Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: April 29, 2021

Respectfully submitted,

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–32]

Melanie Baker, N.P.; Decision and Order

On June 21, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC) to Melanie Baker, N.P. (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. MV3148257 (hereinafter, registration) 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 registration and denial of any pending applications for renewal or modification 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

The OSC alleged that ''[f]rom at least February 2017 to May 2019, [Respondent] issued numerous prescriptions for Schedule IIN through Schedule IV controlled substances to five patients in violation of federal and state law.'' OSC, at 3. The OSC alleged violations of 21 CFR 1306.04(a), Louisiana Statute Annotated § 40:978, and Louisiana Administrative Code tit. 46, Pt. LIII, § 2745(B)(1), and Pt. XLVII,

§ 4513(D). *Id.* at 2. The OSC stated that the prescriptions Respondent issued to the five patients in this case ''were issued outside the usual course of professional practice and not for a legitimate medical purpose.'' *Id.* at 3. The OSC included the expert's opinion that Respondent ''regularly prescribed highly addictive and intoxicating combinations of controlled substances to [her] patients.'' *Id.* The OSC also alleged that Respondent ''consistently failed to: (1) Perform adequate psychiatric and cognitive evaluations; (2) make appropriate diagnoses based on sufficient clinical evidence, and document [those] diagnoses in [her] medical records; (3) document a legitimate medical purpose for the controlled substances that [Respondent] prescribed; (4) monitor [her] patients' medication compliance; and (5) respond to red flags of drug abuse and diversion.'' *Id.* The OSC then went on to outline specific allegations of deficiencies for each of the five patients at issue in this case. *Id.* at 3–10.

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 11 (citing 21 CFR 1301.43).

By letter dated July 22, 2019, Respondent timely requested a hearing and proceeded *pro se.*[1] ALJX 2 (Request for Hearing), at 1; Tr. 11. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On July 23, 2019, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1–2. The Government filed its prehearing statement on July 30, 2019. ALJX 4 (Government's Prehearing Statement), at 1. Respondent filed her Prehearing Statement on August 6, 2019. *See* ALJX 5 (Respondent's Prehearing Statement), at 1. On August 8, 2019, the ALJ issued a Prehearing Ruling that, among other things, set out twenty-five agreed upon stipulations and established schedules for the filing of additional prehearing documents and for the hearing. ALJX 6 (Prehearing Ruling). Respondent filed a supplemental prehearing statement on August 13, 2019. ALJX 7 (Respondent's Supplemental Prehearing).

The hearing in this matter took place in New Orleans, Louisiana, and spanned two days. *See generally* Transcript of Proceedings in the Matter of Melanie Baker, N.P. (hereinafter, Tr.). Both parties filed posthearing briefs. *See* Government's Proposed Findings of Fact and Conclusions of Law (hereinafter, Govt Posthearing), and Respondent's Posthearing Brief (hereinafter, Resp Posthearing). On November 8, 2019, the ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD). According to the ALJ, neither party filed exceptions to the RD and the deadline for doing so has passed. *See* Transmittal Letter from the ALJ, dated December 4, 2019. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.[2]

Having considered the record in its entirety, I find that Respondent issued controlled substance prescriptions to five individuals beneath the applicable standard of care and outside of the usual course of the professional practice in Louisiana in violation of federal law, and I find that Respondent committed violations of state law. I agree with the ALJ that revocation is the appropriate sanction. RD, at 120. I make the following findings of fact.

II. Findings of Fact

A. DEA Registration

The parties stipulated that Respondent is registered with DEA as a practitioner able to handle controlled substances in schedules IIN through V under DEA Certificate of Registration No. MV3148257, at 4480 General DeGaulle Drive, Suite 107, Executive Square, New Orleans, Louisiana 70131. RD, at 44; ALJX 6, Appendix A, at 1; and ALJX 4, Attachment A (Controlled Substance Registration Certificate). This registration expired on July 31, 2020.[3] *See* ALJX 4, Attachment A.

B. Government's Case

The Government's documentary evidence consisted primarily of patient files and prescription records for five individuals prescribed controlled substances by Respondent between February 2017 and May 2019. *See* Government Exhibits (hereinafter, GX) 1–10. The Government's evidence also contained a copy of the Louisiana Prescription Drug Monitoring Results for Respondent from May 23, 2017, to May 23, 2019. *See* GX 11 (Louisiana Prescription Drug Monitoring Results). Finally, the Government included the Curriculum Vitae for its expert witness Dr. Chambers. *See* GX 12 (Curriculum Vitae of Dr. Chambers). The Government called two witnesses to testify at the hearing: A DEA Diversion Investigator (hereinafter, DI) and the Government's expert Dr. Chambers.

DI testified regarding her professional background and training, Tr. 27–28, and about her investigation-related actions in this matter.[4] Tr. 28–48; RD, at 17–18. She testified that in June 2018, DEA discovered questionable prescriptions issued by Respondent while investigating two pharmacies located in New Orleans. Tr. 28. DEA identified several ''red flags'' in the prescriptions issued by Respondent, including ''patients that were living at the same address, patients that were coming from long distances, patients that were being prescribed high strengths of amphetamines and other dangerous combinations.'' *Id.* In July 2018, DI queried the Louisiana Prescription Monitoring Program for Respondent's prescriptions and discovered the same red flags. *Id.* at 29. DI also testified that she received statistics from the Louisiana Board of Pharmacy indicating that Respondent was the number one prescriber of controlled substance dosage units among mid-level practitioners in the state.[5] *Id.* at 29–30.

DI further testified that DEA visited pharmacies where prescriptions issued by Respondent were filled to obtain copies of the prescriptions. *Id.* at 32. DEA also served an administrative subpoena for thirty of Respondent's patient files, which were received in August 2018. *Id.* at 30–31. Finally, DI testified that DEA sent eleven of the patient files to an expert witness, Dr. Andrew Chambers, to review. *Id.* at 31, 73–74. Having read and analyzed all of the record evidence, I agree with the ALJ that DI's testimony was ''credible and should be afforded considerable weight.'' RD, at 77.

[1] I find that the Government's service of the OSC was adequate.

[2] My agreement includes the ALJ's decision to proceed with the scheduled hearing when Respondent's identified witnesses were unavailable. RD, at 14–15. Respondent identified additional witnesses in her Prehearing Statement, but they were not present to testify at the hearing. RD, at 14; Tr. 11–14. Respondent said she was ''prepared to proceed'' to the hearing without the witnesses because one of the witnesses could not ''speak to the reasons [Respondent] made clinical decisions,'' and Respondent was ''unable to reach'' the other witnesses. Tr. 13. I agree with the ALJ's decision to proceed with the hearing. *See* RD, at 14; Tr. 13–15.

[3] The fact that a respondent allows her 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).

[4] DI's testimony explained that that Respondent used to go by the name Melanie Varnado. Tr. 37. I find that Melanie Baker and Melanie Varnado are used interchangeably in the record to describe the same person.

[5] DI defined a ''mid-level practitioner'' as ''nurse practitioners, physician assistants, [prescribers] that are not actual medical doctors.'' *Id.*

Dr. Chambers testified regarding his professional and educational background. Tr. 49–60; RD, at 56–57, 79–80. Dr. Chambers testified that he was a licensed physician and he was a board-certified addiction psychiatrist. GX 12, at 8; Tr. 49–50; RD, at 56. He testified that he maintained a clinical practice, which he had operated since the year 2000, and that approximately 50% of his work was clinical. Tr. 52; RD, at 56, 80. He further testified that he was a teacher, and from his resume it appears that he teaches at various institutions including as a tenured Associate Professor of Psychiatry and director of the addiction psychiatry specialty at the Indiana University School of Medicine. Tr. 53–54; GX 12, at 1; RD, at 56. Dr. Chambers testified that he has had the opportunity to teach nurses and to supervise nurse practitioners including providing oversight of their prescribing decisions. Tr. 53–54; RD, at 56. I agree with the ALJ's finding that ''Dr. Chambers possesse[d] an impressive amount of study, experience, and expertise in th[e] relatively narrow field of addiction psychiatry.'' RD, at 82.

Although Dr. Chambers is licensed in Indiana, he testified that he was familiar with the standard of care for prescribing controlled substances in Louisiana and had reviewed relevant sections of the Louisiana code. Tr. 60; RD, at 80. I agree with the ALJ that Dr. Chambers ''demonstrated a formidable knowledge relating to the Louisiana standard of care involving the prescribing of controlled substances, and the requisite professional practices.'' RD, at 82. Ultimately, Dr. Chambers ''was offered and qualified as an expert in the field of addiction psychiatry and on the standard of care for prescribing controlled substances for psychiatric care in Louisiana.'' *Id.* at 79–80. I find that Dr. Chambers was properly qualified as an expert witness.[6]

The ALJ conducted a thorough assessment of Dr. Chambers' credibility, with which I agree. *Id.* at 79–82. I further agree with the ALJ's finding that ''Dr. Chambers provided consistent, reliable and fully developed testimony in this matter.'' *Id.* at 82. I additionally note that Respondent presented no expert testimony that conflicted with Dr. Chamber's opinions. *Id.; see also, infra* n.7.

[6] Dr. Chambers has previously been qualified as an expert in DEA proceedings and his testimony was found credible. *See, e.g., Bernard Wilberforce Shelton, M.D.,* 83 FR 14,028, 14,036 (2018); *Lon F. Alexander,* 82 FR 49,704 (2017).

C. Respondent's Case

The Respondent's documentary evidence consisted of Respondent's Curriculum Vitae, Initial Psychiatric Evaluation and Medication Management forms implemented in Respondent's practice, starting in October 2018, following a quality review from an insurance company, and the practice's discharge policy. Respondent's Exhibits (hereinafter, RX), 1–4; Tr. 325–29. Respondent also provided eight scholarly articles in defense of her treatment practices.[7] RX 5; RD, at 81. Respondent's testimony on her own behalf was limited to offering and authenticating her five exhibits.[8] Tr. 324–30. The ALJ found, and I agree, that Respondent's limited testimony was ''internally consistent and consistent with the remaining record.'' RD, at 77. Respondent's testimony on this limited scope was also uncontested. *Id.*

Despite being instructed during the hearing that she could not present her case for the first time in closing, Respondent attempted to introduce a number of evidentiary ''facts'' in her posthearing brief[9] that she presumably believed to be mitigating or to explain the rationale behind her prescribing. RD, at 77; Tr. 341; Resp Posthearing. Some of these ''facts'' had little-to-no relevance to this case,[10] and other ''facts'' were blanket statements that Respondent's actions were correct and/or were supported by scientific evidence. Resp Posthearing, at 5–8. None of these supposed ''facts'' were given under oath and none were subject to cross-examination; therefore, I agree with the ALJ that they were ''not part of the evidentiary record.'' RD, at 77. Even if Respondent's ''facts'' had been appropriately submitted through testimonial evidence, they would likely not have outweighed the credible testimony of the Government's expert.[11] Moreover, many of these ''facts'' could not be given significant weight because they were not documented in the patient files, as the Government's expert credibly testified was required to satisfy the standard of care. *See infra* II.E.

