Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

Type of Information Collection: Revision of a currently approved collection.

The Title of the Form/Collection: Report of Multiple Sale or Other Disposition of Pistols and Revolvers.

The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 3310.4.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: Federal Government and State, Local, or Tribal Government.

Abstract: The Report of Multiple Sale or Other Disposition of Pistols and Revolvers—ATF Form 3310.4 is used to report multiple sale or other disposition of two or more pistols, revolvers, or any combination of pistols or revolvers to an unlicensed person, whether it occurs one time or within five consecutive business days.

An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimated 82,011 respondents will complete this form approximately 6.33365 times annually, and it will take each respondent approximately 15 minutes to complete their responses.

An estimate of the total public burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 129,857 hours, which is equal to 82,011 (# of respondents) * 6.33365 (# of responses per respondent) * .25 (15 mins).

An Explanation of the Change in Estimates: The increase in total respondents, responses, and burden hours, by 4,106, 63,495, and 15,873 hours respectively, is due to the revision of agency estimates, and a general increase in the number of respondents since the last renewal in 2018.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: September 14, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–20187 Filed 9–17–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–15]

Salman Akbar, M.D.; Decision and Order

On March 2, 2020, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to Salman Akbar, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificate of Registration Number BA5092856 (hereinafter, registration) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from July 21–22, 2020 at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference. On August 20, 2020, Chief Administrative Law Judge John J. Mulrooney (hereinafter, Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On September 9, 2020, the Government and Respondent filed exceptions to the Recommended Decision (hereinafter, Gov Exceptions and Resp Exceptions, respectively). Having reviewed the entire record, I find the Respondent's Exceptions without merit and I adopt the Chief ALJ's rulings, findings of fact, conclusions of law, and recommended sanction with minor modifications, where noted herein.[*A]

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. BA5092856 issued to Salman Akbar, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending application of Salman Akbar, M.D. to renew or modify this registration, as well as any other pending application of Salman Akbar, M.D. for registration in Virginia. This Order is effective October 20, 2021.

Anne Milgram,

Administrator.

The Respondent's Exceptions

In his Posthearing Brief, Respondent acknowledged that the Government had ''offered sufficient evidence to establish a prima facie case,'' but he argued that his registration should not be revoked, because he had ''countered the Government's showing with substantial mitigating evidence that demonstrates his continued registration will not be harmful to the public interest.'' ALJ Ex. 20 (Resp Posthearing), at 1. The Chief ALJ disagreed with Respondent, finding that revocation was the appropriate remedy, based on Respondent's failure to accept responsibility for his misconduct and his failure to offer sufficient remedial evidence. RD, at 33–38. In determining that Respondent had not adequately accepted responsibility, the Chief ALJ relied in part on Respondent's statements that he always issues prescriptions within the usual course of professional practice and for a legitimate medical purpose. *See, e.g., id.* at 35 (citing Tr. 427–29).

Respondent takes Exception to the Chief ALJ's reliance on these statements. Respondent argues that these statements do not negate his acceptance of responsibility, because he made them ''as a layman physician and not as a person versed in law.'' Resp Exceptions, at 1. Respondent asserts that he ''recognized that he failed to meet the standards of care established by Virginia law,'' but he ''did not . . . recognize

[*A] I have made minor, nonsubstantive, grammatical changes to the RD. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter.

that under DEA regulations this meant as a matter of law that the drugs were not issued for a legitimate medical purpose within the usual course of professional practice.'' *Id.* Respondent states that he ''recognizes now that as a legal matter he did not establish a bona fide doctor-patient relationship, but when testifying he believed as a matter of fact that he was acting as a doctor attempting to provide treatment to a patient in need of care.'' *Id.* at 3.

I reject Respondent's Exception for several reasons. First, Respondent's statement that he ''recognized that he failed to meet the standards of care established by Virginia law'' is not supported by the record. During the following exchange, Respondent repeatedly and emphatically affirmed that the prescriptions that he issued were within the usual course of professional practice in Virginia:

> Q: And you issued [all of] these prescriptions, you believe, acting in the ordinary course of professional practice?
>
> A: Absolutely, it was in the course of my medical practice.
>
> Q: And that's again, true for all of the—for the prescription for tramadol that you issued on July 23, 2019?
>
> A: It's absolutely true.
>
> Q: And that's true for the prescription for tramadol and the prescription for Ativan that you issued on August 28, 2019?
>
> A: That is correct, and I have no doubts about it.
>
> Q: And do you also believe that you issued the prescriptions for Ativan and tramadol on September 27, 2019, when in doing so you were acting in the ordinary course of professional practice for a physician in Virginia?
>
> A: Absolutely acting in the course of my medical practice.
>
> Q: And you were acting in the usual course of professional practice on November 5, 2019, when you issued prescriptions to Patient SD for tramadol and for Ativan?
>
> A: I was acting in the course of my medical practice.

Tr. 428–29. I am also not persuaded by Respondent's implication that he did not understand that by testifying that he issued prescriptions ''in the usual course of professional practice in Virginia,'' he was testifying that the prescriptions were issued in accordance with Virginia law and the applicable Virginia standard of care. Respondent did not convey any confusion when he testified that he ''ha[d] no doubts'' that he ''absolutely'' issued the prescriptions in the usual course of professional practice. *Id.* If he had misunderstood what the phrase ''in the usual course of professional practice'' meant, he could have asked for clarification. This phrase should not have been foreign to Respondent, because he had just observed the testimony of the Government's medical expert, who repeatedly testified that Respondent's prescriptions were not issued in the usual course of professional practice in Virginia. *See, e.g., id.* at 205, 214, 218, 220, 231, 255, 258–59, 261, 282–87, 337, 439.

