that Respondent did not document or conduct a physical examination of Y.H. during any of her eight visits with Y.H. Tr. 92, 338–39. Respondent presented no evidence to demonstrate that a physical examination was conducted.

[20] Throughout the transcripts of the video recorded encounters (GXs 3, 5, 7, 9, 11, and 13), the transcriber used ellipses to depict pauses in the conversation. I have removed these and replaced them with dashes to prevent confusion between pauses and omissions of word from the quotations. Where they would have appeared at the beginning or end of a line, I have omitted them altogether.

[21] Bracketed text that describes the mechanics of the conversation between the confidential sources and Respondent, appear in the original transcript. Examples include, [VOICES OVERLAP], [U/I] which stands for unintelligible (Tr. 155, 159–60), [STUDDERS], and [WHISPERING].

[22] Y.H. requested an increase from one hundred and twenty to one hundred and forty pills a month, and this prescription shows that Respondent agreed to prescribe the additional pills. GX 3, at 10; GX 14.

[23] The parties stipulated that oxycodone HCL is listed by DEA as a Schedule II controlled substance. ALJX 11, at 2.

[24] The parties stipulated that alprazolam is listed by DEA as a Schedule IV controlled substance. ALJX 11, at 2.

''[d]etail[ed] explanation was provided about and against 'shopping' from physician to physicians [sic] and the harm (s) [sic] that can provoke.'' *Id.* According to the patient records, ''[a]pproximately 60 min was spent in this encounter,'' and Y.H.'s pain level was ''9.'' *Id.* However, Y.H.'s testimony and the recordings directly contradict the information in the ''Plan.''

Dr. Hoch opined that the two prescriptions issued by Respondent to Y.H. on September 8, 2016, (namely one hundred and forty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. Tr. 208–09; GX 14. In support of his opinion, Dr. Hoch noted that the plan does not bear any resemblance to the actual visit and discussion between Respondent and Y.H. Tr. 218. *Compare* RX 1, at 22, *with* GX 2 and GX 3. Dr. Hoch explains that Y.H. is a female and the plan refers to a male. Tr. 213, RX 1 (Patient File for Y.H.), at 22. Additionally, the plan discusses managing blood pressure when Y.H. has ''quite a good blood pressure'' that does not need to be controlled. Tr. 214. Also, Dr. Hoch explains that Respondent did not discuss side effects with Y.H., fall precautions, or the harms that occur by shopping from physician to physician, but that those non-existent conversations were recorded in the plan. Tr. 213–218. Additionally, Dr. Hoch pointed out that the plan records that the visit lasted approximately 60 minutes when the visit did not last an hour. Tr. 215. Finally, Dr. Hoch found no indication that Respondent performed a physical exam or took a medical history at the visit. Tr. 227. Further, Dr. Hoch opined that there is no indication in the patient treatment notes that Respondent maintained on Y.H. that Respondent conducted a periodic review of her treatment of Y.H.'s conditions by prescribing controlled substances to her. Tr. 246.

Additionally, Dr. Hoch opined that there was nothing documented in the patient file to justify the oxycodone or alprazolam [25] prescriptions and that ''prescription of these medications together has to be qualified quite extensively in the medical record.'' Tr. 259; *see also id.* at 219. Respondent prescribed Y.H. oxycodone 30 mg. which is a ''very strong'' dosage, and prescribed her one hundred and forty pills which ''means approximately four to maybe five a day . . . [or] 120 milligrams of [o]xycodone a day.'' Tr. 219. According to Dr. Hoch, the oxycodone prescription can cause a number of side effects that Respondent did not discuss with Y.H. Tr. 220–21. He further testified that the side effects of opioid use, in the order of ''the least to the most disabling,'' include pruritus or itching, urinary retention, nausea and vomiting, and constipation. *Id.* at 220.

Dr. Hoch explained that ''the most devastating complication or side effect of an opioid [like oxycodone] is respiratory depression, and that's what kills people.'' Tr. 221–22. Dr. Hoch explained that the risk is particularly high where, as here, the opioid is given with a benzodiazepine like alprazolam. Tr. 222. In light of the medications prescribed, Dr. Hoch explained that Respondent was required to warn Y.H. about the risk of respiratory depression and instruct the patient to make sure there was at least a three to four hour gap between administering the two different medications. *Id.* Based on Dr. Hoch's credible and uncontroverted testimony and based on the video recording and transcript, I find that there was no discussion of the risks at this visit. *Id.*

Dr. Hoch explained that in Florida, ''it is a very big responsibility for prescribing physicians to be concerned about diversion.'' Tr. 224. Accordingly, when Y.H. informed Respondent that ''she[was] either giving or selling pills that she[was] receiving from the doctor,'' Respondent should have been ''[t]remendous[ly] concern[ed].'' *Id.* Dr. Hoch concludes that Y.H.'s diversion admission was ''a very big red flag that [had] to be addressed at that moment.'' Tr. 224–25. I find that Respondent did not address Y.H.'s diversion admission on September 8, 2016. *See also* RD, at 68.

Accordingly, based on the credible and uncontroverted testimony of Dr. Hoch, I find that the two prescriptions issued by Respondent to Y.H. on September 8, 2016, (namely one hundred and forty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. *See* RD, at 68.

2. Y.H.'s October 12, 2016 Visit

On October 12, 2016, Y.H. visited Respondent in her capacity as a confidential source and pursuant to the instructions given to her by her DEA handler. Tr. 43–44. During the visit, Y.H. wore a recording device that provided both audio and visual recordings of the office visit and she activated the device when she began interactions with Respondent. RD, at 27; Tr. 52, 183. As is evident from the records, Respondent spent less than seven minutes with Y.H. GX 4 (Video Recording from October 12, Encounter); GX 5 (Transcript of Recording from October 12, Encounter), at 13. The majority of that time was spent discussing Y.H.'s cancelled wedding and a potential hurricane. GX 5, at 2–9; RD, at 69.

Towards the end of the visit, Y.H. informed Respondent that she had been selling some of her pills to her brother. GX 5, at 12–13.

CS: I tell [my brother], doc. ''Go get your own stuff.'' I'm tired of selling him my pills.
Germeil: You're right!
CS: But I sold him the pills, I sure did it, at twenty (20) bucks a pop, and he paid for them. I said, ''You don't go see the doctor?''
Germeil: You're right about that, but . . . . He has to learn.
CS: Exactly, doc.

Id. The video and transcription of the appointment show that Respondent did not express any concern about Y.H. selling her controlled substances to her brother. RD, at 69; GX 4; GX 5. Instead, Respondent seems to have acknowledged Y.H.'s admission of diversion and to have condoned the conduct. *Id.;* Tr. 231. Dr. Hoch explained, ''[Y.H.] is clearly indicating to [Respondent] that they are diverting the medication to someone else . . . selling their [p]ills at $20 a pop. The doctor notes it, addresses it and condones it.'' Tr. 231. Dr. Hoch explains that Respondent's actions with regard to Y.H.'s admission of diversion were ''a tremendous cause for concern.'' *Id.*

Not only did Respondent fail to address Y.H.'s admission of diversion, but Respondent, as the parties stipulated, went on to prescribe Y.H. one hundred and forty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg. ALJX 11, at 2; Tr. 9. *See also* GX 15 (Prescriptions Issued to Y.H. on October 12).

Dr. Hoch opined that the two prescriptions issued by Respondent to Y.H. on October 12, 2016, were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. Tr. 228–29; GX 15. In support of his opinion, Dr. Hoch noted that the plan documented for the October 12, 2016, visit was identical to, and has the same problems as the plan for the September 9, 2016 visit. Tr. 234, 236. As with the prior visit, Y.H. is a female and the plan refers to a male. Tr.

[25] Dr. Hoch explains that ''[t]wo milligrams of [a]lprazolam is a very high dose of [a]lprazolam.'' Tr. 222.

235; RX 1, at 20. Additionally, the plan discusses managing blood pressure when Y.H.'s does not require management. Tr. 236. Dr. Hoch opined that the plan was too generic and failed to identify what Respondent was ''doing for that particular problem.'' Tr. 235. Dr. Hoch also points out that in the patient record '' . . . Subjective is empty . . . [O]bjective is empty . . . Assessment is empty.'' Tr. 233. Additionally, Dr. Hoch explained that ''back pain'' is an indication of a complaint, but that a proper complaint, unlike this one, would explain ''what the patient is actually feeling, where, . . . what part of their back, the nature and quality of the pain.'' Tr. 234. Dr. Hoch's credible and uncontroverted testimony is that the patient chart does not justify the prescriptions that Respondent gave to Y.H. on October 12, 2016. Tr. 236.

Additionally, Dr. Hoch explained that these were the same two prescriptions issued on October 12, 2016, as were issued on September 9, 2016, and that the same issues about which he had already opined regarding the issuance of both an opioid and a benzodiazepine were present here. Tr. 232. Also, once again Dr. Hoch pointed out that Respondent failed to discuss with Y.H. the risks involved with prescribing opioids and benzodiazepines together. Tr. 232.

Further, Dr. Hoch explained, that Respondent's October 12, 2016 visit with Y.H. lacked the required ''encounter between the physician and the patient [and] discussion of the ongoing problem as this is a chronic pain problem.'' Tr. 229. Dr. Hoch explained that Respondent did not address the patient's pain, conduct a physical examination, take a complete medical history, discuss the risks of controlled substances, develop a treatment plan, or conduct a periodic review of the treatment of Y.H.'s conditions. Tr. 230, 246.