D. Respondent's Practice

As there was no substantive testimony from Respondent or anyone affiliated with Respondent's practice, R.V. Psychiatric Services, L.L.C., it was difficult to determine the structure of the practice from the evidence at hand. It is clear, however, that all of the medical records prior to the year 2013 appear to be created by R.V.[12] Beginning in 2013 for K.W., 2014 for M.G., 2015 for F.P., and 2016 for M.H.,[13] both R.V. and Respondent appear to be seeing and/or prescribing for the individuals identified in this case. *See* GX 3; GX 5; GX 7; GX 9; Tr. 116. At all times relevant to this case, namely February 2017 to May 2019, Respondent appears to be the only provider from R.V. Psychiatric Services, L.L.C., prescribing controlled substances to the five individuals identified in this case.[14]

E. The Standard of Care in the State of Louisiana

In accordance with Dr. Chambers' credible and uncontroverted testimony and the record as a whole, I find that the standard of care for prescribing controlled substances in Louisiana requires the following: (1) An appropriate assessment and evaluation to make a diagnosis; (2) sound rationale for prescribing controlled substances related to that diagnosis; (3) ongoing monitoring to ensure that the desired outcome is achieved and undesirable side effects are not experienced; and (4) appropriate documentation. Tr. 69–70,

[7] The ALJ found, and I agree, that ''Dr. Chambers thoroughly and credibly discounted the articles' prominence, repute, and application to the issues before us.'' RD, at 81; *see also* Tr. 280–307. Ultimately the ALJ concluded, and I agree, that ''the articles provided no defense to the Respondent's charged practices'' and that ''Dr. Chambers' live testimony and opinions greatly outweigh the journal articles submitted by the Respondent.'' RD, at 81 and n.21.

[8] *See supra* n.2.

[9] Many of these same ''facts'' were also referenced in Respondent's opening statement, prehearing brief, and/or cross-examination questions. *See* RD, at 77; ALJX 5; ALJX 7; Tr. 20–24, 243–79.

[10] For example, Respondent included statements that all of the prescription medications at issue were approved by insurance providers. *See, e.g.,* Tr. 24.

[11] Respondent attempted to challenge Dr. Chamber's expertise by providing examples of what she believes reflects Dr. Chambers' unfamiliarity with the manner in which prescriptions must be written in Louisiana. Resp Posthearing, at 3 (arguing that Dr. Chambers ''was unfamiliar with the state board of pharmacy requirement to write certain prescriptions a certain way''). The standard of care violations alleged in this case are related to Respondent's issuance of prescriptions without a legitimate medical purpose; the manner in which the prescriptions were written is not at issue in this case. *Infra* II.E.

[12] In making this decision, I am not attributing to Respondent any actions or inactions of R.V. Respondent was judged herein solely on her actions or inactions during the period of time at issue in this case. Where I have discussed actions or inactions by R.V. or by Respondent outside of the period of time at issue in this case, it is only to provide context to understand the allegations against Respondent. *See also* RD, at 92 n. 24.

[13] F.A. does not appear to have been seen by R.V. since she began treatment at the practice in 2017. GX 1.

[14] There are some notations in the medical records during the time period at issue in this case that do not appear to be written by either Respondent or R.V.; however, the Respondent ultimately signs and therefor adopts those notations as her own. *See supra* II.E.; Tr. 225–27.

72; RD, at 57–58. Throughout his testimony, Dr. Chambers expanded on the standard of care, explaining in detail what a prescriber must do to satisfy each of these four requirements.

First, Dr. Chambers explained what a prescriber must do to satisfy the standard of care's requirement that there be an appropriate assessment and evaluation to make a diagnosis. To satisfy this requirement, a prescriber should conduct ''a clinical interview that would cover psychiatric history, addiction history, social history, and demographics, in order to develop a hypothesis as to the correct diagnosis.'' Tr. 71. To make a psychiatric diagnosis, ''the standard of care is that the physician would evaluate for signs and symptoms that are consistent with that diagnosis and actually write them in the chart.'' *Id.* at 213. Further, ''[i]t is actually not sufficient to simply state the diagnosis and not have evidence to support that diagnosis.'' *Id.* Dr. Chambers explained that a prescriber should also do objective measures testing because ''the nature of addictive disease is such that the self-report is often not as reliable as you might find in other areas of health care. . . .'' *Id.* at 71. Dr. Chambers testified that urine drug screening and evaluation of the prescription drug monitoring program database are two ways to conduct an objective assessment. *Id.* at 71–72

Dr. Chambers also explained that a provider must conduct an appropriate assessment or evaluation to inform the diagnosis even when that provider is sharing in care or taking over care of a patient from a prior prescriber. *Id.* at 116–17. ''There is a responsibility of the second practitioner to look at the information from the prior prescriber, but to also come to their own conclusion and build a treatment plan that would incorporate [the prior] information but also incorporate their own examination, . . . you owe it to the patient to double-check the prior prescriber.'' *Id.* at 117. If a new provider ''[does not] make any changes'' and'' continues to do exactly what [the previous provider] did,'' then the new provider ''own[s] that person's decision.'' *Id.* at 224–25.

Dr. Chambers' opinion that the standard of care in Louisiana requires an appropriate assessment and evaluation to make a diagnosis is reflected in Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) (2019) [15] states that ''no APRN[16] shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith prior examination. . . .''

Second, Dr. Chambers explained what constitutes sound rationale for prescribing controlled substances related to a specific diagnosis. Throughout his testimony, he described sound rationale as having a ''clear, strong basis.'' Tr. 194. He explained that the standard of care required that new controlled substance prescriptions be justified in the medical records. *Id.* at 193. He also explained that ''clinical decision-making about controlled substances especially is a multi-variable decision'' that has to be made within the ''whole context'' of an individual patient. *Id.* at 111.

Dr. Chambers' opinion that the standard of care in Louisiana requires sound rationale for prescribing controlled substances is further supported by Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) states that ''no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith . . . medical indication.''

Third, Dr. Chambers explained what ongoing monitoring the standard of care required to ensure that the desired outcome of treatment is achieved and that negative side effects are avoided. With regard to monitoring, Dr. Chambers explained that an initial evaluation is comprehensive, and that at each subsequent visit a physician should ''continuously [gather] new data to, A, confirm [you are] not running into trouble with your [prescribed medications], but B, are they working, or can you get rid of them, because maybe [the patient got] better.'' Tr. 118. One ''side effect'' Dr. Chambers opined that practitioners should look for is diversion. *Id.* at 246, 272–73. Dr. Chambers testified that he considers ''the potential for diversion'' to be an ''unfortunate side effect,'' and that diversion is ''more common if [a practitioner is] not also monitoring [the patient] or dosing them correctly.'' [17] *Id.* at 246. By ''monitoring,'' Dr. Chambers ''mean[s] urine drug screens, [and/or] prescription drug monitoring program database inquir[ies].'' *Id.* at 317. Dr. Chambers also explained that addiction is a negative side effect that a prescriber should monitor for signs of.[18] *Id.* at 70, 115, 137. Dr. Chambers opined that ''[a]ny time you make a diagnosis, or if you have sufficient evidence that a person has addiction, it [is] absolutely a standard of care to drug-test them . . . [r]andomly and frequently.'' *Id.* at 137. According to Dr. Chambers, a prescriber ''cannot rely on a patient with mental illness and addiction [to] self-report . . . [i]t needs confirmation with drug-testing.'' *Id.* at 149. Appropriate monitoring also requires investigation and documentation of issues that arise, such as reasons for a missed appointment, potential withdrawal if the patient was without medication, and reports of hospitalization. *Id.* at 275, 279.

Fourth, Dr. Chambers explained what appropriate documentation was required to be in compliance with the standard of care. He explained that the record must document a comprehensive evaluation including a mental status or psychiatric exam, and the history including the psychiatric history, substance abuse history, and social history. *Id.* at 72. Appropriate documentation requires the practitioner to ''[build] a narrative that describes real people and events,'' including what the patient is doing that causes concern, in order to establish ''that there really is a cognitive problem.'' *Id.* at 257. The record must also document objective measures testing, such as urine drug screening or inquiries of the prescription drug monitor database. *Id.* at 72, 257. Moreover, for documentation to be appropriate, anyone who sees a patient must sign their notes in the medical record. *Id.* at 201–02, 225. A practitioner signing a note written by another practitioner ''owns it'' despite the ambiguity over ''who actually made [the] decision[s].'' *Id.* at 227.

[15] This citation is to La. Admin. Code tit. 46, Pt. XLVII, § 4513 effective February 20, 2018, through September 19, 2019. There is no substantive changes to the portions of § 4513 that are relevant to this case between the prior version of this law, effective April 2016 to February 19, 2018, and the cited version of the law.

[16] APRN stands for Advance Practice Registered Nurse which means, amongst other things, that the nurse has ''acquired advanced clinical knowledge and skills [to prepare her] to provide direct care to patients'' including the ''assessment, diagnosis, and management of patient problems, which includes the use and prescription of pharmacologic and non-pharmacologic interventions.'' La. Admin. Code tit. 46, Pt. XLVII, § 4505 (2018) (amended on February 20, 2018, with no substantive changes to the cited text). Respondent is an APRN. RX 1 (Respondent's Curriculum Vitae), at 1.

[17] Dr. Chambers further testified that with regard to diversion of controlled substances, a practitioner has ''to really make sure [the dosage is] not too high.'' Tr. 317.

[18] Dr. Chambers explained that monitoring is especially important in a psychiatric practice because people with several varieties of mental illness present in this case have a higher rate of becoming addicted including addiction to prescribed controlled substances. Tr. 70, 77–78. Dr. Chambers explained ''that the circuits in the brain that are impacted by the mental illness cause the individual to have a much more rapid acceleration into the disease process of drug addiction, because the circuits in the brain where mental illness happens and addiction happens are interlinked.'' *Id.* at 78.

Dr. Chambers also explained that the standard of care requires that a prescriber act on data obtained from urine drug screening or the prescription drug monitoring program: ''you [cannot] just gather that and put it in the chart.'' *Id.* at 73.