Second, I disagree with Respondent's argument that he was merely testifying as a layperson who was not well versed in the law, and therefore, that his statements should not be found as undermining his acceptance of responsibility. Respondent was not testifying merely as a layperson, but as a Virginia physician and a DEA registrant who is expected to be knowledgeable about the basic tenets of medical practice and the appropriate prescribing of controlled substances. Respondent's failure to appreciate his obligations under federal and state law further demonstrates that his continued registration is inconsistent with the public interest. *See, e.g., The Medicine Shoppe,* 79 FR 59,504, 59,508–11 (2014). In *Medicine Shoppe,* the respondent initially accepted responsibility for his misconduct, but later testified that he ''never do[es] diversion'' and that he disagreed with the Government's expert's testimony that he filled unlawful prescriptions. *Id.* at 59,509–10. The respondent testified: ''There's no prescription that [the Government's medical expert] said that I should have [sic] filled that I looked at it from her point of view.'' *Id.* at 59,510. Based on this testimony, the former Deputy Administrator found that the respondent's ''understanding of his obligations as a dispenser of controlled substances [was] so lacking as to preclude a finding that Respondent's registration is consistent with the public interest.'' *Id.* at 59,510 (citing 21 U.S.C. 823(f) and 824(a)(4)). Respondent's testimony in this case similarly evidences a failure to appreciate his basic obligations under federal and state law, which demonstrates that his registration is inconsistent with the public interest.

Finally, I give little weight to Respondent's assertion that he *now* recognizes that he did not establish a bona fide doctor-patient relationship, but when he testified ''he believed as a matter of fact that he was acting as a doctor attempting to provide treatment to a patient in need of care.'' *Id.* at 3. I give little weight to these statements that were made off of the record. At the hearing, Respondent's remorse for his misconduct quickly dissipated when he was cross examined. *See, e.g.,* Tr. 428–29. Moreover, Respondent minimizes his misconduct in his Exceptions, which undercuts his acceptance of responsibility and elucidates his lack of familiarity with federal and state law.[*B] For example, Respondent states that when he testified, he believed as a factual matter that he prescribed medication ''for a legitimate purpose . . . of providing medical care to a patient. . . who presented with back pain and anxiety.'' Resp Exceptions, at 3 (citing Tr. 380–81). And although Respondent acknowledges that he did not comply with the Virginia standard of care, he asserts that ''from a layman's perspective,'' he believed that he was ''acting as a physician'' who ''was prescribing [] medication for a licit purpose,'' not ''as a common drug dealer giving drugs to anyone willing to pay a certain price.'' *Id.*

Respondent's attempts to distinguish himself from a ''common drug dealer'' indicate that he fails to appreciate the egregiousness of his misconduct. Respondent ignored Patient SD's admissions that he had taken controlled substances from a friend, and he failed to comply with even the most basic requirements of the applicable Virginia standard of care, such as performing a physical examination and establishing a diagnosis for Patient SD's back pain. *See, e.g.,* Tr. 78–79, 207–211, 228–30. After issuing three tramadol prescriptions to Patient SD, Respondent asked SD during the fourth visit, ''[W]hat diagnosis are we using for you? For the back pain. We got to have a diagnosis, and granted, you aren't getting a whole lot of it from me, but, ah, what can I use. Do you know any reason why you have back pain?'' Gov't Ex. 13, at 2. Respondent issued a fourth tramadol prescription at that visit, even though Patient SD said that he had ''no idea'' what was causing the back pain, and told Respondent that he had been ''pretty good for a while'' when Respondent asked him where his pain was located. *Id.*

Given Respondent's approach to prescribing opioids, I am concerned that Respondent continues to imply that he was ''attempting to provide treatment to a patient in need of care'' and not ''dispensing medications for anyone seeking a fix.'' Resp Exceptions, at 3. Therefore, I reject Respondent's Exceptions and concur with the Chief ALJ's conclusions that Respondent did not unequivocally accept responsibility for his misconduct, and that his

[*B] *See George Pursley, M.D.,* 85 FR 80,162, 80,188 (2020) (finding that Respondent's attempts to minimize his misconduct indicated that he ''lack[ed] familiarity with applicable controlled substance legal requirements'' and ''put into question the value he assigned to practicing medicine in compliance with the applicable standard of care'').

registration is inconsistent with the public interest.

The issue before the Administrator is whether the record as a whole establishes that it would be inconsistent with the public interest under 21 U.S.C. 824(a)(4) and 823(f) to allow Respondent to retain his DEA registration.

The decision below is based on my consideration of the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel. I adopt the ALJ's Recommended Decision with noted modifications.

David M. Locher, Esq. and John E. Beerbower, Esq., for the Government
Joseph R. Pope, Esq. for the Respondent

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

The Allegations *C [1] [2]

The Government alleges that the Respondent's DEA registration should be revoked because, over the course of four visits, the Respondent issued seven illegitimate controlled substance prescriptions to a DEA undercover Task Force Officer. ALJ Ex. 1, at 2.

The Evidence

Stipulations

The parties entered into factual stipulations which were accepted by the tribunal. The following factual matters are deemed conclusively established in this case:

1. The Respondent is registered with DEA as a practitioner to handle substances in Schedules II through V under DEA COR No. BA5092856. The Respondent's registered address is 10708 Old Prescott Road, Richmond, Virginia 23233.*D

2. The Respondent's COR expires by its own terms on June 30, 2020.[3]

3. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R § 1308.12(b)(1)(xiii).*E Percocet is a brand name drug containing oxycodone.

4. Alprazolam is a Schedule IV controlled substance pursuant to 21 CFR 1308.14(c)(2). Xanax is a brand name drug containing alprazolam.

5. Diazepam is a Schedule IV controlled substance pursuant to 21 CFR 1308.14(c)(16).*F Valium is brand name drug containing diazepam.

6. Lorazepam is a Schedule IV controlled substance pursuant to 21 C.F.R § 1308.14(c)(30).*G Ativan is a brand name drug containing lorazepam.

7. Tramadol is a Schedule IV controlled substance pursuant to 21 CFR 1308.14(b)(3).

8. Government Exhibit 1 is a true and correct copy of the Respondent's patient file for Patient SD.

9. On July 23, 2019, the Respondent issued a prescription to Patient SD for 20 dosage units of tramadol 50 mg.

10. Government Exhibit 2 is a true and correct copy of the prescription for 20 dosage units of tramadol 50 mg that the Respondent issued to Patient SD on July 23, 2019.

11. Government Exhibit 3 contains a true and correct recording of the Respondent's interaction with Patient SD on July 23, 2019.