Based on Dr. Hoch's uncontroverted and credible testimony, the ALJ found, and I agree, that Respondent failed to make any statements that addressed Y.H.'s medical concerns during the October 12, 2016 visit. RD, at 27 (citing GX 4 and GX 5). Respondent did not ask any questions to determine Y.H.'s current medical condition, assess Y.H.'s level of pain or determine whether the treatment regimen she had prescribed to Y.H. was effective. RD, at 28 (citing GX 5); Tr. 87–88, 230. Respondent failed to: Conduct a physical examination of Y.H.;[26] discuss the side effects of the medication she was prescribing to Y.H. or the risks of using controlled substances; discuss the risks of doctor shopping; discuss Y.H.'s diet and exercise; discuss any medications Y.H. was taking; take a complete medical history of Y.H.; or develop an adequate treatment plan for Y.H. RD, at 28 (citing Tr. 54, 230, 232); GX 4; GX 5; RX 1, at 20.

In contrast, the patient notes that Respondent created concerning Y.H.'s October 12, 2016 appointment indicate that: The encounter lasted 60 minutes; and that Respondent discussed ''side effects,'' ''adverse reactions,'' ''safety precautions,'' and doctor shopping with Y.H. RD, at 28 (citing RX 1, at 20). The ''Plan'' for the October 12, 2016, visit was identical to the ''Plan'' for the September 8, 2016, visit and did not accurately capture what happened during the October 12, 2016, visit. RD, at 29; *and compare* RX 1, at 20, *with id.* at 22. Y.H.'s chief complaint was recorded as ''I have a lot [of] back pain and I need my pain meds.'' RX 1, at 20. Y.H.'s pain level was recorded as ''9.'' *Id.* But Dr. Hoch explained that a patient who presents with a pain level of nine would show ''a tremendous degree of discomfort.'' RD, at 29 (citing Tr. 331). The October 12, 2016 records lacked any information in the ''Subjective,'' ''Objective,'' and ''Assessment'' sections. RX 1, at 20.

The ALJ found based on Dr. Hoch's testimony, and I agree, that Respondent should have recognized Y.H.'s admission that she was diverting controlled substances as a red flag and considered it a ''deal breaker'' such that Respondent should not have issued prescriptions to Y.H. on October 12, 2016. RD, at 71; Tr. 351. The ALJ found, and I agree, that the prescriptions Respondent issued to Y.H., on October 12, 2016, were not issued for a legitimate medical purpose, and were not issued in the usual course of professional practice in the State of Florida. RD, at 71; Tr. 229, 236.

3. Y.H.'s January 25, 2017 Visit

On January 25, 2017, Y.H. visited Respondent in her capacity as a confidential source and pursuant to the instructions given to her by her DEA handler. Tr. 43–44. During the visit, Y.H. wore a recording device that provided both audio and visual recordings of the office visit and she activated the device when she began interactions with Respondent. RD, at 30; Tr. 58, 183. As is evident from the records, Respondent spent approximately seven and a half minutes with Y.H. GX 6 (Video Recording from October 25, Encounter). The majority of that time was spent on small talk discussing Y.H.'s family matters, including Y.H.'s trip to Cuba following her aunt's death, her brother's drug dependency, and the financial strain that resulted. GX 7 (Transcript of Recording from October 25, Encounter); RD, at 72.

At several points during the visit, Y.H. informed Respondent that she had been selling some of her pills. GX 7, at 4, 6, 9–11. During a discussion regarding an aunt of Y.H.'s who died in Cuba, Y.H., stated, ''I didn't even have money—I had to actually sell my pills unfortunately. I had to make some money. I had to go over there. Everything was on me.'' GX 7, at 4. Y.H. went on to state, ''Thank God I had some—the—some of the—pills that I had I was able to get rid of them and get some money to help me out, which I had to do now, because—I had to pay my rent.'' GX 7, at 6. Then the visit concluded with a final conversation regarding diversion.

CS: You think is right that I have to sell my own pills, my meds to, to pay for stuff for—[STUTTERS] that's just crazy doc.
Germeil: Listen! [STUTTERS] You are a good person . . . good things happen to good people. . . .
CS: . . . Right now, I'll probably go and I'll take some of these, I have to keep some, and then the others I probably have to sell [to my brother]. He probably, he'll probably take some from me 'cause that's all he does.'' . . .
Germeil: I feel sorry for you but uh—that's your call. That's mine, too. . . .
CS: Yeah, [o]xycodone's—thirty milligrams—[MURMERS] Yeah, we're good. Quantity one-forty (140). This is great. You don't know how much this helps me out, doc. You just don't know.
Germeil: Relax! Do not say that to nobody.
CS: Of course, not. . . .
Germeil: I know. I don't want to . . . get into trouble.

Id. at 9–11.

Despite Y.H.'s admission of diversion, Respondent, as the parties stipulated, prescribed Y.H. one hundred and forty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg. ALJX 11, at 2; Tr. 9. *See also* GX 16 (Prescriptions Issued to Y.H. on January 25). Dr. Hoch found that the same two prescriptions were issued on January 25, 2017, as were issued on September 9, 2016, and October 12, 2016, and that the same concerns about which he had already opined regarding the issuance of both an opioid and a benzodiazepine were present here. Tr. 237–38.

Dr. Hoch's credible and uncontroverted opinion was that the two prescriptions issued by Respondent to Y.H. on January 25, 2017, (namely

[26] In fact, during the appointment, Dr. Germeil sat on one side of an office desk and Y.H. sat across the desk from her. RD, at 70 (citing GX 4).

one hundred and forty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida. Tr. 237, 244; GX 16. In support of his opinion, Dr. Hoch found that the plan documented for the January 25, 2017 visit is nearly identical to, and has the same problems as the plan for the September 9, 2016, and October 12, 2016 visits. Tr. 241. As with the prior visits, Y.H. is a female and the plan refers to a male. Tr. 241; RX 1, at 19. Further, as with the prior visits, the plan stated that side effects, adverse reactions, diet and exercise, blood pressure, doctor shopping, and other matters were discussed during the encounter when the transcript and video evidence make clear that they were not. Tr. 241–42. Dr. Hoch opined that the plan has ''a disconnect'' in so far as it fails to address Respondent's approach for treating the diagnoses identified in the assessment section (specifically anxiety disorder and back ache). Tr. 240. Again, Dr. Hoch identified flaws in the chief complaint section of Respondent's records for Y.H., which contained a list of diagnosis rather than a true complaint. Tr. 239. Dr. Hoch's opinion was that the patient chart reflects an incomplete medical record and does not justify the prescriptions that Respondent gave to Y.H. on January 25, 2017. Tr. 250.

Additionally, Dr. Hoch explained that, once again, Respondent failed to conduct a thorough physical exam, take a complete medical history, or conduct a periodic review of the treatment of Y.H. Tr. 242, 246. In fact, during the encounter, Respondent sat on one side of an office desk and Y.H. sat across the desk from her. GX 6; RD, at 72. Dr. Hoch's conclusion is further supported by Respondent's failure to address Y.H.'s admission of diversion. Dr. Hoch explained, that there was a statement from ''the patient to the physician that the pills were being sold[,]'' which ''is diversion[,]'' and that ''the rule states that diversion is not acceptable.'' Tr. 243–44.

Based on Dr. Hoch's expert testimony, the ALJ found, and I agree, that Respondent failed to make any statements that addressed Y.H.'s medical concerns during the January 25, 2017 visit. RD, at 30 (citing GX 6 and GX 7). Respondent did not ask any questions to determine Y.H.'s current medical condition, assess Y.H.'s level of pain or determine whether the treatment regimen she had prescribed to Y.H. was effective. RD, at 32 (citing GX 7; Tr. 87–88, 246). Respondent did not discuss the side effects of the medication she was prescribing to Y.H.; discuss the risks of doctor shopping; discuss Y.H.'s diet and exercise; discuss any medications Y.H. was taking; take a complete medical history of Y.H,; or develop an adequate treatment plan for Y.H. RD, at 32 (citing Tr. 59, 241–243; GX 6; GX 7; RX 1, at 19). Further, Y.H. testified that Respondent did not conduct a physical exam during the encounter. Tr. 59.

In contrast, the patient notes that Respondent created concerning Y.H.'s January 25, 2017, appointment indicate that: the encounter lasted 60 minutes; and that Respondent discussed ''side effects,'' ''adverse reactions,'' ''safety precautions,'' and doctor shopping with Y.H. RD, at 33 (citing RX 1, at 19). The ''Plan'' for the January 25, 2017 visit was nearly identical to the ''Plan'' for the September 8, 2016, and October 12, 2016 visits (the only difference is the first line regarding a request for a urine drug test) and did not accurately capture what happened during the January 25, 2017 visit. RD, at 33; *compare* RX 1, at 19, *with id.* at 20, 22, *and with* GX–6, GX–7. Y.H.'s pain level was recorded as ''10.'' RX 1, at 19. But Dr. Hoch explained that a patient who presents with a pain level of ten would be in ''excruciating pain'' and one would question how such a patient could ''even sit in front of you.'' RD, at 33 (citing Tr. 331). If a person has a pain level of ten, then that person is usually in the hospital. *Id.* As with the prior patient records, the January 25, 2017 records lacked any information in the ''Subjective,'' and ''Objective'' sections. RX 1, at 19.

The ALJ found, and I agree, that Respondent did not advise Y.H. not to sell her controlled substances or otherwise engage in any meaningful conversation about diversion with Y.H. RD, at 72–73; GX 6; GX 7. The ALJ found, and I agree, that Respondent should have recognized Y.H.'s admission that she was diverting controlled substances as a red flag and considered it a ''deal breaker'' such that Respondent should not have issued prescriptions to Y.H. on January 25, 2017. RD, at 73; Tr. 242–44, 351.

The ALJ found, and I agree, that based on Dr. Hoch's testimony, the prescriptions Respondent issued to Y.H., on January 25, 2017, were not issued for a legitimate medical purpose, and were not issued in the usual course of professional practice in the State of Florida. RD, at 73–74.