Dr. Chambers' opinion that the standard of care in Louisiana requires appropriate documentation is additionally supported by Louisiana law. La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4) (2019) states that ''[a]n APRN who prescribed a controlled substance shall maintain a complete record of the examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing controlled substances.'' [19]

F. Patients

1. Facts Relevant to All Patients

During his testimony, Dr. Chambers outlined some of the dangers of prescribing various classes of controlled substances [20] both singularly and collectively. With regard to stimulants or uppers, Dr. Chambers explained that they are addictive, are susceptible to diversion, and one form of stimulants, amphetamine, can be readily converted to methamphetamines in a home lab. *Id.* at 78–80. Additionally, Dr. Chambers noted that recently in the United States there was an increase in prescribing amphetamines to adults and an increase in overdoses caused by stimulants. *Id.* at 81. Prescribing amphetamines to adults to treat ADD, as Dr. Chambers explained, is ''controversial and problematic.'' *Id.* at 81. According to Dr. Chambers, ''[m]ost cases of legitimate ADD and ADHD are diagnosed between [the] age of six and 13, kind of school-aged children. When you get outside of that age zone, you have to worry about a . . . differential diagnosis, where there could be a whole lot of other things going on, and actually [they are] not ADD.'' *Id.* at 88–89.

Regarding sedatives, benzodiazepines or downers, Dr. Chambers described the biggest danger as addiction. *Id.* at 82. When prescribed chronically, patients ''can rapidly develop tolerance and dependence on a benzodiazepine'' and ''when that tolerance occurs, . . . the brain . . . acquire[s] a form of psychopathology that mimics the problem that the drug was originally intended to treat.'' *Id.* at 82. Additionally, Dr. Chambers testified that ''benzodiazepines are central nervous system depressants, so they suppress cognitive and motor function over time.'' *Id.* at 83. Dr. Chambers explained, that in patients with certain mental illnesses these drugs can cause disinhibited behavior, which tends to increase impulsiveness in patients, and they shorten the patients' lifespan. *Id.* at 84. Additionally, when benzodiazepines are combined with additional downers or other drugs, they become quite dangerous, which can cause an overdose death. *Id.* at 79, 84–85, 213. Dr. Chambers further testified that the prescribing of benzodiazepines and addictive medications to preteens and teenagers is especially problematic, because in those years, ''the brain is especially vulnerable to addiction.'' *Id.* at 195; *see also id.* at 120.

Dr. Chambers testified extensively about the dangers of prescribing both an upper and a downer to the same individual, and stated that ''[there is] no legitimate medical indication for that'' combination. *Id.* at 132; *see also id.* at 146, 198, 215, 231. Instead, according to Dr. Chambers, the combination of ''uppers and downers, has long been understood to be a pattern of illicit substance use.'' *Id.* at 146. And the combination ''can create a bipolar pattern of symptoms in someone who [does not] even have bipolar, but if they do have bipolar it could make it worse.'' *Id.*

Dr. Chambers also provided generally applicable testimony about controlled substance prescribing pitfalls for common mental health diagnoses. Regarding ADD diagnoses, Dr. Chambers explained that ''virtually all [of] the major mental illnesses—schizophrenia, bipolar disorder, major depression, PTSD, some of the personality disorders—they all generate cognitive symptoms that look like ADD.'' Tr. 131. He further explained that in a psychiatric practice, ''someone who really [does not] know how to diagnose mental illness could readily diagnose every person that walks in the door with ADD, and if they just follow the FDA guideline, [you are] now delivering amphetamines to everybody who walks in your door with any mental illness.'' *Id.* Similarly, ''insomnia [is] built into [a] depression'' diagnosis. *Id.* at 209.

2. Prescribing for F.A.

Between February 2018 and February 2019, Respondent issued twenty-three controlled substance prescriptions to F.A. for mixed amphetamine salts. GX 2 (Prescriptions Issued to F.A.); RD, at 88. Dr. Chambers testified that each of these twenty-three prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 102–03; RD, at 88.

In support of his opinion, Dr. Chambers testified that Respondent did not perform an appropriate assessment to diagnose the three-year-old patient with ADD. Tr. 88–92, 97; RD, at 89. Dr. Chambers explained that ''normal children [that young] have behaviors that can look like ADD.'' Tr. 89. Accordingly, Dr. Chambers explained, to diagnose a three-year-old with ADD, a practitioner must gather ''more than one independent source of information.'' *Id.* at 90; *see also* RD, at 89. Put another way, Dr. Chambers explained that the standard of care for this particular patient required ''a collection of lines of evidence.'' Tr. 93; *see also* RD, at 89. Per Dr. Chambers, the evidence can come from parents, teachers, or even through objective testing in the form of ''cognitive batteries.'' Tr. 91; *see also* RD, at 89. Dr. Chambers criticized the information Respondent collected to support the diagnosis, which consisted of a report from a day care center and reports from the parents. GX 1 (Patient File for F.A.), at 12; Tr. 90–95. With regard to the day care report, Dr. Chambers criticized that it documented behavior occurring more than a year prior to the diagnosis. Tr. 91. He further explained that preschool

[19] The law further clarifies, ''[t]he name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed must also be documented in the record.'' *Id.*

[20] I find the following facts related to the controlled substances at issue in this case. (1) The parties stipulated that amphetamine is a Schedule II controlled substance, and that Adderall is a brand name drug containing amphetamine salts. ALJX 7, at 13. According to Dr. Chambers, amphetamines are stimulants, and stimulants are sometimes referred to as uppers. Tr. 81, 132, 264. (2) The parties stipulated that lisdexamfetamine is a Schedule II controlled substance, and that Vyvanse is a brand name drug containing lisdexamfetamine. ALJX 7, at 13. According to Dr. Chambers, lisdexamfetamine is a stimulant that is ''very similar'' to and ''essentially has the same effects'' as Adderall. Tr. 186. (3) The parties stipulated that codeine is a Schedule III controlled substance. According to Dr. Chambers, codeine is an opiate and can be found in acetaminophen with codeine. *Id.* at 205. (4) The parties stipulated that alprazolam is a Schedule IV controlled substance. ALJX 7, at 13. According to Dr. Chambers, alprazolam is a short-acting benzodiazepine and it is marketed under the brand name Xanax. Tr. 151; *see also* GX 8, at 7–8. According to Dr. Chambers, benzodiazepines, or ''benzos'' for short, are sedatives and are sometimes referred to as downers. Tr. 206, 264. (5) The parties stipulated that clonazepam is a Schedule IV controlled substance. ALJX 7, at 13. According to Dr. Chambers, clonazepam is a benzodiazepine. Tr. 205. Klonopin is a brand name drug containing clonazepam. *Compare* GX 9, at 23–24 *with* GX 9, at 5; GX 10, at 3. (6) The parties stipulated that lorazepam is a Schedule IV controlled substance. ALJX 7, at 13. Lorazepam is marketed under the brand name Ativan. *See* GX 6, at 1–2. According to Dr. Chambers, Ativan is a benzodiazepine, and is ''even more potent and powerful than the Ambien.'' Tr. 128–29. (7) The parties stipulated that zolpidem is a Schedule IV controlled substance. ALJX 7, at 13. Zolpidem is marketed under the brand name Ambien. *See* GX 10, at 10. According to Dr. Chambers, Ambien is another benzodiazepine. Tr. 207.

teachers are not likely to require enough ''cognitive demand that would elicit a concern [about ADD] in a three-year-old.'' *Id.* at 90. With regard to the parents' reports, Dr. Chambers questioned their credibility, because there were other indications in the patient files that the parents themselves could be addicted to or diverting controlled substances.[21] *Id.* at 94–95. In forming this opinion, Dr. Chamber's noted that F.A.'s parents were also being treated by Respondent and were prescribed a dangerous and addictive combination of controlled substances.[22] *Id.* at 87, 94–95; RD, at 88.

Dr. Chamber's opinion was further supported by Respondent's failure to provide sound rationale for her prescriptions to F.A. in the patient records. Tr. 91–92; RD, at 89–90. Specifically, Dr. Chambers opined that, ''[i]t [was] not at all clear . . . that this child, based on this document, has ADD.'' Tr. 92. This is because F.A.'s ''symptoms describe problems that don't really fit the diagnosis of ADD . . . [they are] either inconsistent or outside the diagnosis of ADD.'' *Id.* at 91; *see also* RD, at 89. In fact, Dr. Chambers testified that based on the documentation, his opinion was that the ADD[23] diagnosis was outside the standard of care. Tr. 97; RD, at 89. Even if ADD had been a proper diagnosis, according to Dr. Chambers, Respondent did not issue the controlled substance prescriptions within the standard of care. Tr. 97–100; RD, at 89–90. This is because, Dr. Chambers opined, there were two other treatment options, namely behavioral therapy and methylphenidate, that should have been tried before issuing a controlled substance prescription for Adderall.[24] Tr. 97–100; RD, at 89–90. Moreover, the 10–30 milligram dosages of Adderall prescribed by Respondent exceeded the 2.5 to 10 milligram dosing range that is recommend for a young child. Tr. 99, 112; RD, at 90. Dr. Chambers ultimately opined that the Adderall prescriptions that Respondent issued to F.A. were ''beyond the dose range . . . for a child of this age and size. . . . [and] [i]n the context of this case, it [was] outside the standard of care.'' Tr. 103.

Dr. Chambers also noted that Respondent did not appropriately monitor F.A.'s use of the controlled substances she was prescribed. Dr. Chambers explained that you cannot rely on a three-year-old child to accurately report on her compliance with a controlled substance treatment regimen. Tr. 105. Although Dr. Chambers noted that basic vital signs, weight, and height were recorded appropriately, *id.* at 105, Dr. Chambers' opinion appears to be that, under the circumstances, the standard of care required Respondent to do some form of compliance monitoring and Respondent did none. Tr. 106; RD, at 91. When asked what monitoring was required to satisfy the standard of care, Dr. Chambers testified that ''the context of this case is so out of the standard of care for 10 different reasons that, for goodness sakes, do something . . . at the very least, get a urine drug screen.'' Tr. 106–07. Dr. Chambers testified, ''if the parents are using benzos and amphetamines from some source, and there's extreme poverty, and they live really far away,[25] and now the patient's been out of [the Adderall for a month], and [it is] possible they could be selling [the controlled substances], you might get a urine drug screen on the child, or do pill counts, or something to understand what's going on.'' [26] *Id.* at 106; *see also id.* at 103.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document F.A.'s file. Tr. 91–92; RD, at 89. Dr. Chambers testified that the documentation had ''distortions and insufficient data streams to inform a diagnosis of ADD.'' Tr. 91. The documentation included shorthand references suggesting that Respondent analyzed what Dr. Chambers called the DSM–IV criteria, but stated there is ''not substantial narrative evidence that any of those criteria were actually well supported.'' *Id.* at 92; *see also* GX 1, at 12; RD, at 89. Dr. Chambers' ultimately opined that there was not a legitimate medical purpose for the prescriptions to F.A. because ''[b]ased on what's documented . . . the diagnosis of ADD is not supported at a sufficient level to make the diagnosis.'' Tr. 103.