12. Government Exhibit 4 is a true and correct transcript of the Respondent's interaction with Patient SD on July 23, 2019.

13. On August 28, 2019, the Respondent issued prescriptions to Patient SD for 20 dosage units of tramadol 50 mg and 30 dosage units of Ativan 0.5 mg.

14. Government Exhibit 5 is a true and correct copy of the prescriptions the Respondent issued to Patient SD on August 28, 2019.

15. Government Exhibit 6 contains a true and correct video recording of the Respondent's interaction with Patient SD on August 28, 2019.

16. Government Exhibit 7 is a true and correct transcript of the Respondent's interaction with Patient SD on August 28, 2019.

17. On September 27, 2019, the Respondent issued prescriptions to Patient SD for 30 dosage units of tramadol 50 mg and 30 dosage units of Ativan 0.5 mg.

18. Government Exhibit 8 is a true and correct copy of the prescriptions the Respondent issued to Patient SD on September 27, 2019.

19. Government Exhibit 9 contains a true and correct video recording of the Respondent's interaction with Patient SD on September 27, 2019.

20. Government Exhibit 10 is a true and correct transcript of the Respondent's interaction with Patient SD on September 27, 2019.

21. On November 5, 2019, the Respondent issued prescriptions to Patient SD for 30 dosage units of tramadol 50 mg and 30 dosage units of Ativan 0.5 mg.

22. Government Exhibit 11 is a true and correct copy of the prescriptions issued to Patient SD on November 5, 2019.

23. Government Exhibit 12 contains a true and correct video recording of the Respondent's interaction with Patient SD on November 5, 2019.

24. Government Exhibit 13 is a true and correct transcript of the Respondent's interaction with Patient SD on November 5, 2019.

25. Patient SD was provided with a document entitled ''Pain Treatment with Opioid Medications: Patient Agreement'' during his visit to the Respondent's clinic on November 5, 2019.

26. Government Exhibit 14 is a true and correct copy of the Virginia Prescription Drug Monitoring Program Audit Report showing searches by the Respondent for Patient SD.

27. Government Exhibit 16 contains a true and correct copy of ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines,'' published by the Food and Drug Administration (FDA).

28. Government Exhibit 16 contains a true and correct copy of the FDA label for Ativan.

The Government's Case

The Government's case consisted of the testimony from the lead Diversion Investigator on the case, the DEA Task Force Officer who made undercover visits to the Respondent's office, and an expert witness.

Diversion Investigator

As its first witness, the Government called a Diversion Investigator (hereinafter, DI), who testified that he has been a DI for seven years, the last two of which have been in the Richmond Field Office. Tr. 27. DI was the lead investigator in the case against the Respondent. *Id.* at 30. He testified that the investigation into the Respondent's prescribing practices began when DEA received a tip from an individual who stated that they were a patient of the Respondent. *Id.* This individual informed DEA that ''a lot of drug addicts'' seemed to be frequenting the Respondent's office. *Id.* This tip was received and documented by the office's assigned Task Force Officer (hereinafter, TFO). *Id.* at 32.

Acting on the tip information, DI consulted numerous databases, both inside and outside DEA. *Id.* at 33. One of the databases he checked was the Virginia Prescription Monitoring Program (hereinafter, the Virginia PMP or the PMP) database to analyze data for any possible patterns regarding the Respondent's controlled substance prescribing. *Id.* at 33, 63; Gov't Ex. 14. The witness explained that the Virginia

*C I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote omitted, *see supra* n.*C]

[2] [Omitted footnote discussing the administrative tribunal's jurisdiction over the immediate suspension order.]

*D According to Agency Records, Respondent's registered address has changed to 909 Hioaks RD, Suite F, Richmond, Virginia 23225–4038.

[3] Counsel for both parties have represented that the Respondent timely filed an application to renew his DEA registration in advance of these proceedings. [Citation omitted.]

*E This stipulation cites to the version of the regulation that was effective from February 7, 2019, to August 15, 2019. The lettering of the regulation's various subsections has changed in subsequent versions, but there were no substantive changes that impact my Decision.

*F This stipulation cites to the version of the regulation that was effective from December 14, 2015, to June 16, 2019. The lettering of the regulation's various subsections has changed in subsequent versions, but there were no substantive changes to the regulation that impact my Decision.

*G This stipulation cites to the version of the regulation that was effective from December 14, 2015, to June 16, 2019. The lettering of the regulation's various subsections has changed in subsequent versions, but there were no substantive changes to the regulation that impact my Decision.

PMP database allows investigators to determine the prescriptions a practitioner has issued and where the prescriptions were dispensed. Tr. 33. DI explained that he was searching for potential ''red flags,'' such as prescriptions for high strengths and dosages of medications that are commonly abused or diverted and prescriptions for high strengths/dosages of these drugs that are dispensed to multiple people residing at the same address. *Id.* at 62. DI testified that the PMP data regarding the Respondent presented some unusual commonalities among individuals within the same household who were patients of the Respondent.[4] *Id.* at 63. He testified that, at least in his view at the time, these data points constituted red flags which warranted further investigation. *Id.*

DI testified that the investigation of the Respondent progressed to the deployment of a DEA TFO who conducted multiple undercover visits to the Respondent's practice. *Id.* at 34. According to DI, TFO made four undercover visits (hereinafter, UC Visits) to the Respondent's office using an alias (Scott Davis).[5] *Id.* at 34–35. The UC Visits were conducted on July 23, 2019 (hereinafter, UC Visit #1), August 28, 2019 (hereinafter, UC Visit #2), September 27, 2019 (hereinafter, UC Visit #3), and November 5, 2019 (hereinafter, UC Visit #4), respectively. *Id.* at 35. It is DI's understanding that the UC Visits were recorded by the TFO using a concealed device, and that controlled substance prescriptions were issued to the TFO by the Respondent at the culmination of each visit. *Id.* at 36; *see* Gov't Exs. 2, 3, 5, 6, 8, 9, 11, 12. Each of the scrips procured by the TFO from the Respondent's office were turned over to the Richmond DEA office and maintained in the DEA evidence system. Tr. 36. The recordings likewise were maintained in the DEA evidence system, and were subsequently transcribed by a Federal Bureau of Investigation (hereinafter, FBI) transcriber. Tr. 36–37, 50; *see* Gov't Exs. 4, 7, 10, 13.