In summary, I find that the six controlled substance prescriptions Respondent issued to Y.H., on September 8, 2016, October 12, 2016, and January 25, 2017, were not issued for a legitimate medical purpose and were issued outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida.

H. Allegation of Improper Prescribing to L.G.

Having read and analyzed all of the record evidence, I agree with the ALJ and find that the record contains substantial evidence that Respondent improperly prescribed controlled substances to L.G. without a legitimate medical purpose, beneath the standard of care, and outside of the usual course of professional practice in the State of Florida. RD, at 77, 80, and 82; *infra.*

L.G. visited Respondent in the capacity as a confidential source for DEA a total of five times between July 2016, and August 2017. Tr. 96–97; RX 2 (Patient File for L.G.). L.G.'s first encounter with Respondent was on July 25, 2016.[27] RX 2, at 22. According to the patient records, L.G.'s chief complaint during the first visit was, ''I have been having this strong right shoulder pain since a few years back. It just started again. I am tired of: [sic] ibuprofen/bengay/tylenol.'' RX 2, at 22. L.G.'s last three visits with Respondent, and the prescriptions resulting therefrom, were presented as evidence in this case—February 3, 2017, July 18, 2017, and August 3, 2017.

1. L.G.'s February 3, 2017 Visit

On February 3, 2017, L.G. visited Respondent in his capacity as a confidential source and pursuant to the instructions given to him by his DEA handler. Tr. 96–97. During the visit, L.G. wore a recording device that provided both audio and visual recordings of the office visit and he activated the device shortly before he went into Respondent's office. Tr. 97, 183. As is evident from the records, Respondent spent approximately seven and a half minutes with L.G. GX 8 (Video Recording from February 3rd Encounter). The vast majority of that time was spent discussing L.G.'s family issues and travels. GX 9 (Transcript of Video Recording from February 3, Encounter). At this visit, there was no discussion between L.G. and Respondent regarding any medical concerns. RD, at 35; GX 8; GX 9.

[27] No videos or transcripts of L.G.'s other visits with Respondent were introduced in this matter. However, based on L.G.'s credible testimony, I find that Respondent did not document or conduct a physical examination of L.G. during any of his five visits with L.G. Tr. 137, 338–39. Respondent presented no evidence to demonstrate that a physical examination was conducted.

Although medical concerns were not discussed at the visit, L.G. made several statements indicating that he was diverting pills. GX 9.

CS: and—what I did last time—with one of the prescriptions—knowing I'm not supposed to do that, I flipped it—I took some for me . . . took the rest to make some money
. . .
CS: I'm not trying to get in trouble or nothing like this.
Germeil: I know. Sometimes you have to help.
. . .
Germeil: But don't worry—uh. [L.G.]. You are okay.
CS: No, I mean—I'm being honest with you. That's what I've been doing. I—I sold a few of them . . . I—kept some for me.
. . .
Germeil: That's okay. Relax. Okay? But try to keep it for yourself. Try to keep your medication for yourself, okay?
. . .
CS: I mean, like I said, I took some—I took some for me and then the rest—just sold some of them
Germeil: Okay.
CS: Well, the majority of them.
Germeil: The majority of them?
Germeil: Okay. That—that is—Isn't, is that illegal, . . . ?
CS: I don't—I don't believe so. I know that but I'm telling you 'cause uh
Germeil: You don't know?
CS: You're my doctor!
. . .
Germeil: Be careful, okay?

Id. at 7–8, 11–13.

Despite L.G. admitting to diversion, Respondent wrote L.G. prescriptions for controlled substances during the visit. GX 17 (Prescriptions Issued to L.G. on February 3). The parties stipulated that on February 3, 2017, Respondent prescribed L.G. one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg. ALJX 11, at 2; Tr. 9.

During the encounter, there was no discussion regarding the amount of L.G.'s pain. GX 9. L.G. testified that on February 3, 2017, Respondent did not conduct a physical exam—in fact, the video evidence shows that Respondent sat on one side of an office desk and L.G. sat across the desk from her. Tr. 103; GX 8. Respondent also did not discuss any medical conditions L.G. had, did not discuss the side effects of or adverse reactions to the medications she was prescribing to L.G., did not discuss other medications L.G. was taking (other than the ones Respondent was prescribing), did not discuss L.G.'s diet or exercise. Tr. 103. L.G. testified that the employee at the Clinic who took his vitals on February 3, 2017, did not conduct a physical exam, ask any question about his medical conditions or ask about his pain. Tr. 98.

The ''Plan'' in L.G.'s records stated that Respondent, among other things, explained the side effects of the medication, advised regarding adverse reactions, discussed lifestyle modifications to control weight and blood pressure, and that a ''[d]etail[ed] explanation was provided about and against 'shopping' from physician to physicians [sic] and the harm (s) [sic] that can provoke.'' RX 2, at 20. According to the patient records, ''[a]pproximately 60 min was spent in this encounter,'' and L.G.'s pain level was ''9.'' *Id.*

Dr. Hoch opined that the two prescriptions issued by Respondent to L.G. on February 3, 2017 (namely one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. Tr. 248, GX 17. In support of his opinion, Dr. Hoch explained that the plan does not bear any resemblance to the actual visit and discussion between Respondent and L.G. Tr. 254. *Compare* RX 2, at 20, *with* GX 8 and GX 9. Additionally, the plan discusses managing blood pressure, when L.G.'s blood pressure does not require monitoring. Tr. 253. Also, Dr. Hoch explains that Respondent did not discuss side effects with L.G., fall precautions, or the harms that occur from shopping from physician to physician, but those conversations are recorded in the plan. Tr. 251–54. Additionally, Dr. Hoch explains the plan records that the visit lasted approximately 60 minutes when the visit did not last an hour. Tr. 252–53.

Dr. Hoch testified that the plan Respondent recorded for L.G.'s February 3, 2017 visit was ''very similar to,'' the plan for Y.H.'s September 9, 2016 visit which, as discussed above, was riddled with problems. Tr. 250. *Also compare,* RX 1, at 22, *with* RX 2, at 20.

Additionally, Dr. Hoch's credible and uncontested opinion was that there was nothing documented in the patient file to justify the oxycodone or alprazolam prescriptions. Tr. 250. As Dr. Hoch has mentioned, this combination of controlled substances is a particular concern due to the risk of respiratory depression—and Respondent did not discuss those risks with L.G. during this visit as was required. Tr. 247. Moreover, Dr. Hoch opined that it was ''a source of tremendous concern'' (for L.G.'s safety) that L.G. was prescribed this combination of a high-dose opioid and benzodiazepine after Respondent informed the physician that he drinks alcohol (and Respondent again did not discuss the risks with L.G.). Tr. 255.

Dr. Hoch, as discussed above, explained that in Florida, ''it is a very big responsibility for prescribing physicians to be concerned about diversion.'' Tr. 224; *see supra* II(E). Accordingly, when L.G. informed Respondent that he was selling these ''potentially deadly medications'' that was ''a huge issue for the community at large.'' Tr. 256. Dr. Hoch opined that Respondent failed to follow the ''state's recommendation of being always cautious about diversion of the medications . . .'' and that she should not have written another prescription for L.G. following his admission of diversion. Tr. 256–57. I find that Respondent did not engage L.G. in any meaningful discussion about diversion. RD, at 76; GX 8; GX 9.

Further, Dr. Hoch testified that Respondent did not conduct a periodic review of her treatment of L.G.'s conditions before prescribing controlled substances to him and also did not document a periodic review in the medical record. Tr. 250.

In conclusion, I concur with the ALJ and find that, based on Dr. Hoch's testimony, the two prescriptions for controlled substances issued by Respondent to L.G. on February 3, 2017, were not issued for a legitimate medical purpose and were issued outside of the usual course of professional practice and beneath the standard of care in the State of Florida. RD, at 77; Tr. 248.

2. L.G.'s July 18, 2017 Visit

On July 18, 2017, L.G. visited Respondent in his capacity as a confidential source and pursuant to the instructions given to him by his DEA handler. Tr. 96–97. During the visit, L.G. wore a recording device that provided both audio and visual recordings of the office visit and he activated the device shortly before he went into Respondent's office. Tr. 97, 183. As is evident from the records, Respondent spent approximately seven minutes with L.G. GX 10 (Video Recording from July 18, Encounter). Much of that time was spent discussing travel to Cuba. GX 11 (Transcript of Recording from July 18, Encounter), at 8–12. At this visit, discussion between L.G. and Respondent regarding medical concerns was limited to L.G. stating that he had pain ''like last time.'' GX 11, at 6–7; RD, at 40. However, there was no further elaboration of L.G.'s pain intensity or even where it was located, and Respondent and L.G. did not discuss pain at the prior visit. *Id.* Respondent also pointed out that L.G. did not visit Respondent often, in fact, his last

appointment had been more than four months prior, and that he could have an appointment every month. GX 11, at 11. Respondent did not ask L.G. how he had managed his pain between appointments without a prescription. *Id.*

Respondent and L.G. had a more elaborate conversation discussing diversion at the July 18, 2017 visit. GX 11. The conversation began with Respondent admonishing L.G. for selling his pills. GX 11.

CS: Between you and me, [WHISPERING] remember last time I told you I was selling my script.
Germeil: Yes, I know.
CS: I had to sell it to get to Cuba, to help somebody in the family, which I did. And that's why I say, ''Thank you!''
Germeil: Yeah, but you cannot sell that. That's a controlled medication, uh, ... [Y]ou have to keep that for your pain. . . .
Germeil: Don't do that or I can't give you the meditation—medication.