I find that, the twenty-three controlled substance prescriptions Respondent issued to F.A. between February 2018 and February 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. *See also* RD, at 91.

[21] Respondent, likely in an attempt to challenge Dr. Chambers' credibility, argued that Dr. Chambers ''offered statements in each of the five patient cases that there was subversive abuse and diversion,'' and ''demonstrated clear suspicion of everyone, including these patients whom he has never met.'' Resp Posthearing, at 2. I believe Respondent missed Dr. Chambers' point. Dr. Chambers' testimony was not that every patient was abusing or diverting controlled substances, but that every patient should have been monitored to ensure that potential abuse or diversion was not occurring. Tr. 246 (Dr. Chambers testified, ''I don't think every patient diverts. I think [there is] a high rate of it, and I think that you have to anticipate it could happen with any patient.''); *see also id.* at 70, 115, 137, 149, 272–73; *supra* II.E.

[22] F.A.'s parents were each prescribed two benzodiazepines and amphetamines by Respondent. Tr. 90, 95; RD, at 88.

[23] Dr. Chambers often referred to the diagnosis as ADD, but there are other references in the record to F.A. being diagnosed with ADHD. *See, e.g.,* Tr. 96–97; GX 1, at 15. It is clear from the testimony and the record as a whole that the acronyms ADD and ADHD are used interchangeably throughout this case.

[24] Respondent argued, both with regard specifically to F.A. and generally, that while Dr. Chambers described situations where a non-controlled substance could have been used in lieu of a controlled substance, the Government failed to establish that the non-controlled substance had to be used. Resp Posthearing, at 4. The Government does not have to establish that Respondent *should have* prescribed a different medication or that the controlled-substances Respondent prescribed were *wrong.* The standard of care requires that Respondent have a sound rationale for prescribing a controlled substance, whether or not a non-controlled substance alternative is available, and that she document her justification or rationale for prescribing any controlled-substance. Tr. 97–100, 193; *supra,* II.E.; La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4) (stating that medical records ''must include documentation of the . . . reason for prescribing controlled substances''). Here however, Dr. Chambers opined that Respondent did not have sound rationale for prescribing the controlled substances at issue nor did she document any rationale.

[25] Dr. Chambers testified that F.A. and her family ''live very far away, hundreds of miles away, and so . . . that creates monitoring problems.'' Tr. 96; *see also id.* at 252–53.

[26] Dr. Chambers identified several red flags of diversion, which he testified needed to be monitored under the standard of care. Specifically, Dr. Chambers identified the following red flags: Traveling a long distance to see a practitioner, Tr. 253, 309; getting multiple controlled substance prescriptions from one practitioner, *id.* at 308–09; and getting controlled substance prescriptions from multiple practitioners, *id.* at 169. Respondent has conclusively asserted both with regard to F.A. and other patients, that there were no red flags of diversion. Resp Prehearing, at 10–12, 15; Resp Posthearing, at 6, 8. However, there is no evidence in the record to support Respondent's indications that she conducted the necessary inquiries to resolve the red flags that Dr. Chambers identified. *See supra* II.C. And even if Respondent had investigated any red flags, the results of those hypothetical investigations were not appropriately documented in the medical records. *See supra* II.E.

3. Prescribing to K.W.

Between July 2017 and April 2019, Respondent issued twenty-three [27] controlled substance prescriptions to K.W. for mixed amphetamine salts and alprazolam. GX 8 (Prescriptions Issued to K.W.); Tr. 113–14; RD, at 92. Dr. Chambers testified that each of these twenty-three controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 140–41, 150–52, 155–56; RD, at 95.

In support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to K.W. to treat her diagnosed ADD, bipolar disorder, and insomnia. Tr. 115, 119–20, 122–23, 128, 132–33, 142, 144, 146, 150–53, 159; RD, at 89–90. First, Dr. Chambers opined that the amphetamine salt prescriptions were contraindicated because K.W. was diagnosed as being bipolar, an ''[illness] that greatly increase[s] the risk of adverse effects of controlled substances and addiction.'' Tr. 114; RD, at 92. Dr. Chambers explained that K.W.'s symptoms, ''cutting, depression, quasi-psychotic hearing voices,'' were coming from her mental illness, but ''all of it could also be contributed to by the drugs. . . . if you put people on high-dose amphetamines you can actually cause them to get psychotic as if they have schizophrenia.'' Tr. 159; RD, at 95. Moreover, Dr. Chambers testified that, ''the patient [had] been using various drugs, street drugs, that are closely akin to the drugs that [Respondent] [was] prescribing.'' Tr. 114. Dr. Chambers explained that K.W.'s use of illegal street drugs; [28] including ecstasy at age fourteen, GX 7, at 272, 274; crack cocaine, GX 7, at 53, Tr. 138–39; and methamphetamines, GX 7, at 38, Tr. 38; was evidence that K.W. had a stimulant addiction and that the amphetamines should no longer have been prescribed. Tr. 115; RD, at 92.

Second, Dr. Chambers opined that the benzodiazepine prescriptions were contraindicated. According to Dr. Chambers, ''benzodiazepines can unleash out-of-control behavior, especially in people with . . . bipolar disorder who are already prone to that.'' Tr. 128. K.W. exhibited those side effects while on benzodiazepines. *Id.* at 119–20, 127. While taking prescription benzodiazepine (Ambien) at the age of fourteen, K.W. experienced hallucinations and was hearing voices, so the benzodiazepine prescription was discontinued.[29] GX 7 at 293, 295; Tr. 119–20. While on a benzodiazepine (Ativan) at the age of seventeen, she suffered from blackouts that lead to her being arrested and charged with resisting arrest, domestic violence, and violence against a police officer.[30] Tr. 127–29; GX 7, at 133. While on a different benzodiazepine (Restoril) at the age of twenty-one,[31] K.W. reported to Respondent that she ''used a 'rock,' became agitated, took sleeping [medication] (Restoril), blacked out, hit mom, police came, was arrested . . . 5 days in jail.'' [32] GX 7, at 53; *see also* Tr. 129. Following that incident, K.W. requested, and was prescribed by Respondent, a different benzodiazepine (Valium) [33] to be taken as needed. GX 7, at 53; Tr. 129, 144–46. By November 2017, which was in the timeframe of the prescriptions underlying the allegations in this case, Respondent was prescribing K.W. another benzodiazepine (Xanax) for insomnia. Tr. 151–52; GX 7, at 41. According to Dr. Chambers, a practitioner should ''not prescribe Xanax for insomnia because it is a very short-acting benzoid and there are other ones . . . that are milder, less risky.'' Tr. 151–52. As explained by Dr. Chambers, those risks played out in July 2018, when K.W. attempted suicide again and was placed in emergency detention and hospitalized. GX 7, at 29; Tr. 160–61; RD, at 94. ''Grandmother stated it all started over zanie[34] bars. Patient takes zanie bars and goes in a rage. Patient went crazy because she woke up and [could not] find the zanie bars.'' Tr. 154; *see also* GX 7, at 29; RD, at 94–95.

In addition to testifying that K.W. should have been prescribed neither the amphetamines nor the benzodiazepines by themselves, he explained the compounding impact of prescribing both at the same time. Tr. 151. Dr. Chambers testified, ''[w]e have an upper, which is the amphetamine, and a downer [the benzodiazepine] being delivered to a patient with a mental illness [that is] defined by out-of-control ups and downs, bipolar disorder.'' *Id.* at 132. Ultimately, Dr. Chambers opined that for K.W. ''[there was] no legitimate medical indication'' for prescribing ''a cocktail of an upper and downer.'' *Id.; see also id.* at 114; RD, at 92.

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor K.W.'s use of the controlled substances she was prescribed. As I found above based on Dr. Chamber's expert testimony, the standard of care requires monitoring of side effects and monitoring to ensure an appropriate outcome is reached. *Supra* II.E.; Tr. 118. Regarding K.W., Dr. Chambers opined that the ''most important and deadly outcome of [the prescribed drugs] . . . is addiction, and death, and legal outcomes, and worsening mental illness.'' Tr. 115. Many of those side effects occurred. *Supra*. Dr. Chambers further opined that ''despite the incoming evidence [of an amphetamine addiction], [there was] no attempt to actually treat or do further monitoring to investigate an addiction.'' *Id.; see also id. at* 160; RD, at 92. Dr. Chambers further stated that he ''never saw evidence that [a urine drug screen] test was ordered or acted on by [Respondent] or the whole practice'' as required by the standard of care. Tr. 136; *see also* RD, at 94.

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document K.W.'s file. Tr. 124, 161; RD, at 93. Dr. Chambers testified that the documentation Respondent kept for K.W. was ''a problem'' because ''[there was] no kind of detail.'' Tr. 124. As an

[27] The OSC alleged that there were ''at least 24 prescriptions'' issued to K.W. outside the usual course of professional practice. OSC, at 7. However, the Government only presented evidence on twenty-three prescriptions. *See* GX 8.

[28] Additionally, there is a Psychosocial Assessment in K.W.'s medical record that was performed on December 17, 2013, by an outside professional unaffiliated with R.V. Psychiatric Services, L.L.C. GX 7, at 223. In that assessment, K.W. reported that she ''was 12 [years] old when she first drank alcohol,'' . . . ''has abused [A]mbien before, [and] was 12 [years] old when [she] first smoked marijuana.'' *Id.* at 224.

[29] K.W. was first prescribed a benzodiazepine in 2009 by R.V., not Respondent. GX 7, at 295; Tr. 119–20. In 2009, K.W.'s benzodiazepine prescription was stopped in light of the side effects she experienced. GX 7, at 293.

[30] By the year 2014, while being treated by both Respondent and R.V., K.W. was prescribed Ativan which is ''even more potent and powerful than the Ambien.'' Tr. 129, *see also id.* at 127–28; GX 7, at 133. According to Dr. Chambers, Respondent misattributed the side effects K.W. experienced, while taking Ambien to another medication K.W. was prescribed (which, according to Dr. Chambers, does not include blackouts as a side effect), and continued K.W. on the benzodiazepine. Tr. 128–29. Dr. Chambers opined that by this time in 2014, ''the evidence [was] overwhelming that the diagnostic indication [was not] right, the diagnosis [was not] correct, the treatment [was] worsening the diagnosis . . . contributing to worsening of the mental illness,'' but Respondent continued to prescribe benzodiazepines. Tr. 129; RD, at 93.