Using the information acquired during the course of the investigation, a search warrant was secured by DEA and executed at the Respondent's clinic on March 3, 2020. Tr. 37. In the course of this search, the medical records for the TFO under his fictitious name (Scott Davis or Patient SD) were among the documents identified and seized. *Id.;* Gov't Ex. 1. Additionally, DEA requested data from the Virginia Department of Health Professions, which reflected that the Respondent had queried the Virginia PMP regarding Patient SD.[6] *[H] Tr. 38; Gov't Ex. 14. DI's testimony was used to authenticate multiple Government exhibits, which included documents uncovered during the search as well as those produced in the course of the investigation.[7] Following the execution of the search warrant, DEA personnel hired an expert, Dr. John F. Dombrowski, to evaluate what they had acquired and learned during the course of their investigation. Tr. 62.

DI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. The testimony of this witness was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

TFO

The Government presented the testimony of the agent who conducted the undercover visits to the Respondent's practice, TFO. TFO testified that he has been a detective with the City of Greenfield (Wisconsin) Police Department (GPD) for eighteen years and has been cross-designated by DEA as a TFO for the past seven years. Tr. 66–69. He was assigned to assist in the investigation that spawned the current charges against the Respondent. *Id.* at 66–68. TFO testified that he is experienced in undercover work, having personally conducted and provided testimony regarding somewhere between 100 and 200 undercover operations. *Id.* at 69.

TFO testified that he assumed the name Scott Davis (for which he had a fabricated driver's license) to conduct his operation at the Respondent's office and that he recorded his UC Visits on audio visual recording equipment. *Id.* at 70, 87. TFO testified that following a preliminary visit with the Respondent's office staff, he appeared for a July 23, 2019 office visit (UC Visit #1). *Id.* at 71. Upon his arrival, the Respondent's office staff had the TFO pay an office visit fee[8] and fill out a medical questionnaire. *Id.* at 73; Gov't Ex. 1, at 7. According to TFO, based on his experience, he completed the questionnaire in such a way as to monitor whether the prescriber was fulfilling his responsibility to ensure that pain medications were not being diverted. *Id.* at 75–77. Under the heading ''Reason for Visit,'' the TFO put the words ''need new doctor prescription.'' Gov't Ex. 1, at 7; Tr. 119. Although he knew he planned to (falsely) describe back discomfort to the Respondent, the TFO intentionally declined to check the box adjacent to ''Back Problems'' in the ''Past Medical History'' section of the form. Gov't Ex. 1, at 7; Tr. 74. Similarly, the TFO left a blank response to the query, ''Do you use recreational drugs?'' Gov't Ex. 1, at 7. TFO recounted that neither of these potential diversion red flags were raised with him by the Respondent or his staff during any of his UC Visits.[9] Tr. 74–75.

After completing the medical questionnaire during UC Visit #1, the TFO was escorted to an exam room by a staff member and had his vitals taken. *Id.* at 75, 77, 88. The Respondent met with the TFO after the staff finished taking his vitals. *Id.* at 77. The cover story the TFO presented to the Respondent was that he is an active

[4] The Government did not base its case on multiple patients living at the same address. This information was offered and considered strictly to explain information which informed the DI's investigative progress.

[5] DI Pumphrey confirmed that Scott Davis is a fictitious name. Tr. 34.

[6] [Content of footnote addressed in text.]6

[*H] This sentence was modified to clarify that DEA requested Respondent's Virginia PMP queries from the Virginia Department of Health Professions.

[7] Government Exhibit 1 contains the medical records that the Respondent's office maintained under the name Scott Davis (Patient SD), which were retrieved during the search of the Respondent's clinic. Tr. 38–39. Government Exhibit 2 is a copy of a prescription for tramadol written by the Respondent for Patient SD at UC Visit #1. *Id.* at 40–41, 42–46. Government Exhibit 3 is a video recording of UC Visit #1. *Id.* at 46–48. Government Exhibit 4 is a transcript of the UC Visit #1 videotape. *Id.* at 49–50. Government Exhibit 5 contains the prescriptions written for Patient SD at UC Visit #2. *Id.* at 51–52. Government Exhibit 6 is the video recording of UC Visit #2. *Id.* at 53–54. Government Exhibit 7 is a transcript of the UC Visit #2 videotape. *Id.* at 54–55. Government Exhibit 8 contains the prescriptions for tramadol and Ativan that were written by the Respondent for Patient SD at UC Visit #2. *Id.* at 55–56. Government Exhibit 9 is the video recording of UC Visit #3. *Id.* at 56–57. Government Exhibit 10 is a transcript of the UC Visit #3 videotape. *Id.* at 57. Government Exhibit 11 is the two prescriptions for tramadol and Ativan written by the Respondent for Patient SD at UC Visit #3. *Id.* at 57–58. Government Exhibit 12 is a video recording of UC Visit #4. *Id.* at 58–59. Government Exhibit 13 is the transcript of the UC Visit #4 videotape. *Id.* at 59. Government Exhibit 14 documents the queries to the Virginia PMP made regarding the Respondent as part of the investigation. *Id.* at 59. DI confirmed that he ran the query and received the information on April 3, 2020. *Id.* at 59–60. He further testified that this data was a ''special request'' in that he directly contacted the Virginia Department of Health Professionals to request this data. *Id.* at 60. Government Exhibit 14 is the document he received as a result of this inquiry. *Id.* at 60–61.

[8] Tr. 75.