GX 11, at 2–3, 6. Following the admonition, Respondent stated that she was going to ''send [L.G.] to have a drug test done.'' GX 11, at 7. But then, Respondent said that she would still give L.G. a prescription because she knew that L.G. was in pain and she knew that L.G. was joking when he said that he was selling his pills. GX 11, at 8.

Germeil: I know that you have pain so, that's the reason I'm gonna give them to you.
CS: Okay, thank you.
Germeil: Yeah, but I shouldn't [U/I]. Never tell a doctor that you, you sell your medication. I know you didn't sell them, okay?
CS: Okay.
Germeil: You just wanted to be—to be—[i]t's fashionable now, okay?
CS: Okay.
Germeil: It's fashionable that everybody sells their medications but uh . . . I know that you don't do that.
CS: [CHUCKLES] Okay, no
Germeil: Because you joke, right?
CS: Yeah. A joke. Big joke.

Id.

Respondent wrote L.G. prescriptions for controlled substances during the visit. GX 18 (Prescriptions Issued to L.G. on July 18). The parties stipulated that on July 18, 2017, Respondent prescribed L.G. one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg. ALJX 11, at 2; Tr. 9.

L.G. testified that on July 18, 2017, Respondent did not conduct a physical exam—in fact, the video recording reveals that Respondent sat on one side of an office desk and L.G. sat across the desk from her. Tr. 108–09, GX 10. Again, L.G. testified that Respondent did not discuss any medical conditions L.G. had, did not discuss the side effects of or adverse reactions to the medications she was prescribing to L.G., did not discuss other medications L.G. was on, did not discuss L.G.'s diet or exercise. Tr. 109. L.G. testified that the clinic employee who took his vitals on February 3, 2017, did not conduct a physical exam, ask any question about his medical conditions or ask about his pain. Tr. 107.

The ''Plan'' in the patient records for L.G.'s July 18, 2017, visit was identical to the plan for the February 3, 2017, visit. *Compare* RX 2, at 18 *with* RX 2, at 20. The ''Plan'' again documents that Respondent, among other things, explained the side effects of the medication, advised regarding adverse reactions, discussed lifestyle modifications to control weight and blood pressure, and that a ''[d]etail[ed] explanation was provided about and against 'shopping' from physician to physicians [sic] and the harm (s) [sic] that can provoke.'' RX 2, at 18. According to the patient records, ''[a]pproximately 60 min was spent in this encounter,'' and L.G.'s pain level was ''9.'' *Id.*

Dr. Hoch opined that the two prescriptions issued by Respondent to L.G. on July 18, 2017 (namely one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. Tr. 259; GX 18. In support of his opinion, Dr. Hoch noted that there was no indication that a physical exam was conducted or that a medical history was taken. Tr. 261.

Dr. Hoch explained that the plan Respondent recorded for L.G.'s July 18, 2017 visit was similar to the plan for L.G.'s February 3, 2017, visit. Tr. 262. *Also compare,* RX 2, at 18, *with* RX 2, at 20. Accordingly, Dr. Hoch opined that the patient's record does not bear any resemblance to the actual visit and discussion between Respondent and L.G. Tr. 264. *Compare* RX 2, at 18, *with* GX 10 and GX 11. Again, Dr. Hoch explained that Respondent did not discuss side effects or adverse reactions with L.G., fall precautions or safety measures, or the dangers of shopping from physician-to-physician, but those conversations are recorded in the plan as if they had happened. Tr. 263–64.

Additionally, Dr. Hoch opined that there was nothing documented in the patient file to justify the oxycodone or alprazolam prescriptions here. Tr. 258–59, 263. As found above, this combination of controlled substances, namely ''a very strong opioid with a very strong [b]enzodiazepine[,] . . . has to be qualified quite extensively in the medical record to justify that both of them are being given at the same time.'' Tr. 258–59. Dr. Hoch explained that the justification was not present here. Tr. 259.

Regarding diversion, Dr. Hoch again opined that L.G. ''was admitting to [Respondent] that he was diverting medications that were given to him, and regardless of that statement, he did, in fact, get the prescription[s].'' Tr. 259. Accordingly, I agree with the ALJ's finding that Respondent did not engage L.G. in any meaningful discussion about diversion. RD, at 79; GX 10; GX 11.

Further, Dr. Hoch opined that the record for L.G. did not indicate that Respondent conducted a periodic review of her treatment of L.G.'s conditions. Tr. 262. Dr. Hoch explained that Respondent's Medical record for L.G.'s July 18, 2020 visit was not accurate, complete, or otherwise sufficient to meet the Florida standard of care. Tr. 262.

In conclusion, based on the credible and uncontroverted opinion of Dr. Hoch, I concur with the ALJ that the two prescriptions for controlled substances issued by Respondent to L.G. on February 3, 2017, were not issued for a legitimate medical purpose and were outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida. RD, at 80; Tr. 259.

3. L.G.'s August 30, 2017 Visit

On August 30, 2017, L.G. visited Respondent in his capacity as a confidential source and pursuant to the instructions given to him by his DEA handler. Tr. 96–97, 113. During the visit, L.G. wore a recording device that provided both audio and visual recordings of the office visit and he activated the device shortly before he went into Respondent's office. Tr. 97, 183. As is evident from the records, Respondent spent approximately seven minutes with L.G. GX 12 (Video Recording from August 30, Encounter); RD, at 45. The vast majority of that time was spent on small talk and discussing potential appointments for people L.G. knew. GX 13 (Transcript of Recording from August 30, Encounter).

At this visit, there was limited discussion between L.G. and Respondent regarding a new medical concern. RD, at 35; GX 12; GX 13.

CS: . . . Can you, really quick, check my knees right here, cause it's discomfort—Ouch, you saw, you heard?
Germeil: Let me see, let me see.
CS: It's still in discomfort. . . .

Germeil: Uh-huh. Yeah, you have arthritis, bones against bones . . . . Listen, you have to put [STUTTERS] a, uh, support. . . .
CS: Yeah, cause it's always been in discomfort.
Germeil: Uh-huh. Maybe you had a, a trauma in this knee before? You, you hit—did you hit it—somewhere? . . .
CS: I mean, I think so. . . .
Germeil: You have arthritis, the worst arthritis . . . . [Y]ou need to put a, a support, and then massage. Buy Bengay

GX 13, at 9–10. In response to the newly identified knee problem, L.G. testified that Respondent touched his knee; she ''grabbed [his] knee [right on his kneecap] with her two fingers and her thumb, and for like no more than three seconds, and she said [he] had arthritis.'' Tr. 143. L.G. further testified that Respondent did not conduct ''a thorough physical exam.'' Tr. at 115. *See also* RD, at 81; GX 12.

In addition to the limited discussion of his knee concern, L.G. stated during this appointment that he was no longer selling his pills. GX 13, at 4–5. Later in the visit, Respondent seemed to advise L.G. to ''be careful with the medications.'' GX 13, at 7. L.G. also explained to Respondent that the guys he was selling to would like to become Respondent's patients and Respondent told him to check with the front desk. GX 13, at 4–5.

CS: Anyways—pss—[WHISPERING] I'm not selling no more. I'm taking my own stuff.
Germeil: Okay. . . .
CS: . . . I was gonna mention it to you, if I can, the guys that I was, whatever they need to see a doctor. I don't know if you want new patients or you might need new patients, because they want to get the meds. . . . The [o]xycodone or whatever. . . .
Germeil: You can, you can, you can ask [at the front desk] if they have any, any, uh—any, any spot . . . [f]or new patients.
CS: Yeah, they guys, okay the guys I was selling to, but they are good people, they're reliable people. They won't even miss their appointments or nothing. They are good people. . . .

Id.

Respondent wrote L.G. prescriptions for controlled substances during the visit (prior to touching L.G.'s knee). GX 19 (Prescriptions Issued to L.G. on August 30); GX 12. The parties stipulated that on August 30, 2017, Respondent prescribed L.G. one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg. ALJX 11, at 2; Tr. 9.

Prior to issuing the prescriptions on August 30, 2017, there was no discussion of the amount of L.G.'s pain. GX 12. After receiving the prescriptions, L.G. mentioned that he had ''discomfort'' in his right knee, which Respondent quickly looked at and claimed was the result of arthritis. GX 13, at 9; Tr. 115; RD, at 45. L.G. testified that Respondent did not conduct a thorough physical exam. Tr. 115. For most of the appointment, Respondent sat on one side of an office desk and L.G. sat across the desk from her. GX 13; RD, at 81. Respondent also did not discuss any medical conditions L.G. had, did not discuss the side effects of or adverse reactions to the medications she was prescribing to L.G., did not discuss other medications L.G. was on, did not discuss L.G.'s diet or exercise. Tr. 115–16. L.G. testified that the person who took his vitals on August 30, 2017, did not conduct a physical exam, ask any question about his medical conditions or ask about his pain. Tr. 113–14.

The ''Plan'' in Respondent's records on L.G. for the August 30, 2017, visit, was identical to the plans for L.G.'s July 18, 2017, and February 3, 2017, visits; and was nearly identical to the plan sections purporting to capture Y.H.'s three visits at issue in the case. *Compare* RX 2, at 16, *with* RX 2, at 18 and 20, and RX 1, at 19, 20, and 22. Once again, the ''Plan'' stated that Respondent, among other things, explained the side effects of the medication, advised regarding adverse reactions, discussed lifestyle modifications to control weight and blood pressure, and that a ''[d]etail[ed] explanation was provided about and against 'shopping' from physician to physicians [sic] and the harm (s) [sic] that can provoke.'' RX 2, at 16. According to the patient records, ''[a]pproximately 60 min was spent in this encounter,'' and L.G.'s pain level was ''9.'' *Id.*

Dr. Hoch opined that the two prescriptions issued by Respondent to L.G. on August 30, 2017, (namely one hundred and twenty dosage units of oxycodone HCL 30 mg. and sixty dosage units of alprazolam 2 mg.) were issued outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida. Tr. 270–71; GX 19. In support of his opinion, Dr. Hoch explained that the plan differs from the actual visit and discussion between Respondent and L.G. Tr. 267–69. *Compare* RX 2, at 16, *with* GX 12 and GX 13. Dr. Hoch explained that Respondent did not discuss side effects or adverse reactions with L.G., fall precautions, or the harms that occur by shopping from physician to physician, but those conversations are recorded in the plan. Tr. 268–69. Dr. Hoch explained that the plan Respondent recorded for L.G.'s August 30, 2017 visit was ''identical'' to the plan for L.G.'s July 18, 2017, and February 3, 2017, visits. Tr. 267–68. *Compare* RX 2, at 16, *with* RX 2, at 18 and 20.