[31] By March 2017, Respondent appears to be K.W.'s only treating practitioner. *See, e.g.,* GX 7, at 53.

[32] The quoted medical notes contained arrows between each phrase; I have replaced those arrows with commas for clarity.

[33] Dr. Chambers testified that ''Valium and Restoril are both benzoids, so there is not really much gained by stopping the Restoril which she just blacked out on and merely replacing that with another benzoid.'' Tr. 139; RD, at 94.

[34] Dr. Chambers testified that ''zanie bars is normal street usage for Xanax.'' Tr. 154.

example, Dr. Chambers explained that following K.W.'s July 2018 emergency detention at a hospital, Respondent's outpatient note did not express any acknowledgment or investigation of the incident. *Id.* at 161. ''[There was] a check-mark for billing[;] . . . [t]here [were] some check-marks in the evaluation[;] but there is no conversation here about what just happened. How did you get this way? What happened with your meds? How was it in the hospital? . . . [it is] like it never happened.'' *Id.* Dr. Chambers also stated that ''any time an outside professional submitted a work-up or evaluation,[35] it provid[ed] a whole higher level of clarity and detail that is non-existent'' in the medical records prepared by Respondent. *Id.* at 124.

I find that, the twenty-three controlled substance prescriptions Respondent issued to K.W. between July 2017 and April 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. *See also* RD, at 95–96.

4. Prescribing to M.G.

Between February 2017 and May 2019, Respondent issued forty-two [36] controlled substance prescriptions to M.G. for mixed amphetamine salts, and clonazepam. GX 4 (Prescriptions Issued to M.G.); RD, at 96. Dr. Chambers testified that each of the forty-two controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 172, 175, 180, 181; RD, at 98–99.

In support of his opinion, Dr. Chambers found Respondent's diagnosis of M.G. with ADD to be problematic in-light-of the existing bipolar disorder diagnosis. Tr. 165–66; RD, at 96; *supra* II.F.1. Dr. Chambers opined that the benzodiazepine prescription Respondent issued to M.G. can ''cause ADD symptoms because any benzo[diazepine] causes cognitive problems and memory disturbances that look like ADD.'' Tr. 166.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to M.G. to treat his diagnosed ADD and bipolar disorder. *Id.* at 165, 166, 169, 172, 180. Dr. Chambers explained that Respondent should have treated M.G. ''with mood-stabilizers[,] not an addictive drug that bipolar people are vulnerable to getting addicted to and [that] could inflame the bipolar.'' Tr. 165; *supra* II.F.1; RD, at 96. In addition to the controlled substances Respondent prescribed, on May 22, 2017, M.G. informed Respondent that he was taking ''Norco for back from [primary care physician]'' due to ''4 herniated disks [from a] motorcycle accident.'' GX 3, at 176. Dr. Chambers opined that the stimulant and benzodiazepine prescriptions Respondent issued to M.G. were already outside the standard of care, but they became ''super-dangerous both with respect to addiction and worsening of mental illness,'' when M.G. started receiving narcotics from his primary care physician.[37] Tr. 170; GX 3, at 176; RD, at 97. Dr. Chambers opined that ''outside of an intensive care unit setting, . . . there is just no indication of any disease that would justify that kind of dangerous regimen.'' Tr. 170; RD, at 97. Dr. Chambers testified that it was ''outside the appropriate standard of care'' for Respondent to issue the clonazepam and amphetamine salt prescriptions to M.G. knowing that he was on Norco. Tr. 172; RD, at 97.

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor M.G.'s use of the controlled substances he was prescribed. For example, in May 2017, Dr. Chambers testified, Respondent was aware that M.G. was taking Norco prescribed by another practitioner and yet she issued to M.G. three months of prescriptions for Adderall and Klonopin. Tr. 173. First, Dr. Chambers opined that ''you would expect the patient to be back in August, but we [did not] see that . . . then there [was] a note for October and the patient [was] a no-show.'' *Id.* at 173. Dr. Chambers explained that the patient had ''been going on for five months on a lethal combination of drugs prescribed by doctors[,] and [Respondent] [knew] this.'' *Id.* at 174. Dr. Chambers explained that, at this point, some investigation was necessary to determine what had happened in the two months during which M.G., had he taken the controlled substances as prescribed, would have been out of medication. *Id.* at 175; RD, at 97–98. Dr. Chambers opined that there were three possible scenarios. First, the controlled substances may not have ''actually gotten in his body'' as he could have been ''selling every bit of it.'' [38] *Id.* at 175. Alternatively, M.G. could have run out and gotten the drugs ''from street sources.'' *Id.* A third possibility was that M.G. was ''fine going with these big gaps [without controlled substances] . . . [so] he [should not] be on [them] anyway.'' *Id.* Dr. Chambers' testimony made clear that there was ''[n]othing appropriate'' going on in any of the three scenarios and that some investigation was required to appropriately monitor M.G. *Id.* at 175, 275. Dr. Chambers opined that ''[t]his [was] not health care.'' *Id.* at 174.

Dr. Chambers testified that, for M.G., ''[t]here [was] not a single drug-screen in the record.'' *Id.* at 175; *see also id.* at 182. Dr. Chambers further explained that Respondent should have monitored M.G. with drug testing upon receiving the May 27, 2014 report from Dr. L.G., Ph.D. that diagnosed M.G. with ''Cannabis Use Disorder—Mild to Moderate,'' and ''Tobacco Use Disorder—Moderate.'' GX 3, at 39; Tr. 178–79. Dr. Chambers explained that where ''there [are] substance use issues, you have to start drug-testing. People [do not] have compartmentalized addictions . . . [t]he part of the brain where addiction happens does not care what the source of the drug is.'' Tr. 179; RD, at 99.[39]

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document M.G.'s file. Tr. 164, 173, 175–76. Dr. Chambers explained that ''there [was] no documentation of warnings'' provided

[35] The patient file for K.W. included copies of hospital records and of assessments performed by other practitioners. *See* GX 8, at 4–28, 188–190, 208–226.

[36] The OSC alleged that there were ''at least 57 prescriptions'' issued to K.W. outside the usual course of professional practice. OSC, at 5. However, the Government only presented evidence on forty-two of those prescriptions at the hearing in this matter. *See* GX 4.

[37] According to Dr. Chambers, Respondent should have inquired about narcotic use during the February 20, 2017, visit when M.G. reported he had missed appointments because of back pain. Tr. 169; GX 3, at 179. It is also clear that Respondent was again notified that M.G. was taking narcotics on October 23, 2017 and August 1, 2018. GX 3, at 161, 171.

[38] Dr. Chambers later explained that ''you have to assume that anybody might divert [controlled substances]'' and that ''without monitoring them, [you are] not applying appropriate controls to make sure [they are] not diverting. . . .'' Tr. 272.

[39] Dr. Chambers further opined that it was outside the standard of care for Respondent to issue any controlled substance prescriptions to M.G. after receiving the May 27, 2014 report and that it was outside the standard of care for Respondent to receive the report and not act on it; however only the prescriptions issued between February 2017 and May 2019 are at issue in this case. Tr. 178, 180.

to M.G. when he was taking the ''lethal combination'' of a narcotic, amphetamine salts, and a benzodiazepine. *Id.* at 173–74; RD, at 97. And after M.G. went five months without a visit, as Dr. Chambers explained, ''all you see in [the] assessment is . . . ADD and bipolar diagnosis and check-marks'' for billing purposes. Tr. 174. He generally described the medical record for M.G. as being ''devoid of information.'' *Id.* at 175. Dr. Chambers contrasted Respondent's documentation with the May 27, 2014 report from Dr. L.G. which, according to Dr. Chambers, provided an example of a ''thorough, adequate evaluation that has a lot of information about this patient and is at the standard of care when you are taking care of people with mental illness.'' *Id.* at 176; RD, at 98.

I find that, the forty-two controlled substance prescriptions Respondent issued to M.G. between February 2017 and May 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. *See also* RD, at 99.

5. Prescribing to F.P.

Between April 2017 and May 2019, Respondent issued seventy-two controlled substance prescriptions to F.P. for mixed amphetamine salts, Vyvanse, and lorazepam. GX 6 (Prescriptions Issued to F.P.); RD, at 99. Dr. Chambers testified that each of the seventy-two controlled substance prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 189–90, 192–94, 196–98; RD, at 100–01.

In support of his opinion, Dr. Chambers found that Respondent's diagnosis of F.P. with depressive disorder and post-traumatic stress disorder (hereinafter, PTSD) lacked sufficient supporting clinical evidence. Tr. 191–92, 200, 202; RD, at 101. On January 6, 2017, when F.P. was eleven years old, Respondent diagnosed F.P. with depressive disorder and the medical records reflected very little information—just ''circles and check-marks, . . . father has leukemia.'' Tr. 192; GX 5, at 39–40. According to Dr. Chambers, ''father having leukemia is terrible, but that is not a diagnosis of depression'' and ''there is no clinical data that would'' support the depression diagnosis. Tr. 192. Respondent continued to treat F.P. for depression throughout the time period relevant to this case (April 2017 to May 2019). GX 5, at 2–40. Additionally, Dr. Chambers explained that on April 27, 2017, ''now suddenly [there was] a new psychiatric diagnosis, PTSD, for which there [was] not sufficient clinical evidence to support that diagnosis.'' Tr. 200. Dr. Chambers noted that F.P.'s files demonstrated his father had died, ''but that is not PTSD.'' *Id.* With regard to Respondent's diagnosing and treatment of F.P., Dr. Chambers testified, ''[i]t just [does not] make any sense. It is like chaos.'' *Id.* at 202.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to F.P. both individually and as a group of prescriptions. *Id.* at 192–201. By way of background, the medical records reflect that F.P. first began visiting the practice in 2013 at the age of seven and he was seen by R.V. GX 5, at 95–99; Tr. 184. At that time, F.P.'s mother reported that F.P. experienced auditory and visual hallucinations, so R.V. diagnosed him with psychosis and prescribed Seroquel, an anti-psychotic medication. GX 5, at 75, 95–99; Tr. 184–86. Respondent first visited with F.P. on August 12, 2014, and at that time she discontinued his Seroquel prescription. GX 5, at 74. Dr. Chambers opined that it was unwise to discontinue the Seroquel because ''the history of psychosis is really clear from before.'' Tr. 187. Beginning in October of 2016, when F.P. was eleven, and continuing throughout the relevant time period in this case, Respondent prescribed Adderall to F.P. GX 5, at 44; GX 6. Dr. Chambers testified that prescribing ''Adderall, given the psychosis that happened earlier and the fact that [F.P.] is no longer on an antipsychotic, . . . [was] a mistake'' and was outside the standard of care. *Id.* at 190; RD, at 100. Dr. Chambers also opined that there was ''no adequate data or rationale explain[ing]'' the prescriptions for two different stimulants, Vyvanse and Adderall,[40] which were prescribed throughout the relevant time period in this case. Tr. 192; *see also* GX 5, at 1, 4, 7, 10, 13, 22, 25, 34, 40; RD, at 100. In January 2017, Respondent began prescribing Ativan/lorazepam, a benzodiazepine, to F.P. and continued to prescribe it throughout the relevant time period in this case. Tr. 192; GX 5, at 1, 4, 7, 10, 13, 22, 25, 34, 40. Dr. Chambers questioned the rationale for the Ativan prescription, ''[F.P.'s] [s]leeping has always been poor . . . so now all of the sudden there is Ativan . . . he's had insomnia before, why the Ativan? . . . there is no adequate data or rationale explained.'' [41] Tr. 192. Collectively, Dr. Chambers opined that ''there is no rationale'' for prescribing a benzodiazepine to a ''child who is also on amphetamine, and two different types.'' *Id.* at 194. Moreover, the three controlled substances were prescribed alongside a non-controlled substance, Prozac. *Id.* at 195. According to Dr. Chambers, prescribing Prozac and the two stimulants to ''a kid with a history of psychosis'' could ''provoke [psychosis].'' *Id.* Ultimately Dr. Chambers explained that ''[t]here are four meds here . . . [and] [t]hey all could worsen the side effects of the other. [It is] not good.'' *Id.*