[9] The form demonstrates a miniscule dot outside each of the respective boxes pertaining to the use of recreational drugs and back problems. Gov't Ex. 1, at 7; Tr. 120–21, 154–56. The dots are tiny and do not provide any level of ambiguity as to the responses (or lack thereof). Indeed, during his testimony, the Respondent, beyond a general acknowledgement of their existence, Tr. 378, did not allude to any significance that should be attached to these two little dots, and no significance is placed on their presence for the purposes of this recommended decision.

construction worker[10] who recently moved to the Richmond area from Milwaukee and needed to establish with a new doctor to refill his medications. *Id.* at 78; Gov't Ex. 4, at 2. On his questionnaire, the TFO indicated a specific strength and dosage of Percocet[11] under the ''Current Medications'' section. Gov't Ex. 1, at 7. Upon meeting TFO, the Respondent initiated his contact with ''What's going on? What can I help you with?'' Gov't Ex. 4, at 2. When the TFO started to explain his move to the area and need for a new physician (all of which was contrived), the Respondent interrupted with ''For this kinda stuff? Percocet?'' and described Percocet as ''[a]lmost outlawed.'' *Id.; see also* Tr. 123. The TFO told the Respondent that the Percocet he referred to on the questionnaire was for his back, and that he moved to perform construction work in the Richmond area. Gov't Ex. 4, at 2. The Respondent asked the TFO, ''[s]o where in the back, and how much Percocet are you needing?'' *Id.* The TFO volunteered the following rather startling admission: ''Unfortunately, I had to, uh, like from a friend or a girlfriend, that sort of thing, get some pills here and there. Uh, the tramadol's actually been working pretty decent.'' [12] *Id.* at 3; Tr. 78–79. Without any follow-up or even apparent reaction to the revelation that his patient had just admitted to acquiring diverted drugs,[13] the Respondent asked him about the source of his back pain, to which the TFO replied that he did not know, but that at some point he had fallen from a ladder and recovered by ''just doing [his] job.'' Gov't Ex. 1, at 4; Tr. 79. Later in their conversation, the Respondent admonished the TFO that ''[j]ust because you fell off of a ladder doesn't mean anything.'' Gov't Ex. 1, at 7. The witness told the Respondent that there were no radiation symptoms down the legs.[14] *Id.* at 4. There was some additional discussion about other options and creams and the Respondent reiterated that ''[t]he rules are so strict about Percocet. Especially 10 [milligram dosage].'' *Id.* at 5. After confirming on multiple occasions that the TFO brought no imaging, and explaining that he would, at some point, have to procure an x-ray, the Respondent explained that while he would not be prescribing Percocet, ''I can give you a few tramadols[15] until you can get an x-ray, and you're going to have to show me that there is something going on with your back.'' *Id.* The TFO testified that he never provided any imaging to the Respondent at that visit. Tr. 89–90.

The TFO told the Respondent that he thought he could procure an ''older'' x-ray or MRI[16] from his former address in Milwaukee, that he kept working while prescribed oxycodone for a couple of years,[17] and that since he was on oxycodone for that long, ''it's like, I mean, I can't just stop.'' [18] Gov't Ex. 4, at 6, 8. There was no follow-up from the Respondent regarding the TFO's estimation that he was unable to ''just stop'' taking oxycodone. *Id.* The Respondent gave no indication that he was concerned about potential dependence or addiction.

When the TFO raised the issue that he has ''a tough time, like falling asleep, and relaxing at the end of the day,'' the Respondent's reaction was ''Ok, and here's some Trazadone[19] for that,'' describing the medication as the ''[m]ost commonly prescribed sleeping medicine in the country.'' *Id.* at 6–7. Although at one point during their brief, eight-minute[20] time together, the Respondent touched the TFO's back through his shirt for one-to-two seconds,[21] no physical exam was conducted on the undercover officer by anyone at any time during UC Visit #1. Tr. 77, 83. The Respondent prescribed twenty 50 milligram (mg) tramadol tablets, which the TFO did not fill. Gov't Ex. 2; Tr. 85–86.

The TFO returned to the Respondent's office for another undercover visit on August 28, 2019 (UC Visit #2). Tr. 87. Similar to his first UC Visit, the TFO paid an office visit fee, and was escorted to an exam room for two-to-three minutes, where his vital signs were taken and he was asked the reason for his visit. *Id.* at 89. He was joined in the exam room by the Respondent shortly thereafter, where the TFO informed the doctor that he had come for a tramadol refill. *Id.* at 89. In response to the Respondent's inquiry about the imaging results the TFO had agreed to bring, the latter told him that he had located them in Milwaukee, but neglected to bring them with him. *Id.* at 89–90, 136; Gov't Ex. 7, at 2. The Respondent replied, ''Uhhh, I need that. Alright, I'll just give you twenty for now, and ah, I need you to bring that . . . . Then I'll give you more.'' Gov't Ex. 7, at 2; *see also* Tr. 136. The Respondent went on to explain that once he has the opportunity ''to look at'' the imaging ''we could do regular sixty [tablets], if there is . . . [s]ignificant pathology . . . [o]f your back.'' Gov't Ex. 7, at 3.

The Respondent asked the TFO if he experienced spasms, but got no answer. *Id.* He again touched a spot on the TFO's back through his shirt for one-to-two seconds, and was told by his patient that he had identified the locus of pain, ''if it's bothering me, uh, that's where it is.'' Gov't Ex. 7, at 3; Tr. 90–91, 137. Remarkably, the Respondent explained his understanding of the prescribing standard to the TFO in this way:

> Alright, right now, I can only list back pain as a diagnosis, but ya know, in our file we need more than that. Like a herniated disc, or a compressed disc, or something, ya know? Something more concrete.

Gov't Ex. 7, at 3. After another assurance that he would bring his imaging on his next visit, the TFO made the following request: ''Oh, oh, I was gonna say, c-can I get a scrip for Xanax too?'' explaining that the tramadol ''helps me during the day, but the Xanax makes me feel a lot better and relaxed in the evening.'' *Id.* at 4. A few follow up questions by the Respondent made it clear that the TFO did not know (or was not willing to say) what his prior dose of Xanax was. *Id.* The Respondent confided in his patient that since the emergence of the current opioid crisis, ''I don't like to prescribe Xanax anymore,'' and noted the addictive qualities of Xanax. *Id.* The Respondent said he would be willing to prescribe Ativan as a less addictive alternative. *Id.* at 4–5; Tr. 92. No mental status exam was conducted. Tr. 92. In fact, no questions about any mental health conditions were directed to the TFO. *Id.* The TFO's response to all of this was to let the Respondent know that he had also tried Valium in the past, to which the Respondent replied, ''No, no, no, no, no.'' Gov't Ex. 7, at 4–5. Just as was true at UC Visit #1, no physical exam was conducted by the Respondent or any staff member during UC Visit #2. Tr. 89. The TFO was asked no questions about how he was doing on the previously-prescribed tramadol, but at the conclusion of his four-minute visit with the Respondent, he received

[10] Tr. 125.