Additionally, Dr. Hoch's expert opinion was that the patient file was insufficient to justify the oxycodone or alprazolam prescriptions here. Tr. 267. He also explained that the record was not complete and accurate. Tr. 269. As found above, per Dr. Hoch, this combination of controlled substances is a particular concern due to the risk of respiratory depression, and Respondent did not discuss those risks with L.G. during this visit as was required. Tr. 247, 265–66.

Regarding diversion, Dr. Hoch pointed out that once again at this visit, L.G. informed Respondent that he had been selling his medication. Tr. 266. Dr. Hoch noted that Respondent did inform L.G. that he needed to be careful with the medications, but opined that the statement was not sufficient to warn L.G. of the dangers of diversion. Tr. 270.

Further, Dr. Hoch opined that Respondent did not conduct a periodic review of her treatment of L.G.'s conditions before prescribing controlled substances to him (let alone document it in the medical record). Tr. 269. He also opined that there was no indication in the record that Respondent gave a physical exam [28] or took a full and complete medical history. Tr. 269.

In conclusion, and based on the credible and uncontroverted testimony of Dr. Hoch, I concur with the ALJ that the two prescriptions for controlled substances prescriptions issued by Respondent to L.G. on August 30, 2017, were not issued for a legitimate medical purpose and were outside the usual course of professional practice and beneath the applicable standard of care in the State of Florida. RD, at 83; Tr. 270–71. In summary, I find that the six controlled substance prescriptions Respondent issued to L.G., on February 3, 2017, July 18, 2017, and August 30, 2017, were issued outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida.

[28] Dr. Hoch testified that merely touching a knee is insufficient for a doctor to determine that a patient has arthritis. Tr. 330. To adequately conduct a physical examination regarding knee pain, a physician would ''have to do flexion extension exercises . . . palpate or examine the knee, press it and try to find particular locations and then if you['re] very concerned . . . [t]his is where x-rays and perhaps MRIs do come into play.'' Tr. 329. Thus, I agree with the ALJ's finding that Respondent's touching of L.G.'s right knee on August 30, 2017, did not constitute a sufficient physical examination. RD, at 81.

I. Allegation of Recordkeeping Violations and Other State Law Violations

The medical records at issue in this case cover the six different encounters [29] discussed in detail above: Y.H.'s encounters with Respondent on September 8, 2016, October 12, 2016, and January 25, 2017; and L.G.'s encounters with Respondent on February 3, 2017, July 18, 2017, and August 30, 2017. *See* OSC; *supra* II. According to Dr. Hoch's credible and uncontroverted testimony, the records Respondent maintained for Y.H. and L.G. do not document a complete medical history, a physical examination, or a periodic review as required by state law. RD, at 50; Tr. 324, 338–39; RX 1; RX 2. Based on Dr. Hoch's testimony and the record as a whole, I find that the medical records for each of the six encounters are insufficient, inaccurate, and incomplete.

Consistent with the findings of the ALJ and based on the uncontroverted and credible testimony of Dr. Hoch, I find that the ''Plan'' sections of the patient records for each of the six encounters at issue in this case are identical (with the exception of Y.H.'s January 25, 2017, plan which contains one additional line regarding the need for a drug test). *Compare* RX 1, at 19, 20, 22; and RX 2, at 16, 18, 20; *see also* Tr. 234, 236, 241, 250, 262, 267–68. All six of the patient records document that Respondent, among other things, explained the side effects of the medication, advised regarding adverse reactions, discussed lifestyle modifications to control weight and blood pressure, discussed safety precautions, and that a ''[d]etail[ed] explanation was provided about and against 'shopping' from physician to physicians [sic] and the harm (s) [sic] that can provoke.'' RX 1, at 19, 20, 22; and RX 2, at 16, 18, 20. In contrast to the patient records, I have found that Respondent did not discuss the side effects of the medication, adverse reactions, lifestyle modifications to control weight and blood pressure, safety precautions, or shopping from physician to physician during any of the six encounters at issue. *See supra* and GX 3, GX 5, GX 7, GX 9, GX 11, and GX 13. My finding is consistent with Dr. Hoch's testimony that the plan section of the patient records does not bear any resemblance to the actual visits and discussions between Respondent and the confidential sources. *See* Tr. 218, 241–42, 251–54, 263–64, 268–69. I agree with the ALJ's finding that ''merely by comparing the recordings made by both Y.H. and L.G. when they met with [Respondent] with her treatment notes, it is readily obvious that the records [Respondent] prepared do not accurately report what happened during those encounters.'' RD, at 91.

Not only are the plans inaccurate, but even if they were accurate, Dr. Hoch opined that none of the plans explain what the objectives are that the Respondent was planning to use to determine the success of her treatment. Tr. 353. *See also* 230, 246. This is because, as Dr. Hoch characterized it, there was a ''generic rehashing of the same plan visit after visit'' and the plans fail to identify what Respondent was ''doing for [any] particular problem.'' Tr. 235.

I have found above that the patient records for each of the six encounters at issue reflect that ''[a]proximately 60 min was spent in [each] encounter.'' RX 1, at 19, 20, 22; and RX 2, at 16, 18, 20. In contrast to the patient records, I have found that the lengthiest encounter at issue in this matter was only approximately ten minutes, and that most of the encounters were around seven to seven–and-a-half minutes long. GX 2, GX 4, GX 6, GX 8, GX 10, and GX 12.

I have found above, based on the record as a whole and Dr. Hoch's testimony, that Respondent did not conduct a physical exam during any of the six encounters and that none of Respondent's medical records reflect that a physical exam was conducted at any of the six encounters at issue. GX 2, GX 4, GX 6, GX 8, GX 10, and GX 12; RX 1, at 19, 20, 22; and RX 2, at 16, 18, 20; Tr. 48–49, 54, 103, 109, 115, 230, 232, 242, 246, 269, 324, 339. Additionally, I find, consistent with Dr. Hoch's testimony, that none of the medical records at issue in this matter reflect a complete medical history. Tr. 324. Additionally, I find, consistent with Dr. Hoch's testimony, that there was no periodic review conducted at any of the six encounters at issue here. Tr. 230, 242, 246, 250, 262, 269. Therefore, I agree with the ALJ and find substantial evidence that Respondent issued a total of twelve prescriptions to two different CSs without maintaining sufficient, accurate or complete records.

To summarize my findings above, I agree with the ALJ and find substantial evidence that Respondent issued these twelve prescriptions for controlled substances outside of the usual course of professional practice and beneath the standard of care in the State of Florida in violation of federal and state law.

III. Discussion

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

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

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

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

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

[29] Dr. Hoch explains that the word ''encounter refers to the direct encounter for the physician with the patient,'' and does not include time the patient spent with a medical assistant. Tr. 303.

(2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Under DEA's regulation, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the relevant evidence is confined to Factors One, Two and Four. I find that the evidence satisfies the Government's *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 One and Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Respondent's Conviction Record Under Federal or State Laws Relating to Controlled Substances

Respondent suggests that Factor One weighs in her favor because the parties stipulated and the ALJ found that Respondent holds a valid state medical license in Florida. ALJX 28 (Respondent's Posthearing Brief), at 11; ALJX 11, at 1; RD, at 59.

In determining the public interest, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020); *see also Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002).

In this case, neither the State Board nor any other state entity has made a direct recommendation to the Agency regarding whether the Respondent's registration should be suspended or revoked; however, as previously discussed, the State Board issued an Order incorporating a Settlement Agreement reached following an Administrative Complaint filed by the State of Florida Department of Health against Respondent based on Respondent's treatment of one patient, M.N., between July 2013 and August 2015. RX 11, at 19. The Florida allegations regarding Respondent's treatment of M.N. are similar [30] to the facts I found above regarding Respondent's treatment of Y.H. and L.G between 2016 and 2017; however, they clearly do not constitute the same matter as the facts alleged in the OSC (they involved an entirely different patient during a preceding timeframe). *See supra* II(F).

I have much more evidence of misconduct before me than the State Board had at the time that it made its decision. Further, the fact that the State Board did not choose to revoke Respondent's state medical registration carries minimal to no weight under Factor One, because there is no evidence that the State Board would have made the same decision in the face of the egregious conduct found herein involving two further patients, who were openly diverting their prescriptions, *after* the State Board had already disciplined Respondent for similar behavior.[31] Accordingly, the terms of the State Board Order have been considered, but I find that they have no impact on the public interest inquiry in this case. *See John O. Dimowo, M.D.,* 85 FR at 15,810.