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document F.P.'s file. Tr. 202. As with the other medical records, Dr. Chambers commented on the insufficiency of Respondent's recordkeeping for F.P., which he describes and ''just some circles and check-marks.'' *Id.* at 191; *see also id.* at 192; RD, at 100. Additionally, he explained that there was ''chaos with who [was] assessing the patient.'' Tr. 201. ''[T]here is [a] totally different set of handwriting, so it looks like there [were] three or four people seeing the same patient and they [were] not even signing the chart, which is also not an acceptable standard of care for documentation.'' *Id.* at 201–02. When asked whether the level of documentation in F.P.'s record was ''adequate given the controlled substances that [were] being prescribed,'' Dr. Chambers said, ''No.'' *Id.* at 202.

I find that, the seventy-two controlled substance prescriptions Respondent issued to F.P. between April 2017 and May 2019, were issued outside of the usual course of professional practice and beneath the applicable standard of

[40] When asked how Vyvanse was different from Adderall, Dr. Chambers explained that ''it is amphetamine with a slight variation on the molecule and it essentially has the same effects.'' Tr. 186.

[41] Dr. Chambers further testified ''there has been an insomnia diagnosis, but it's been there without the Ativan and it is here now, so nothing has changed in the diagnosis or the clinical data to justify the introduction of a heavy-duty benzo in a child.'' Tr. 193.

care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, and failed to appropriately document any of the above in the patient file. *See also* RD, at 100–01.

6. Prescribing to M.H.[42]

Between May 2017 and April 2018, Respondent issued forty-three[43] controlled substance prescriptions to M.H. for mixed amphetamine salts, acetaminophen with codeine, clonazepam, and zolpidem tartrate. GX 10 (Prescriptions Issued to M.H.); RD, at 101. Dr. Chambers testified that each of the forty-three prescriptions was issued outside the usual course of professional practice and without a legitimate medical purpose. Tr. 207–08, 218, 235–36.

In support of his opinion, Dr. Chambers questioned Respondent's diagnosis of M.H. *Id.* at 209, 213, 216; RD, at 104. The medical records reflect that M.H. had been a patient of R.V.'s at the practice since 2009. GX 9, at 249. On June 10, 2016, according to the medical records, Respondent began treating Respondent and adopted R.V.'s earlier diagnoses of depressive disorder, ADD, and insomnia. GX 9, at 44–45, 47. While Respondent maintained the ADD and insomnia diagnoses for M.H. through the relevant time period in this case, her diagnosis of M.H. with depressive disorder was intermittently left off of the patient records (*id.* at 11, 16, 19, 22, 34, 37, 40) and on (*id.* at 25, 28, 30, 44) including during the relevant time period in this case. Dr. Chambers questioned Respondent's diagnosis of M.H. with depressive disorder, ADD, and insomnia because ''depression alone, all by itself, could account for attention deficit and insomnia.'' Tr. 209. Additionally, Respondent added a diagnosis of anxiety on October 16, 2016, and maintained that diagnosis throughout the relevant time period in this case. GX 9, at 11, 16, 19, 22, 25, 28, 30, 34, 37. Dr. Chambers opined that there was no clear ''basis for an anxiety diagnosis'' in the record, Tr. 213, and that it is possible that any anxiety symptoms could have been caused by the Adderall prescription or M.H.'s nicotine use.[44] *Id.* at 214–16, 227; RD, at 75. Finally, Respondent diagnosed M.H. with tension headaches on February 1, 2017, and maintained that diagnosis throughout the relevant time period in this case except for omitting it from the patient record on October 26, 2017. GX 9, at 11, 16, 19, 22, 25, 28, 30. Dr. Chambers noted that Respondent just ''check-mark[ed] the tension headache diagnosis,'' without an examination or work-up, Tr. 221, and that again, the Adderall could have been the cause of the headaches.[45] *Id.* at 222; RD, at 102.

In further support of his opinion, Dr. Chambers testified that Respondent failed to provide sound rationale for the controlled substance prescriptions issued to M.H. *See, e.g.,* Tr. 207, 209–16, 218, 220, 223, 227–30, 235. Dr. Chambers explained that Respondent's prescribing to M.H. showed ''dose escalation over time without clear justification or diagnostic rationale.'' [46] *Id.* at 216; RD, at 102. Additionally, Dr. Chambers explained, that with regard to Klonopin, Ambien, and Butalbital,[47] ''just those three [prescriptions] alone could be . . . lethal.'' Tr. 207; RD, at 101. Dr. Chambers testified that those three prescriptions combined with codeine[48] and Adderall[49] created ''a very high-risk . . . an unacceptable risk'' of ''[a]cceleration [or] worsening of mental illness, acquisition or worsening of addiction, medical injury, legal consequences and death.'' Tr. 207; *see also id.* at 208. The record evidence demonstrates that on or about February 2018, M.H. reported to Respondent that she was hospitalized for ''failure to thrive, . . . malnutrition, [being] too weak to walk.'' *Id.* at 229; *see also* GX 9, at 12; RD, at 76. Dr. Chambers testified that ''something [was] not right, and in this collapse [Respondent had] a patient who [was] being prescribed every class of addictive drug and multiple addictive drugs and dangerous drugs within each class, a whole laundry list of controlled drugs, so it is not a surprise.'' Tr. 229. Dr. Chambers concluded that the prescriptions Respondent issued to M.H. were not only lacking justification, but were likely ''contributing to [her] deterioration.'' [50]

In addition to not having sound rationale for prescribing, Dr. Chambers noted that Respondent did not appropriately monitor M.H.'s use of the controlled substances that she was prescribed. *Id.* at 204, 211, 214–15, 219, 227–28, 230. Respondent did not monitor to ensure an appropriate outcome; according to Dr. Chambers, ''if someone is on . . . that load of benzos and they are still anxious, you've got to think that the treatment doesn't work.'' *Id.* at 227. Additionally, Dr. Chambers noted several indicators that M.H. had addiction disorder and vulnerability to multiple addictions. *Id.* at 215–16; RD, at 101–02. First, Dr. Chambers testified that according to the Louisiana Prescription Drug Monitoring Report,[51] M.H. received suboxone, which is usually used to treat opioid addiction, from another provider, Tr. 205, 208; second, she smoked a pack of cigarettes

[42] M.H. (which appears to be her unmarried name) is also referred to as M.G. (which appears to be her married name) throughout the patient records. *See, e.g.,* Tr. 75, 166, 168.

[43] The OSC alleged that there were ''at least 54 prescriptions'' issued to M.H. outside the usual course of professional practice. OSC, at 9. However, the Government only presented evidence on forty-three of those prescriptions at the hearing in this matter. *See* GX 10.

[44] Dr. Chambers testified that ''there [were] all kinds of reasons the anxiety could be there that [had] nothing to do with a generalized anxiety disorder,'' and where ''there [was] a constant march in dose escalation of the benzo[s],'' and ''[M.H.] [was] still anxious, [you have] got to think that the treatment [does not] work.'' Tr. 227.

[45] Dr. Chambers also explained that M.H. could have been diverting her medication and then ''going into withdrawal from benzos and developing headaches from that.'' Tr. 222. Though it is clear that Dr. Chambers is speaking hypothetically when he discusses the potential causes for the anxiety symptoms or tension headaches, his point is that Respondent failed to perform an appropriate assessment to make these diagnoses. *See, e.g., id.* at 214–16, 222. I agree.

[46] Dr. Chambers specifically noted the lack of rationale for dosing increases of Ambien, Tr. 212; the addition of and then the doubling and tripling of Klonopin, Tr. 213, 220, 223; dosing increases of Adderall, Tr. 217–18; and the addition of butalbital, Tr. 220, 223.

[47] While issuing to M.H. controlled substance prescriptions for Klonopin and Ambien, Respondent also issued prescriptions for Fioricet, which contains butalbital. *See, e.g.,* GX 9, at 21. The Fioricet/butalbital prescriptions are not at issue in this case and are only discussed herein as necessary to understand Dr. Chamber's opinion that the controlled substances at issue in this case were prescribed beneath the standard of care.

[48] Regarding the prescribed codeine, Dr. Chambers explained that the Louisiana Prescription Monitoring Program shows that M.H. had been prescribed Suboxone by another provider, which in his opinion, could indicate an opiate addiction. Tr. 208. According to Dr. Chambers, ''if someone is treating opiate addiction with an opiate that is approved for opiate addiction, [and] you . . . are prescribing an opiate on top of that, you are directly fueling the disease.'' *Id.* at 208.