[11] The TFO testified that he chose Percocet based on his understanding that it is a medication that is ''more highly sought after by addicts.'' Tr. 164.

[12] The questionnaire contained no reference to tramadol. Gov't Ex. 1, at 4.

[13] Tr. 79; Gov't Ex. 1, at 4.

[14] The TFO testified that he volunteered this in ''trying to minimize the symptoms.'' Tr. 83.

[15] Tramadol is a Schedule IV controlled substance. 21 CFR 1308.4(b)(3); Stip. 7.

[16] Tr. 89–90. The TFO was unable to recall whether he told the Respondent that he had an x-ray or an MRI. *Id.* at 79.

[17] The questionnaire contained no reference to oxycodone. Gov't Ex. 1, at 4.

[18] The TFO testified that he told the Respondent he could not just stop ''because I wanted to show that I was dependent—potentially addicted but dependent upon that pain medication.'' Tr. 84.

[19] Trazadone is not a controlled substance.

[20] Tr. 85.

[21] Tr. 81–82, 90–91, 133. The TFO testified that he was wearing a T-shirt. Tr. 82.

prescriptions for tramadol and Ativan. Gov't Ex. 5, at 1–2.

The TFO paid another undercover visit to the Respondent's practice on September 27, 2019 (UC Visit #3). Tr. 94. Like his other visits, he paid his office fee, was escorted to an exam room, had his vitals taken, and waited for the doctor. *Id.* at 96. Before the staff member departed, the TFO did take the opportunity to assure her that he was presently experiencing neither pain nor anxiety. *Id.* at 97.

Upon the Respondent's arrival in the exam room, the TFO told him he was there for tramadol and Ativan refills. *Id.* Consistent with the TFO's assurances to the staff member, he told the Respondent, regarding his back pain, ''I'm feeling pretty good.'' Gov't Ex. 10, at 2; *see also* Tr. 98–99, 142, 162. When he re-told the Respondent that he did not know the cause of his back pain,[22] the Respondent presented the following suggestion: ''Why don't we just give you twenty of tramadol? It's no big deal.'' Gov't Ex. 10, at 2. When the Respondent inquired about any factors that might exacerbate the back issues, the TFO responded with, ''Yeah, I mean, like right now I feel ok, but [you n]ever know.'' *Id.* The Respondent's reaction to this non-sequitur answer was to propose various activities that possibly could make this worse, but this patient was not taking the bait. *Id.* at 2–3. He merely offered that ''the Ativan was pretty good.'' *Id.* at 3. The Respondent's astonishing response to this colloquy was:

> Alright, no problem. Ativan is a low, uh, low benzodiazepine, um, equivalent. Ok. So it's probably a better one to use anyway. Ok? Yeah. I'll increase the number of tramadols to thirty. Ok?

Id. Not surprisingly, the TFO readily concurred in this unsolicited medication increase, which was unsupported by any discussion about the relative merits or efficacy of the prior dose of twenty tablets, to which the Respondent amicably replied, ''You happy? Good.'' *Id.* Following some level of banter, doctor and patient ended their time together. *Id.* As was true in the other adventures at the Respondent's office, the TFO provided no imaging or other medical records,[23] and no physical exam was performed on the TFO by the Respondent or any staff member. Tr. 96, 98. One variation in this visit is that the Respondent did not touch the TFO's back at all. *Id.* at 98. There was no inquiry about the efficacy of (or anything else about) the previously-prescribed tramadol, but at the conclusion of the two minutes the two men spent together during UC Visit #3, the Respondent issued prescriptions for Ativan and an increased dosage of tramadol. *Id.* at 99–102, 162; Gov't Ex. 8, at 1–2.

The TFO's final undercover visit to the Respondent's office (UC Visit #4) occurred on November 5, 2019. Tr. 102. As had generally been the routine, the TFO paid his office visit fee and was taken back into an exam room by a staff member where vital signs were taken. *Id.* at 104. In a slight variation from prior experience, the TFO was presented with a pain management contract[24] and two questionnaires. *Id.* at 104–107, 111. The first questionnaire is entitled, ''Generalized Anxiety Disorder 7–Item (GAD–7) Scale'' (Anxiety Questionnaire), and the second bore the title, ''Pain Diagram and Pain Rating'' (Pain Questionnaire). *Id.;* Gov't Ex. 1, at 12–13. The TFO put extremely low marks and low frequency of occurrence on both questionnaires, demonstrating a low level of symptoms. Gov't Ex. 1, at 12–13; Tr. 107, 109–11, 146–52.

After the staff member departed, the Respondent entered. Tr. 112. The TFO told the Respondent that he was feeling ''[n]ot too bad,'' and that he came in for the ''[s]ame thing as the last few times. Just the refills.'' Gov't Ex. 13, at 2; Tr. 112. The Respondent told the TFO he was refreshing his recollection by examining his chart, and narrated his recall process as follows:

> Ok. So what diagnosis are we using for you? For the back pain. We got to have a diagnosis, and granted, you aren't getting a whole lot of it from me, but, ah, what can I use[?] Do you know any reason why you have back pain?

Gov't Ex. 13, at 2. Once again, the TFO assured the Respondent that he ''ha[d] no idea'' why he had back pain. *Id.; see also* Tr. 112. He elaborated that he liked what the Respondent was prescribing, ''[b]ecause it's been pretty good for a while . . . .'' Gov't Ex. 13, at 2. The TFO pointed to a spot on his back and identified the spot as the locus of the pain, ''[i]f it would be bothering me.'' *Id.*

As had become their custom during their visits, the TFO provided neither imaging nor prior medical records,[25] but Respondent asked, ''[D]o you mind getting a chest film for me?'' Gov't Ex. 13, at 3. Beyond a two-to-three second finger push on the back through the TFO's shirt, no physical examination took place, and no dialogue occurred regarding the efficacy of the medications prescribed in the past, physical function, mental health, or pain level. Tr. 113–15. This time, the TFO pushed back a bit on acquiring an x-ray, citing a current lack of insurance as an impediment.[26] Tr. 145. However, the lack of insurance and concomitant lack of imaging did not serve as an impediment to the Respondent continuing to write controlled substance prescriptions, and at the end of the visit, the TFO walked away with prescriptions for tramadol and Ativan. Gov't Ex. 11; Tr. 115–17.