As to Factor Three, the parties stipulated that Respondent has never been convicted of violating any federal or state law relating to the manufacture, distribution, or dispensing of controlled substances. ALJX 19; Tr. 11. *See also* 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

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

Respondent asks that I consider evidence of her positive dispensing experience. ALJX 28, at 12. In evaluating Respondent's dispensing experience, I note that Respondent has significant experience as a licensed physician in Florida since October 2007, and running her own medical practice since 2011. RX 5, at 1. Respondent claimed, without providing any evidence to support the claim, that she has treated ''thousands of patients for pain medicine, and there have been no reported overdoses or deaths during that period of time.'' [32] Tr. 19. The Agency assumes that all of the prescriptions Respondent issued were issued lawfully, except for those prescriptions that the Government alleged and established were issued unlawfully. *See Wesley Pope, M.D.,* 82 FR 14,944, 14,982–84 (2017). Respondent also claimed, and included 38 unique letters to patients as evidence, that she has discharged patients who refused urine testing. RX 8. However, Respondent's evidence shows that both Y.H. and L.G. were ordered to take urine drug tests, did not take those urine drug tests, and did not receive discharge letters (although they were not seen again). RX 1, at 13, 18; RX 3; RX 8; Tr. 405–06, 409–10, 413. Furthermore, even without the urine drug tests, Respondent knew that Y.H. and L.G. were not taking their medication as prescribed because they directly told her that they were diverting the controlled substances.

Respondent's handling of the two confidential sources as found herein demonstrates that her prescribing practices fell short of the applicable standard of care for twelve

[30] Respondent's Posthearing Brief states: ''In January 2017, a complaint was filed against Dr. Germeil before the Florida Board of Medicine for allegations similar to the instant case.'' ALJX 28, at 15. Additionally Respondent's counsel stated in her oral closing arguments, ''the allegations, as you'll see, are similar in prescribing medication for not a legitimate purpose and for medical records.'' Tr. 489–90.

[31] In *Dimowo,* the Acting Administrator found that ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state;'' however, *Dimowo* also limited the ''recommendations'' DEA would consider to the ''actions of an appropriate state entity on the same matters, particularly where it rendered an opinion regarding the practitioner's medical practice in the state due to the same facts alleged in the DEA OSC.'' *John O. Dimowo,* 85 FR at 15,810. Although the same ''matters'' may include the same types of violations, in this case, I have no indication that the Board would have made a similar decision in the face of these additional egregious violations and continued misconduct. In fact, Respondent specifically agreed in the settlement not to commit further violations of law. RX 11, at 12.

[32] I decline to consider that ''no reported overdoses or deaths'' is an indicator of positive dispensing experience and there is no legal authority for the proposition that I must find death or an overdose before I may suspend or revoke a registration. Agency decisions have found that ''diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .'' *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014)).

prescriptions. As I discuss further below, Respondent failed to address patient admissions of diversion, failed to conduct physical exams, failed to discuss the risks of controlled substances, and falsified medical records.

Factor four is demonstrated by evidence that a registrant has not complied with laws related to controlled substances, including violations of the CSA, DEA regulations, or other state or local laws regulating the prescribing of controlled substances.

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

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

As I have found, in agreement with the RD and based on the credible expert testimony of Dr. Hoch, Florida regulations require that a doctor: Take a complete medical history and conduct a physical examination [33] before issuing a prescription for a controlled substance; develop a written treatment plan; discuss the risks and benefits of controlled substances with a patient; and maintain complete and accurate records with respect to a patient. RD, at 9; Tr. 205–06, 338. Additionally, a physician is required to conduct a periodic review of the course of treatment provided to a patient. RD, at 50; Tr. 337–38.

[33] The Florida Code does not define what constitutes a physical exam and does not necessarily require that a physician conduct a physical examination of a patient each time the patient presents for an appointment. RD, at 50; Tr. 289. However, Dr. Hoch opined that the standard of care requires a physician to perform a physical examination in certain circumstances including when the patient requests a higher dose of controlled substances, presents with new symptoms or complaints, has a new diagnosis, or hasn't been seen for a period of months. *See* Tr. 290, 341–42, 345–46.

Based on the credible and uncontroverted testimony of Dr. Hoch, and in agreement with the RD, I find that Respondent issued a total of twelve prescriptions outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida in violation of 21 CFR 1306.04(a). RD, at 92.

i. Failure To Address Patients' Admissions of Diversion

The Florida Code provides that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes.'' Fla. Admin. Code r. 64B8–9.013(1)(d) (West 2020). Dr. Hoch explained that when a patient tells a doctor that he or she is diverting his or her controlled substances that statement ''is a very big red flag that has to be addressed at that moment.'' Tr. 224–25; RD, at 51. In fact, Dr. Hoch stated that if a patient tells a doctor that he or she is selling or giving away controlled substances, ''that's sort of a deal breaker . . . .'' Tr. 351. In other words, as I found above the standard of care in Florida requires that a physician stop writing prescriptions for a patient following statements from the patient that are consistent with diversion. *See supra,* II(E).

I have found above that each of the CIs admitted to having engaged in diversion at each of the six encounters at issue in this matter. Y.H. clearly admitted to Respondent that she had been selling at least some of her pills to her brother on September 8, 2016, October 12, 2016, and January 25, 2017. GX 3, at 17, 19; GX 5, 13 12–13; GX 7, at 4, 6, 9–11. Yet, as I have found, Respondent did not advise Y.H. not to sell her controlled substances or otherwise engage in any meaningful conversation about diversion with Y.H. *See* RD, at 68, 71, 73. In fact, on October 12, 2016, Respondent clearly acknowledged Y.H.'s admission of diversion and seems to have even condoned the conduct. *See supra,* II(G)(2); GX 5, at 12–13. And on January 25, 2017, Respondent replied to Y.H.'s admission of selling pills by reassuring Y.H. that she was a good person. GX 7, at 9–11. The only counseling Respondent did with Y.H. regarding diversion was to warn Y.H. not to tell anyone that Respondent was helping her out because Respondent ''d[idn't] want to . . . get into trouble.'' *Id.* at 11.

L.G. also clearly admitted to Respondent that he had been selling at least some of his pills to people on February 3, 2017, July 18, 2017, and August 30, 2017. GX 9, at 7–8, 11–13; GX 11, at 2–3, 6; GX 13, at 4–5. Yet, as I have found above, Respondent did not engage in any meaningful conversation about diversion with L.G. either. *See supra,* II(H); RD, at 76, 79. Respondent did discuss diversion in greater detail with L.G. than she did with Y.H., and Respondent did provide warnings to L.G. at each of the three encounters including: That he needed to ''try to keep [his medication] for himself,'' GX 9, at 12; that ''[he] cannot sell [the scripts because] [t]hat's a controlled medication,'' GX 11, at 3; and that he should ''be careful with the medications.'' GX 13, at 7. However, Respondent issued prescriptions to L.G. immediately following these warnings, which renders her comments perfunctory. *See* RD, at 80.

Dr. Hoch opined that each of the twelve prescriptions at issue in this case were issued without a legitimate medical purpose because diversion was not appropriately addressed at any of the six visits in this case.[34] *See* Tr. 224, 231, 243–44, 256–57, 259, 270. Indeed, the confidential sources admitted to having engaged in diversion during each of the six visits and the parties have stipulated that prescriptions were issued during each of the six visits.

For all of these reasons, I find that Respondent violated federal law and Florida Administrative Code § 64B8–9.013(1)(d) by prescribing controlled substances to Y.H. and L.G. in spite of their admitting to engaging in diversion immediately prior to the issuance of the prescriptions.

ii. Failure To Conduct Physical Examinations

As I found above based on Dr. Hoch's testimony, the State of Florida requires that, when prescribing controlled

[34] The ALJ found that diversion was not properly addressed at only five of the encounters. We both found that the prescriptions issued by Respondent to L.G. were not issued for a legitimate medical purpose on August 30. 2017; however, the ALJ found that Respondent did not have any obligation during this visit to address L.G.'s diversion, because L.G. stated that he was no longer selling pills and that the people he was selling pills to wanted to become patients. RD, at 81–82. I agree that L.G.'s statements indicate that he did not plan to engage in diversion in the future, however L.G. did still admit that he had engaged in diversion of Respondent's prescriptions in the past. Dr. Hoch seemed to be fully aware that L.G. was admitting to past diversion (stating, ''[t]he CS or patient informs the doctor that he was selling the medication . . .'' Tr. 266 (*emphasis added*), when he opined that Respondent's discussion of the dangers of diversion at the August 30, 2017, encounter were insufficient and that the prescriptions that followed were not issued in the usual course of professional practice. Tr. 270. I see no reason to stray from Dr. Hoch's credible and uncontroverted opinion. Further, the fact that the former customers of L.G. who previously obtained controlled substances unlawfully might visit Respondent to obtain controlled substances directly from Respondent hardly seems to address the diversion issue.

substances for pain, a ''physical examination must be conducted and documented in the medical record.'' Fla. Admin. Code r. 64B8–9.013(3)(a) (West 2020); *supra,* II(E). According to Dr. Hoch, the Florida Code does not define what constitutes an initial physical exam and does not necessarily require that a physician conduct a physical examination of a patient each time the patient presents for an appointment. RD, at 50; Tr. 289. However, Dr. Hoch opined that the standard of care requires a physician to perform a follow up physical examination in certain circumstances including when the patient requests a higher dose of controlled substances, presents with new symptoms or complaints, has a new diagnosis, or has not been seen for a period of months. *See* Tr. 290, 341–42, 345–46.

I found above that Respondent did not conduct a physical exam during any of the confidential sources' six visits.[35] *See supra,* II(I); Tr. 230, 232, 242, 246, 269, 324, 339. Not only did the confidential sources credibly testify that no physical examination was conducted during their respective encounters, *see* Tr. 48–49, 54, 59, 104, 109, 115, but Dr. Hoch's uncontroverted testimony was that there was no indication in the record (including the video evidence) that Respondent performed a physical exam during the six visits. Tr. 227, 230, 242, 249, 261, 269, 338–39. I find that Respondent's failure to perform a physical exam during any of the six visits in this matter violates the standard of care.