[49] Regarding the Adderall prescription, Dr. Chambers explained that Respondent prescribed M.H. 60 and then 80 milligrams a day when the FDA guidelines recommend a maximum daily dose of 40 milligrams. Tr. 209–10. Though, Dr. Chambers explained, there are circumstances when the recommended maximum dose can be exceeded, none of those circumstances are present here. *Id.* at 210. One example of when the dosage could be higher, according to Dr. Chambers, is when there are no other controlled substances prescribed and the patient is not responding to the medication due to something like high body weight (M.H. weighed only 92 pounds). *Id.* at 210.

[50] As examples, Dr. Chambers explained that benzos can contribute to pneumonia because the patient would not be inhaling or breathing as rapidly and not aerating the lungs the same way, and opioids suppress the cough reflex which is necessary to get rid of bacteria. Tr. 229–30.

[51] Copies of two Louisiana Prescription Drug Monitoring Reports were contained in Respondent's patient file for M.H. at GX 9, at 9, and 93–98.

a day which is indicative of a nicotine addiction, *id.* at 215; and third, M.H. received dose escalations of addictive drugs over time, which is indicative of drug addiction, *id.* at 216, 222. Yet, as Dr. Chambers testified, there was no drug-screening of this patient.[52] *Id.* at 211. Ultimately, on March 28, 2018, M.H. was ''discharged from [Respondent's] care.'' GX 9, at 1; RD, at 104. While the discharge letter did not state the reason for the discharge, a note in the medical records for M.H. with a March 28, 2018, date indicated that M.H. was ''noncompliant w[ith] medications'' and that it was her ''[second] time calling about her Fioricet [and] Tylenol.'' GX 9, at 1–2. Even after M.H. was discharged as a patient, Respondent wrote M.H. prescriptions for a two-month supply of Klonopin and Ambien. GX 9, at 2; RD, at 104. Dr. Chambers testified that ''it appears that after firing the patient[,] she prescribed the patient more benzoids,'' and they were ''prescribed without any link to a provider or any supervision or appointments.'' Tr. 235. Moreover, when asked whether the professional standard required a prescriber to drop a patient who was addicted, Dr. Chambers stated, ''No.'' *Id.* at 273–74. He said ''dropping them would be abandoning a sick person. . . . [it is] a failure of appropriate care for the patient.'' *Id.* at 274. Instead, Dr. Chambers testified, a prescriber should expand treatment to ''include addiction treatment,'' and ''make adjustments in [the] practice to stop the diversion but hold on to the patient.'' *Id.*

As final support for his opinion that the alleged prescriptions were issued outside of the standard of care, Dr. Chambers opined that Respondent failed to appropriately document M.H.'s file. *Id.* at 212–14, 221, 223, 225, 228, 235. As with the other medical records, Dr. Chambers commented on the insufficiency of Respondent's recordkeeping for M.H., which he again described as ''check-marks and circles.'' *Id.* at 212; *see also id.* at 213, 221. Additionally, Dr. Chambers again explained that there was insufficient documentation indicating who was seeing the patient, because while Respondent's handwriting and signature appeared on the records, there was also unknown handwriting with no corresponding signature. *Id.* at 223, 228; RD, at 103. Dr. Chambers testified that ''part of what is complicating the picture is again more unknown writers and evaluators entering the chart.'' Tr. 223. Moreover, with regard to the prescriptions issued to M.H. after Respondent discharged her from care, Dr. Chambers explained that there was no ''charting that goes along with [those prescriptions].'' [53] *Id.* at 235; *see also* RD, at 104.

I find that, the forty-three controlled substance prescriptions Respondent issued to M.H. between May 2017 and April 2018, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana. This is because, based on Dr. Chambers' credible and uncontroverted expert testimony and the record as a whole, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the controlled substance prescriptions that were issued, did not monitor compliance with the prescription instructions, and failed to appropriately document any of the above in the patient file. *See also* RD, at 104.

7. Summary of Fact Findings Relevant to All Patients

In accordance with Dr. Chambers' testimony and the record as a whole, and in agreement with the ALJ, I find that, for each of the two-hundred and three prescriptions at issue, Respondent did not obtain sufficient information to diagnose, did not have sound rationale for the prescriptions that were issued, did not monitor compliance with the controlled substance prescriptions, and/or did not appropriately document the file. *See* RD, at 105. Ultimately, I find that there is substantial evidence on the record that Respondent issued two-hundred and three prescriptions without a legitimate medical purpose, outside of the usual course of professional practice and beneath the applicable standard of care in Louisiana.

III. Discussion

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

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

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

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

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

In a likely attempt to argue that her continued registration was consistent with the public interest, Respondent stated that her practice occurred in a ''Health Care Shortage Area, with very few providers accepting underserved populations,'' and that her practice

[52] Dr. Chambers also testified that drug-screening was necessary to rule out diversion in light of the high doses of Adderall given. Tr. 210–11

[53] Dr. Chamber's exact testimony referred to ''that prescription'' in the singular. Tr. 235. I have edited the quote because it is clear from the context of the testimony that when Dr. Chambers refers to ''that prescription'' he is referencing GX 9, p. 3 which is a copy of one page of a prescription pad upon which two prescriptions for controlled substances were written. Tr. 235; GX 9, at 3.

managed a case load of 9,500 patients during the 2017–2018 period at issue in this case. Resp Posthearing, at 1. Even assuming the truth of all of these alleged ''facts'' that are not in evidence, community impact evidence is generally considered to be irrelevant to DEA revocation proceedings. *See, e.g., Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,239 (2020) (declining to consider Respondent's argument that his revocation ''would deprive the low-income and homeless patients . . . of his medical services''); *Mark De La Lama, P.A.,* 76 FR 20,011, 20,020 n.20 (2011) (declining to consider a registrant's service to underserved and underinsured persons).

Respondent also argued that ''the [G]overnment failed to produce evidence of actual abuse or diversion [for] the 750,000 doses/year [prescribed] . . . by way of arrest records, law enforcement testimony, or drug rehabilitation admissions of patients.'' [54] Resp Posthearing, at 3. Respondent does not, however, cite legal authority for the proposition that I must find that patients became addicted or drugs were sold before I can find that continued registration is inconsistent with the public interest. Agency decisions have found that ''diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA. . . .' '' *Id.* (citing *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014)). *See also, Jeanne E. Germeil, M.D.,* 85 FR 73,786, 73,799 (rejecting Respondent's argument that ''no reported overdoses or deaths'' was indicative of positive dispensing experience).

DEA regulations state, ''[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,[55] the relevant evidence is confined to Factors 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 Two and Four—the Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

(a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice in Violation of Both Federal and State Law

According to the CSA's implementing regulations, 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).[56] 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).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Ralph J. Chambers,* 79 FR 4962 at 4970 (2014) (citing *Paul H. Volkman,* 73 FR 30,629, 30,642 (2008), pet. for rev. denied *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 223–24 (6th Cir. 2009)); see also *U.S.* v. *Moore,* 423 U.S. 122, 142–43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR 30,642.

Based on the credible expert testimony on the record, I found above that the standard of care for prescribing controlled substances in Louisiana requires the following: (1) An appropriate assessment and evaluation to make a diagnosis; (2) sound rationale for prescribing controlled substances related to that diagnosis; (3) ongoing monitoring to ensure that the desired outcome is achieved and undesirable side effects are not experienced; and (4) appropriate documentation. *See supra* II.E. Based on the credible expert testimony on the record, I also found above that each of the two-hundred and three prescriptions at issue in Respondent's case were issued without an appropriate assessment to diagnose, sound rationale for prescribing, adequate monitoring, and/or appropriate documentation. *See supra* II.F.7. Accordingly, I found that Respondent dispensed controlled substances beneath the applicable standard of care and outside of the usual course of the professional practice in Louisiana. *See supra* II.F.7. I find that in issuing two-hundred and three prescriptions beneath the applicable standard of care and outside the usual course of professional practice in Louisiana, Respondent violated 21 CFR 1306.04(a). Similarly, I find that Respondent violated La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) by issuing two-hundred and three prescriptions without a legitimate medical purpose and outside the usual course of professional practice.

Respondent, however, appears to have argued and believed that her actions were permissible and were supported by scientific evidence. Resp Posthearing, at 5–8. I have already rejected these arguments because they were based solely on facts that were not in evidence. *Supra* II.C. However, even if

[54] Respondent also argued that the Government has only alleged CSA violations related to ''0.052% of patients.'' Resp Posthearing, at 1. Assuming the truth of these facts not in evidence, the Agency already 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).

[55] As to Factor One, there is no evidence in the record of any recommendation from Respondent's state licensing board or professional disciplinary authority. 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration. . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15,230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why even 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.*

[56] Similarly, La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) (2021) (last amended July 2016) states that ''[a] prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [her] professional practice.'' Additionally, La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(xi) states that ''no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith . . . medical indication.''

Respondent believed the controlled substance prescriptions she issued were issued within the usual course of professional practice, DEA has found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration. . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28,643, 28662 (2015) (quoting *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601 (1998).

(b) Allegation That Respondent Violated State Law

I have found that Respondent issued prescriptions for controlled substances without a ''legitimate medical purpose'' and outside of ''the usual course of [her] professional practice'' in violation of La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) for the same reasons that I found she violated 21 CFR 1306.04(a). La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). I also find that the record contains substantial evidence that Respondent's actions violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D), which addresses the prescriptive authority of advanced practice registered nurses in Louisiana.

Under that section, ''no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication.'' *Id.* at § 4513(D)(2)(b)(ix) (2019). Dr. Chambers testified repeatedly about Respondent's failure to perform an appropriate assessment to make a diagnosis prior to prescribing controlled substances, and testified to instances where ''the evidence [was] overwhelming that the diagnostic indication [was not] right.'' Tr. 129. *See also id.* at 88–92, 97, 166, 191–93, 200, 202, 209, 213, 216. Dr. Chambers also testified that the controlled substances prescribed by Respondent were often contraindicated. *Id.* at 115, 141, 170, 221, 270. Repeatedly, Dr. Chambers testified that ''[there is] no legitimate medical indication'' for ''prescribing . . . a cocktail of an upper and downer.'' *Id.* at 132; *see also id.* at 133, 146, 170, 198. For these reasons, I find that Respondent violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(2)(b)(ix) by prescribing controlled substances without a good faith prior examination and medical indication.