The TFO presented as an objective law enforcement officer with no apparent agenda beyond telling the truth. When asked, he was freely willing to agree with the Respondent's counsel on numerous points, but presented the impression of being confident in what he remembered about the case. Overall, this witness's testimony was sufficiently detailed, internally consistent, and plausible to be afforded full credibility in this case.

Dr. John F. Dombrowski, M.D., F.A.S.A.

The Government called Dr. John F. Dombrowski as its final witness. Tr. 168. Dr. Dombrowski testified that he is currently employed as a physician at the Washington Pain Center in Washington, DC[27] *Id.* He holds licenses to practice medicine in Maryland, Virginia, Florida, and the District of Columbia. *Id.;* Gov't Ex. 15. Dr. Dombrowski received his medical training at Georgetown University and Yale University before entering private practice in Richmond, Virginia, and eventually coming to practice in Washington, DC Tr. 170; Gov't Ex. 15. In addition to working as a physician, he is presently the CEO of the Washington Pain Center. Tr. 171; Gov't Ex. 15. In his capacity as a physician, Dr. Dombrowski performs injection therapy as an anesthesiologist as well as medication management for chronic pain patients. Tr. 171. He is additionally the director of several methadone clinics in the Washington, DC, area, as well as a detox facility in Maryland. *Id.* at 171–72; Gov't Ex. 15. His primary areas of expertise are anesthesiology, addiction medicine, and pain medicine. Tr. 172. Dr. Dombrowski is a member of the American Society of Anesthesiology, the Interventional Pain Societies, and some other professional organizations relating to his areas of specialty. *Id.;* Gov't Ex. 15. Dr. Dombrowski has board certifications from the American Board of Pain

[22] Tr. 97.

[23] Tr. 98.

[24] Gov't Ex. 1, at 2–3.

[25] Tr. 112.

[26] The Respondent asked the TFO to ''let [him] know when [he has] insurance so [the Respondent] can set [him] up for that x-ray.'' Gov't Ex. 13, at 5.

[27] Dr. Dombrowski's *curriculum vitae* (hereinafter, CV) was received into evidence without objection. Gov't Ex. 15; Tr. 170.

Medicine, the American Board of Addiction Medicine, the American Board of Anesthesiology, the National Board of Medical Examiners, and the American Board of Preventive Medicine. Tr. 348; Gov't Ex. 15. Additionally, he maintains a clinical practice and is a DEA registrant. Tr. 172–73. His practice includes the regular prescribing of controlled substances, including but not limited to opioids and benzodiazepines. *Id.* at 173. In the past, he has provided expert testimony regarding the medical practice of other physicians.[28] *Id.* He has previously opined professionally on the use of opioid medications to treat chronic pain. *Id.* at 174. In forming his expert opinion, Dr. Dombrowski reviewed the relevant Virginia laws relating to the standard of care for prescribing opioids for chronic pain. *Id.* at 175. In the absence of an objection, Dr. Dombrowski was tendered and accepted as an expert in the applicable standards of care for prescribing controlled substances within the usual course of professional practice in Virginia. *Id.* at 176–77.

Dr. Dombrowski testified that in order to be compliant with the standard of care in Virginia, a physician must establish a medical relationship with a patient by taking a thorough history, performing a physical exam, and acquiring any necessary lab work before prescribing a controlled substance.[29] *Id.* at 179, 211–12. Dr. Dombrowski described finding a diagnosis as the ''hallmark'' for proper controlled substance prescribing in Virginia. *Id.* at 185. According to the witness, discerning a correct diagnosis, or in other words, divining the etiology for the pain symptom, ''is everything because once I determine what the problem is, then I can come up with a host of modalities to treat that one problem.'' *Id.* at 199. ''Pain,'' Dr. Dombrowski explained, ''is just a symptom, it's not the reason.'' *Id.* at 200.

In regard to establishing a valid diagnosis, he testified that a medical history and physical constitute about eighty percent of a proper diagnosis. *Id.* at 179. It is Dr. Dombrowski's view that the objective aspects of the physical examination ''bolster'' the subjective observations of the patient. *Id.* at 182. The physical examination, as described by Dr. Dombrowski, generally includes some level of bodily manipulation to attempt to explore and replicate the pain symptoms, followed by testing to investigate potential issues, such as neurologic compromise.[30] *Id.* at 182–83. The witness described some of the fairly extensive standard steps required in a proper physical examination, to include spine palpation, having the patient stand up and touch their toes, twisting movements of various parts of the body, conducting a heel-toe walk, a sensory evaluation, and conducting a straight-leg raise exercise. *Id.* at 195–97. The witness also discussed the vital role of testing, such as obtaining an MRI, CT scan, or other imaging ''to back up your diagnosis.'' [31] *Id.* at 211–12. In response to a query by the Respondent's counsel at the hearing about a patient presenting with a generalized complaint of back pain, Dr. Dombrowski supplied the following explanation of some of the precursor steps required in Virginia to meet the minimum controlled substance prescribing standard:

> So basically what you first want to do is take a thorough history, before you even get to the exam. Talking about where's the pain; how has the pain affected you; how has it affected your quality of life, your activities of daily living; the quality of the pain in terms of burning, stabbing, aching, et cetera? Where is the pain located, where does the pain go? Does it run down a leg, does it remain in your back? Et cetera. And then along with that—before you even get into the physical, which I'll get to, you also want to understand . . . how long have you had it for? Is this acute? Is this chronic? [ ] [W]hat have you tried in the past? Were there x-rays in the past? Things like that to give me, as a new physician, some understanding of then how to move forward. Once I understand the patient's thorough history and getting all that information, before we even do the exam, then we go do the exam. The exam for back pain just would be obviously having the patient stand. Ask them . . . [to] point to where it hurts. And they would then direct me where it hurts. I would place my hand or hands there, palpate, feel, in terms . . . of if the muscles are tight or are they soft? If I push hard, does it reproduce the pain? And then along with that, we start then having the patient move, to see if movement would cause pain, such as forward flexion, back extension, or rotation to the sides. To see if it, again, exacerbates the pain that they have or mitigates—makes it better. And that gives me an understanding on what particular diagnosis it is. And then moving forward outside of the back exam . . . you . . . do a neurologic exam. Again, assessing for any pain to the extremities. And with that pain, is there associated weakness? Having them stand on their feet, heels, feeling their thighs . . . . That's just a cursory exam. There's other things that we can talk about, but that's a basic exam. I hope that explained it.