The record in the evidence establishes that Respondent never performed a physical examination on Y.H.[36] RD, at 22; Tr. 92. Additionally, Dr. Hoch opined that, even if an initial physical examination had been performed, Respondent would have been required to give a new physical examination to Y.H. on September 8, 2016, to justify the 40% increase in oxycodone HCL 30 mg. that Respondent prescribed. RD, at 25; Tr. 339–342.

Similarly, there is no indication in the record that Respondent ever performed a physical examination of L.G.[37] RD, at 79; RX 2, at 16, 18, 20–22. Additionally, Dr. Hoch opined that, even if an initial physical examination had been performed, Respondent would have been required to give a new physical examination to L.G. on February 3, 2017, because of the new diagnosis of chronic back pain on that date. Tr. 345–46. Per Dr. Hoch a new physical examination would also have been required on both February 3, 2017, and July 18, 2017, because it had been over five months between Respondent's prescriptions to L.G. for controlled substances for pain and the delay in treatment gives rise to the question of whether L.G. had such severe pain that he needed the controlled substances to relieve his pain. RD, at 37, 43, 76, 79; Tr. 345–48.

For all these reasons, I find that Respondent violated Florida Administrative Code § 64B8–9.013 and issued prescriptions outside the usual course of professional practice and beneath the applicable standard of care by prescribing controlled substances for pain without conducting a physical exam.

iii. Failure To Discuss Risk of Controlled Substances With Patients

In accordance with Dr. Hoch's opinion, I found above that the State of Florida requires that a doctor discuss the risks and benefits of controlled substances with a patient. *See supra,* II(E); RD, at 9; Tr. 205–06; Fla. Admin. Code r. 64B8–9.013(3)(c) (West 2020). Here Respondent prescribed each confidential source both oxycodone 30 mg., which Dr. Hoch stated is a very strong dose, and alprazolam 2 mg., which Dr. Hoch stated is a very strong dose, during each of the six encounters at issue in this case (for a total of twelve prescriptions). RX 1, at 16; RX 2, at 14; Tr. 219, 222.

Dr. Hoch explained that the oxycodone prescription alone can cause a number of side effects that Respondent did not discuss with Y.H. Tr. 220–221. Some of the less disabling side effects of opioid use include pruritus or itching, urinary retention, nausea and vomiting, and constipation. Tr. 220–221. Dr. Hoch explained that ''the most devastating complication or side effect of an opioid [like oxycodone] is respiratory depression, and that's what kills people.'' Tr. 221–222. Dr. Hoch explained that the risk is particularly high where, as here, the opioid is prescribed with a drug like alprazolam. Tr. 222.

In light of the medications prescribed, Dr. Hoch opined that Respondent was required to warn of the risk of side effects including respiratory depression and instruct the patient to make sure there was at least a three-to-four hour gap between administering the two different medications. *Id.* Based on Dr. Hoch's credible and uncontroverted opinion, I find that there was no discussion of the risks of using these controlled substances (much less the risk of respiratory depression that can occur when using them together) at any of the six encounters. Tr. 222, 230, 232, 237–38, 241, 247, 251, 258–59, 263, and 268.

Another example of Respondent's failure to discuss the risks of using controlled substances occurred when L.G. informed Respondent he drinks alcohol. Tr. 255. According to Dr. Hoch, when a physician learns that a patient could be drinking while being prescribed a high dose opioid and benzodiazepine, the patient ''should be warned very strongly'' that the medications and alcohol should not be taken together. Tr. 255. According to Dr. Hoch, ''[w]hen [patients] tell you that they're drinking, that's a huge issue for their safety.'' Tr. 256. Dr. Hoch opined that on February 3, 2017, L.G. informed Respondent that he drinks alcohol, Respondent was required to warn L.G. of the risks of taking the prescribed controlled substances with alcohol, and Respondent failed to issue the required warning. Tr. 255–56.

For all these reasons, I find that Respondent violated Florida Administrative Code § 64B8–9.013 and issued prescriptions outside of the usual course of professional practice and beneath the applicable standard of care by failing to discuss the risks of using the prescribed controlled substances with Y.H. and L.G.

In light of the above, the ALJ found, and I agree, that Respondent issued a total of twelve prescriptions outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida. RD, at 92.

iv. Recordkeeping Violations

Florida Administrative Code, Rule 64B8–9.013 lays out a physician's responsibilities when prescribing controlled substances for pain management.[38] *See supra,* II(E); RD, at 9; Tr. 203–05. With regard to medical records, the Florida Administrative Code provides that a physician is required to ''keep accurate and complete

[35] In fact, the ''objective'' section of each and every one of the patient records Respondent introduced into evidence was empty. *See* RX 1, and RX 2. Dr. Hoch testified that the ''objective'' section is where a doctor should identify her objective findings based on a physical examination. RD, at 51; Tr. 212. Based on the records and Dr. Hoch's testimony, it is fair to conclude that Respondent never conducted a physical exam of either confidential source.

[36] *See supra* n.19.

[37] *See supra* n.27.

[38] Admin. Code r. 64B8–9.013 provides guidelines that are authoritative on physicians in Florida; however, ''[t]he Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation.'' Fla. Admin. Code r. 64B8–9.013(1)(f) (West 2020); *see also* RD, at 9; Tr. 272, 280–81.

medical records'' to include, but not be limited to:

—''The complete medical history and a physical examination, including history of drug abuse or dependence as appropriate.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(1) (West 2020).
—''Treatment objectives.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(4) (West 2020).
—''[D]iscussion of risks and benefits.'' Fla. Admin. Code r. 64B8–9.013(3)(f)(5) (West 2020).
—''Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with Rule 64B8–9.003 . . . .'' Fla. Admin. Code r. 64B8–9.013(3)(f)(10) (West 2020).

Fla. Admin. Code r. 64B8–9.013(3)(f) (West 2020) (*emphasis added*).

Additionally, a physician's ''medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed . . . .'' Fla. Admin. Code r. 64B8–9.003(3) (West 2020) (*emphasis added*). Similarly, the Florida Statute provides that the ''following acts constitute grounds for denial of a license or disciplinary action . . .: Failing to keep legible . . . medical records . . . that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.'' Fla. Stat. Ann. § 458.331(1)(m) (West 2020).

Dr. Hoch testified that the ''plan'' portion of Respondent's records was where Respondent should have provided ''a justification as to why [she] was doing what [she was] doing'' with regards to her treatment of a patient. Tr. 212. Dr. Hoch further opined that the ''plans'' contained in Respondent's medical records concerning L.G. and Y.H. are not plans in so far as they did not contain any objective standards by which treatment success could be measured. Tr. 335–36, 353. In light of Dr. Hoch's testimony, I find that the Respondent's records were insufficient to meet the requirements set by the State of Florida. Dr. Hoch also testified that the plans do not bear any resemblance to the recorded corresponding visits they were meant to document. Tr. 218. In fact, the ALJ found, and I agree, that merely by comparing the recordings made by both Y.H. and L.G. when they met with Respondent with the treatment notes, it is readily obvious that the records that Respondent prepared do not accurately report what happened during these encounters. RD, at 91. I therefore find that Respondent did not maintain the records required by the State of Florida. In fact, Respondent admitted as much in her Posthearing Brief, stating ''that her medical records for Y.H. and L.G. were not complete and accurate.'' ALJX 28, at 15. Therefore, I find, consistent with the ALJ and Dr. Hoch's testimony, that in failing to keep sufficient and accurate records as required by the State of Florida, Respondent violated Florida Administrative Code § 64B8–9.013 and 9.003.

The Government further alleged that Respondent violated the state law by ''falsif[ying] numerous patient records in order to conceal [her] illegal prescribing.'' OSC, at 2. More specifically, the OSC alleged that Respondent falsified her records by documenting that 60 minutes was spent on each encounter when none of the encounters exceeded 15 minutes and by documenting that she discussed side effects, adverse reactions, safety precautions and the risks of physician shopping, when ''those issues were never discussed.'' OSC, at 9; *see also* RD, at 83.

To support the allegation that Respondent's recordkeeping was fraudulent, the Government points to the Administrative Complaint filed against Respondent by the State of Florida. ALJX 27 (Gov Posthearing Brief), at 29. The Government states that, regardless of the merits of the allegations contained in the Administrative Complaint, it clearly put Respondent on notice ''no later than January 2017 that the standard of care required her to discontinue prescribing controlled substances to patients engaged in diversion and required her to properly maintain medical records.'' ALJX 27 (Gov Posthearing), at 30. Despite this notice, Respondent continued to issue prescriptions for controlled substances to Y.H. and L.G, without maintaining proper records in violation of the relevant standard of care and Florida law.

The ALJ found, and I agree, that not only do Respondent's medical records for Y.H. and L.G. fail to contain the minimum information required under Florida law, they also clearly report events that did not occur during the medical appointments. RD, at 91. DEA has recognized that the falsification of medical records creates a ''fair inference'' that a prescriber is issuing prescriptions ''outside the usual course of professional practice and lacked a legitimate medical purpose.'' *Syed Jawed Akhtar-Zaidi, M.D.,* 80 FR 42,962, 42,964 (2015). Here, the ALJ found, and I agree, that Respondent falsified the medical records of Y.H. and L.G., and that these false entries allow for the fair inference that Respondent acted outside of the usual course of professional practice and beneath the standard of care in the State of Florida in issuing the twelve prescriptions to Y.H. and L.G. RD, at 91–92.

For all these reasons, I find that Respondent violated 21 CFR 1306.04(a), Florida Statute § 458.331(1)(m), and Florida Administrative Code §§ 64B8–9.013 and 64B8–9.003, by falsifying patient records.