Moreover, even if Respondent had conducted a good faith examination and established a medical indication prior to prescribing the controlled substances, her failure to document appropriately is an independent violation of Louisiana law. Under Louisiana law, ''[a]n APRN who prescribes a controlled substance shall maintain a complete record of the examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing controlled substances.'' La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4)(a) (2019). Dr. Chambers repeatedly testified regarding the deficiencies in Respondent's documentation and explained that there was no documentation of Respondent's reasons for prescribing the controlled substances at issue. Tr. 213–14, 335. Specifically, Dr. Chambers described Respondent's documentation as ''a façade,'' *id.* at 92; ''check-marks'' with ''no conversation . . . about what just happened,'' *id.* at 161; and ''superficial [and] not credible,'' *id.* at 258. *See also id.* at 174, 192, 212, 221. For these reasons, I find that Respondent violated La. Admin. Code tit. 46, Pt. XLVII, § 4513(D)(4)(a) by failing to ''maintain a complete record of the examination, evaluation and treatment of the patient . . . includ[ing] . . . [the] reason for prescribing controlled substances.

For all these reasons, I find that the record contains substantial evidence that Respondent violated La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), and La. Admin. Code tit. 46, Pt. XLVII, § 4513(D).

In total, I find that the record contains substantial evidence that Respondent issued two-hundred and three 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 Louisiana in violation of 21 CFR 1306.04(a), La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), and La. Admin. Code tit. 46, Pt. XLVII, § 4513(D). As Respondent issued these prescriptions without complying with her obligations under the CSA and Louisiana law, I find that Factors Two and Four weigh in favor of revocation. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010)). 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, there is substantial record evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice and beneath the applicable standard of care in Louisiana and in violation of state law. I, therefore, have concluded 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 uncontroverted, substantial evidence that Respondent repeatedly issued prescriptions without having a sound rationale or legitimate medical purpose for doing so 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 also* Tr. 79, 115 (testimony of Dr. Chambers that Respondent was prescribing a ''whole host of high-volume addictive drugs'' which could have a ''deadly outcome''); 143, 171 (testimony of Dr. Chambers that ''the combination of a benzo and opiate is an imminently lethal combo''), 207, 228, 272.

Not only was Respondent prescribing highly addictive drugs with a potentially ''deadly outcome'' without a legitimate medical purpose for so doing, but she was prescribing combinations of controlled substances known to be ''imminently lethal.'' *Id.* at 115, 171; *see also supra* IV (providing examples of egregious misconduct by Respondent which had a substantial likelihood of causing serious bodily harm or leading to abuse of a controlled substance).

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-hundred and three controlled substance prescriptions Respondent issued without obtaining sufficient information to diagnose, having sound rationale to prescribe, monitoring compliance with the controlled substance prescriptions, and appropriately documenting the file. *See supra* III.A.1.a.

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

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 arguments Respondent submitted to determine whether or not she has presented ''sufficient mitigating evidence to assure the Administrator that [s]he 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).

Here, Respondent has presented no evidence on the record that I could consider as accepting responsibility and I agree with the ALJ's finding that ''the Respondent has failed to unequivocally accept any responsibility in this matter.'' RD, at 118. Respondent has maintained throughout these proceedings that she believes that her prescribing to the five individuals in question, was proper. *See* RD, at 117; *supra* II.C. Respondent did admit that she ''agree[d] that the documentation [was] lacking,'' but she seemed to minimize her inadequate documentation when she stated that ''[e]very spoken word that a patient says in a visit, as well as every thought that crosses a clinician's mind in making a decision, cannot possibly be written down on paper.'' [57] Tr. 22. Respondent also stated in her opening statements, that she ''suspect[ed] that the reason that we're really here is because of a pattern of behaviors by the previous owner of the practice . . . [who was] also [her] ex-husband.'' Tr. 21. Specifically, she suggested that her ex-husband had maliciously reported her actions to various places ''hoping that [she] would lose [her] license.'' *Id.* The limited evidence presented by Respondent and her failure to testify substantively demonstrate a complete unwillingness to accept responsibility for her actions or to appreciate the seriousness of her misconduct.

In all, Respondent failed to explain why, in spite of her misconduct, she can be entrusted with a registration. ''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 46968, 49973.

Even if I were to consider her remedial measures, in spite of her complete lack of acceptance of responsibility,[58] Respondent's statements that she adjusted her forms following an insurance company's review of her records for quality compliance is nonetheless insufficient to ensure me that her documentation deficiencies will not be repeated in the future. Tr. 22; 332 (Dr. Chambers testified that ''at the end of the day, [it is] not the form, [it is] what goes in it'' that matters, and that he cannot tell from Respondent's blank forms how she would ''change [her] practice mode.'').

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). Here, the ALJ found, and I agree, that the evidence suggests that Respondent's violations ''were egregious.'' RD, at 105. Respondent prescribed controlled substances to three year old F.A. that were ''beyond the dose range . . . for a child of [F.A.'s] age and size,'' Tr. 103, to treat ADD when ''it [was] not at all clear to [Dr. Chambers] that [F.A.] . . . [had] ADD.'' *Id.* at 92; *see also supra* II.F.2. Respondent prescribed addictive medications to F.P. at age eleven when ''the brain is especially vulnerable to addiction.'' *Id.* at 195; *see also id.* at 120. Respondent prescribed benzodiazepines to K.W. (who already had a history of blackouts, violence, and arrests while on benzodiazepines, *supra* II.F.3.) that sent K.W. into ''a rage,'' caused her to attempt suicide, and necessitated her being placed in emergency detention and hospitalized. GX 7, at 29. Respondent prescribed ''every class of addictive drug and multiple addictive drugs,'' to M.H., which Dr. Chambers stated likely ''contribut[ed] to [her] deterioration'' and hospitalization. Tr. 229; *see also supra* II.F.6. Respondent prescribed both ''uppers and downers'' to K.W., M.G., F.P., and M.H., the combination of which Dr. Chambers testified is often used for ''illicit substance use,'' and ''can create a bipolar pattern of symptoms in someone who [does not] even have bipolar, but if they do have bipolar it could make it worse.'' Tr. 146.

Indeed, Respondent's found violations go to the heart of the CSA by not complying with the closed regulatory system devised to ''prevent the diversion of drugs from legitimate to illicit channels.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13–14, 27 (2005).

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 find that considerations of both specific and general deterrence weigh in favor of revocation in this case. 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 as contained in the Order below.

[57] Obviously, capturing ''every spoken word'' and ''every thought that crosses a clinician's mind'' is not the documentation standard of care to which Respondent has been held in this matter. *See supra* II.E; Tr. 335.

[58] *See Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,202–03.

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. MV3148257 issued to Melanie Baker, N.P., and deny any pending applications for renewal or modification of that registration. This Order is effective June 4, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–09463 Filed 5–4–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michele L. Martinho, M.D.; Decision and Order

On December 4, 2019, the Drug Enforcement Administration (hereinafter, DEA or Government) Administrative Law Judge Mark M. Dowd (hereinafter, ALJ), issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) on the action to revoke the DEA Certificate of Registration Number BM9434440 of Michele L. Martinho, M.D. The ALJ transmitted the record to me on January 7, 2020, and asserted that no exceptions were filed by either party. ALJ Transmittal Letter, at 1. Having reviewed and considered the entire administrative record before me, I adopt the ALJ's RD with minor modifications, where noted herein.*

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby dismiss the Order to Show Cause issued to Michele L. Martinho, M.D. This Order is effective immediately.

D. Christopher Evans,

Acting Administrator.

Paul E. Soeffing, Esq., for the Government

Douglas M. Nadjari, Esq. and David Durso, Esq., for the Respondent

*I have made minor, nonsubstantive, grammatical changes to the RD. Where I have made any substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have bracketed the modified language and explained the edit in a footnote marked with an asterisk and a letter in alphabetical order.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

The Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OSC),[1] dated February 26, 2019, seeking to revoke the Respondent's Certificate of Registration (COR), number BM9434440, pursuant to 21 U.S.C. 824(a)(5), and deny any applications for renewal or modification of such registration and any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(5), because the Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42. The Respondent requested a hearing on March 13, 2019,[2] and prehearing proceedings were initiated.[3] A hearing was conducted in this matter on October 3, 2019, at the DEA Hearing Facility in Arlington, Virginia.

The issue ultimately to be adjudicated by the Acting Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's subject registration with the DEA should be revoked pursuant to 21 U.S.C. 824(a)(5).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

In the OSC, the Government contends that the DEA should revoke the Respondent's DEA COR because she has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42.

Specifically, the Government alleges the following:

1. The Respondent is registered with the DEA as a practitioner in Schedules II through V under DEA COR BM9434440. The Respondent's COR expires by its terms on January 31, 2020.

2. On June 14, 2017, the Respondent was found guilty in the United States District Court for the District of New Jersey of ''Transporting in Aid of-Travel Act-Accepting Bribes in Violation of the Travel Act.'' Judgment was entered in *U.S.* v. *Michele Martinho,* No. 2:14–CR–00271–SRC–1 (D.N.J. filed June 14, 2017).

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

Human Services, Office of Inspector General (''HHS/OIG''), by letter dated July 31, 2018, mandatorily excluded the Respondent from participation in Medicare, Medicaid, and all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a), effective August 20, 2018. Notwithstanding the fact that the underlying conduct for which the Respondent was convicted had no nexus to controlled substances, mandatory exclusion from Medicare, Medicaid, and all federal health care programs by HHS/OIG warrants revocation of the Respondent's registration pursuant to 21 U.S.C. 824(a)(5).

The Hearing

Government's Opening Statement

In the Government's Opening Statement, the Government indicated that revocation is sought for the Respondent's COR involving Schedules II through V, pursuant to 21 U.S.C. 824(a)(5). Tr. 10. The facts in this matter are undisputed and have been stipulated to by the parties. *Id.* The Respondent was found guilty in U.S. District Court of transporting in aid of the Travel Act and accepting bribes in violation of the Travel Act. *Id.* The following year, HHS/OIG mandatorily excluded the Respondent from participation in Medicare, Medicaid, and all federal health care programs. *Id.* at 10–11. Pursuant to 42 U.S.C. 1320a–7(a), the Respondent's exclusion remains in effect, which is the basis upon which the DEA seeks to revoke the Respondent's COR. *Id.* at 11.

Respondent's Opening Statement

The Respondent asserted in her opening statement that this matter is not about controlled substances, and it has nothing to do with the issuance of prescriptions or record keeping for controlled substances. *Id.* at 11. The Respondent admitted that the Government is correct that she accepted cash payments in exchange for referring blood work to a particular lab, that she pleaded guilty to a single count violation of the Travel Act, and that she has been excluded by HHS/OIG from participation in Medicare, Medicaid, and all federal health care programs. *Id.* at 11–12. The Respondent maintained that the evidence will show that the she can be entrusted to maintain and properly use her DEA COR. *Id.* at 12. Revocation in this matter is not mandatory. *Id.* at 12. The Respondent

[1] ALJ Ex. 1.

[2] ALJ Ex. 2.

[3] ALJ Ex. 3.