In total, I find that the Government has proven by substantial evidence that Respondent issued twelve controlled substance prescriptions without a legitimate medical purpose and outside of the usual course of professional practice and beneath the applicable standard of care in the State of Florida in violation of 21 CFR 1306.04(a), Florida Statute § 458.331(1)(m), and Florida Administrative Code §§ 64B8–9.013 and 64B8–9.003. Overall, I find that the Government has established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest.

B. 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 FR 14,944, 14,985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice establishes ''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 registration. *Id.; see e.g.,* Tr. 256 (opinion of the Government's expert, Dr. Hoch, that Respondent was prescribing ''potentially deadly'' medications); Tr. 221–22 (opinion of Dr. Hoch that using ''an opioid [can result in] respiratory

depression, and that's what kills people'').

Not only was Respondent prescribing a ''potentially deadly'' combination of medications to confidential sources without properly warning them of the risks associated with taking those controlled substances, but, Respondent continued writing the prescriptions after the confidential sources admitted to diverting these ''potentially deadly'' controlled substances. *See supra,* III(A)(2)(a)(i) and (iii); Tr. 221. According to Dr. Hoch, when a patient diverts medication ''that's a huge issue for the community at large.'' Tr. 256.

Thus, as I have found above, at the time the Government issued the OSC/ISO, the Government had clear evidence of violations of law based on the two confidential sources, who had been unlawfully prescribed controlled substances, with no physical exam, with no explanation of the risks associated with the potentially deadly combination of controlled substances, and after the confidential sources had admitted to diverting the prescriptions.

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, the burden shifts to the Respondent to show why she can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made little to no effort to establish that she can be trusted with a registration.

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 259 (2006). 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 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 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 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23,853; *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 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 FR 8247, 8248 (2016).

In evaluating the degree required of a respondent's acceptance of responsibility to entrust him with a registration, in *Mohammed Asgar, M.D.,* 83 FR 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 FR 49,704, 49,728).

In this case, Respondent made statements to the confidential sources during their encounters that I believe demonstrate that she knew it was unlawful to prescribe controlled substances after the confidential sources had admitted to diversion. For example, on January 25, 2017, Y.H. told Respondent how much the prescriptions helped her out (in connection with her need to sell pills to make money) and Respondent replied, ''Relax! Do not say that to nobody . . . . I don't want to . . . get into trouble.'' [39] GX 7, at 10–11. Additionally, the State of Florida Administrative Complaint,[40] clearly notified Respondent that the professional standard of care required that Respondent discontinue prescribing scheduled medications upon learning that a patient was sharing medications. RX 11, at 19. The ALJ found, and I agree, ''it is clear that when [Respondent] issued prescriptions to Y.H. and L.G. after they told her they were selling their prescriptions, her actions constituted a knowing diversion of oxycodone HCL and alprazolam.'' RD, at 100.

But there is no clear acceptance of responsibility in the record. Here, Respondent did not testify on her own behalf, and did not attempt to explain why, in spite of her egregious misconduct, she can be entrusted with a registration.[41] Such silence weighs against the Respondent's continued registration. *Zvi H. Perper, M.D.,* 77 FR 64,131, at 64,142 (citing *Medicine Shoppe,* 73 FR at 387); *see also Samuel S. Jackson,* 72 FR at 23,853.

Respondent argued, that even though she did not testify in this case, her actions showed her acceptance of responsibility. ALJX 28, at 15. Respondent claimed that she updated the practice's procedures and equipment, completed continuing education courses, and discharged patients who refused to submit to urine drug screening.[42] *Id.;* RD, at 105. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ''magic words'' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that [s]he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,973 (2019). In this case, Respondent has not issued any words of repentance or acceptance of responsibility, because she has not testified, nor has she made any admissions of fault. As such, I cannot trust that Respondent would not repeat her behavior. *See MacKay,* 664 F.3d at 820 (upholding the Agency's finding that a respondent's failure to testify warranted an adverse inference,

[39] Additional examples include Respondent's statement on July 8, 2017, that if L.G. sells his medication then Respondent cannot give him medication. GX 11, at 3 and 6. And during the same appointment Respondent tried to cover herself by stating that she knew L.G. was just joking and really did not sell his medication. GX 11, at 8.

[40] Respondent seems to have received the Administrative Complaint on or about January 20–23, 2017, but certainly received it no later than February 8, 2017, when she signed the Settlement Agreement. *See* RX 11, at 15, 24.

[41] In *Zvi H. Perper,* the Respondent did not testify in this proceeding; therefore, the Agency found, ''he neither took responsibility for his misconduct nor provided any assurances that he has implemented remedial measures to ensure such conduct is not repeated.'' *Zvi H. Perper, M.D.,* 77 FR 64,131, at 64,142.

[42] The continuing education courses were required by Respondent's Settlement Agreement and the remaining actions appear to have been related to the Settlement Agreement's requirement to engage a risk manager to conduct a quality assurance consultation or risk management assessment. *See* RX 11, at 10–12; Tr. at 385–386.

because there was ''no evidence that [respondent] recognized the extent of his misconduct and was prepared to remedy his prescribing practices''); *see also T.J. McNichol, M.D.,* 77 FR 57,133 (2012) (stating that ''it is appropriate to draw an adverse inference from Respondent's failure to testify.'').

Indeed, the facts on the record irrefutably demonstrate that Respondent cannot be entrusted to amend her behavior. The State of Florida Administrative Complaint, dated January 20, 2017, notified Respondent that she should discontinue prescribing after learning that a patient is diverting. RX 11, at 19. Days later, on January 25, 2017, Respondent prescribed to Y.H. following an admission of diversion. *See supra* II(G)(3). On or about February 8, 2017, Respondent signed a Settlement Agreement (which became a Final Order on April 21, 2017), wherein Respondent agreed to not violate Chapters 456, 458 or 893 of the Florida Statutes or any other state or federal law relating to the practice of medicine. RX 11, at 15. Yet, on both July 18, 2017, and on August 30, 2017, Respondent violated those laws when she again issued prescriptions (this time to L.G.) following an admission of diversion. *See supra* II(H)(2) and (3).

The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). In this case, I agree with the ALJ that Respondent's actions can be characterized as ''particularly egregious.'' RD, at 100. On six separate occasions over an eleven-month period, Respondent issued twelve prescriptions to confidential sources without having conducted a physical exam or warning of the potential risks in violation of state law. *Supra* III(A)(2)(a); RD, at 104. Furthermore, Respondent issued prescriptions to the confidential sources immediately after those confidential sources admitted to diverting the medication. *Supra* III(A)(2)(a)(i); Tr. 221. As a separate matter, the medical records that Respondent maintained on the confidential sources not only contained false information, but they did not document any physical examinations, medical history, or periodic reviews. *See supra* II(I). I agree with the ALJ's finding ''that [Respondent's] misconduct of diversion and falsifying records to cover it up, as proven in the Administrative Record, is egregious and supports the revocation of her registration.'' RD, at 104.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. I agree with the ALJ who found ''that considerations of both specific and general deterrence weigh in favor of revocation in this case.'' RD, at 105. There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust her with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration be revoked and that any pending applications be denied as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FG0560765 issued to Jeanne E. Germeil, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Jeanne E. Germeil, M.D. to renew or modify this registration, as well as any other pending application of Jeanne E. Germeil, M.D. for registration in Florida. This Order is effective December 21, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–25528 Filed 11–18–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hil Rizvi, M.D.; Decision and Order

On July 20, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Hil Rizvi, M.D. (hereinafter, Registrant) of Tyrone, Pennsylvania. OSC, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BR4988599. It alleged that Registrant is without ''authority to handle controlled substances in Pennsylvania, the state in which [Registrant is] registered with DEA.'' *Id.* at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that the Pennsylvania State Board of Medicine (hereinafter, the Board) revoked Registrant's license to practice medicine effective October 28, 2018.[1] *Id.* The OSC concluded that ''DEA must revoke [Registrant's] DEA registration based on [his] lack of authority to handle controlled substances in the State of Pennsylvania.'' *Id.* at 2.

The OSC notified Registrant 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 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated August 20, 2020, the Chief of Police for the Borough of Tyrone Police Department, stated that on July 22, 2020, he, another police officer, and two DEA Diversion Investigators (hereinafter, DIs) traveled to Registrant's registered address located at 910 Pennsylvania Avenue, Tyrone, PA 16686. Request for Final Agency Action dated July 10, 2019 (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 8, at 2 (Chief of Police's Declaration). The Chief of Police stated that upon arrival at the registered address, ''[he] knocked repeatedly on the office door to no response.'' *Id.* The team then proceeded to Registrant's residence and again, ''knock[ed] repeatedly on the front door of the residence,'' but there was no answer. *Id.* The Chief of Police then stated that ''[a]fter unsuccessful attempts at reaching [Registrant] on his landline and cell telephone numbers, [he] left [his] business card in the front door slot of the residence.'' *Id.* Later that afternoon, the Chief of Police received a phone call from Registrant at the telephone number on his business card. *Id.* at 3. The Chief of Police stated that he had a letter to deliver, but Registrant ''insisted'' that he was not in town ''despite placing a call to [the Chief of Police] at the business card [he] left at the residence earlier that day.'' *Id.* Following the phone call, the Chief of Police ''immediately returned to [Registrant's] office location. When [he] knocked on the front door of the office, [Registrant] answered. [He] then handed the envelope containing the [OSC] to [Registrant] and left the premises.'' *Id.*

The DEA DI assigned to the case stated that ''[s]tarting immediately after his July 22, 2020 receipt of the [OSC], and on several occasions since, [the DI has] received numerous calls and an

[1] It is noted that the effective date of the Order was September 12, 2018. *See* Request for Final Agency Action, at 1 n.1; Exhibit 3, at 12.