Id. at 325–27.

Dr. Dombrowski highlighted the importance of acquiring prior medical records and probing issues such as past substance abuse in compiling an adequate medical history. *Id.* at 183–84. He explained that prior substance abuse does not necessarily stand as a barrier to pain treatment, but it could oblige the physician to employ more caution, potentially requiring such measures as urine drug screens (hereinafter, UDS) and/or pill counts. *Id.* at 184, 202.

A mental status evaluation, according to the witness, may also be required to gauge the patient's true need for pain medication, as well as a discussion regarding the risks, benefits, and dangers associated with prescribed drugs. *Id.* at 184–87. Dr. Dombrowski also testified that informed consent and the utilization of an opioid contract is a required controlled substance prescribing standard in Virginia. *Id.* at 187–88. Documentation of the steps taken, according to Dr. Dombrowski, is also an element in meeting the controlled substance prescribing standard in Virginia. *Id.* at 189–91.

Dr. Dombrowski testified that after reviewing the transcripts of visits and medical records prepared in connection with the Respondent's care of the TFO, in his expert opinion, the Respondent's controlled substance prescribing fell below the applicable standard in Virginia. *Id.* at 205, 214, 218, 220, 231, 255, 258–59, 261, 282–87, 337, 439. The witness determined that a proper physical exam was never conducted, and that to the extent the progress notes indicated such an exam was conducted, those notes, when compared to the UC videotapes and transcripts, are patently false. *Id.* at 207–211, 228–30. No proper physical [32] or mental health diagnoses were ever made or supported by the charts. *Id.* at 230, 232–36, 254, 283. Lacking also across board in the visits is a substance abuse history, a

[28] Dr. Dombrowski estimates that his work as an expert witness is roughly comprised of sixty percent defense work and forty percent plaintiff work. Tr. 173–74.

[29] Dr. Dombrowski described the taking of a thorough history and conducting a thorough physical as the ''mainstay'' of the prescribing standard. Tr. 211.

[30] The witness acknowledged that there could be a difference between the comprehensive level of examination conducted during a first visit to a physician and subsequent visits where the examination may become more focused. Tr. 192–93, 227.

[31] In a confusing and peculiar twist, at another point in his testimony, Dr. Dombrowski also testified that in his opinion, today's doctors ''get way too many tests [and] don't spend enough time talking to patients.'' Tr. 329.

[32] Dr. Dombrowski also observed that the TFO's pain symptoms as self-reported in the Pain Questionnaire (Gov't Ex. 1, at 12) appear to be so minimal that they call into question the Respondent's decision to prescribe controlled substances to address them. Tr. 261–65. The Government's expert made the same observations and conclusions regarding the TFO's purported mental health issues as self-reported in the Anxiety Questionnaire (Gov't Ex. 1, at 13), which were likewise so mild as to call into question the decision to prescribe controlled medications to treat them. Tr. 270–73.

psychosocial history, a mental status evaluation, UDS testing, a documented risk/benefits discussion, an exit strategy discussion, a medication disposal discussion, or anything approaching a proper, documented diagnosis. *Id.* at 212–218, 221–24, 227–28, 237–38, 244–48, 252–60, 277–82, 337, 443. Regarding UC Visit #2, Dr. Dombrowski specifically observed that the TFO returned to the office well beyond a time where the prescribed medication would, if taken as directed, have run out, and despite this lapse, no follow-up was pursued by the Respondent. *Id.* at 223–25. The standard of care, according to Dr. Dombrowski, would require the prescriber to seek clarification from the patient as to what effect the lapse had on symptom control, or as the witness put it, ''I mean, do you even need my medication?'' *Id.* at 224. UC Visit #3 had the same gapped medication issue, with the same lack of follow-up on the Respondent's part. *Id.* at 248–50. The witness testified that in some cases the Respondent's prescribing fell below the standard of care by his absence of preliminary ground work, other times by the relative paucity of (even subjective) symptoms, and other times by his lack of follow-up questions in the face of indicia that should have called the *bona fides* of the patient's intentions and genuine need for medication into issue. *Id.* at 268–69, 272–73, 277, 337–38. The Respondent also fell short of the Virginia prescribing standard of care when he increased the TFO's tramadol dosage with no documented explanation and no conceivable basis being provided by the chart entries or interactions as video-recorded at the time of UC Visit #3. *Id.* at 255–56.

Dr. Dombrowski also discussed his observations regarding a PMP report generated to reflect the Respondent's queries concerning the TFO. *Id.* at 225. Specifically, the fact that the Respondent (or his staff) actually queried the PMP and were, thus, aware that the TFO was not filling any of the prescriptions he issued needed, at a minimum, to be explored and resolved with the patient, and his failure to do so fell below the applicable prescribing standard in Virginia. *Id.* at 226, 250–51, 273–74, 276–77. Failure by the Respondent to follow up on the patient's request for specific medications by name also fell below the applicable standard. *Id.* at 235–36, 251.

Also below the applicable standard, according to Dr. Dombrowski, was a failure to comply with follow-up requirements attendant upon the black box warning issued by the FDA regarding the simultaneous prescribing of opiates and benzodiazepines.[33] *Id.* at 239–44. The Respondent prescribed this dangerous combination of medicines without engaging in any precautionary and follow-up steps, such as establishing and documenting extenuating circumstances. *Id.* at 239–44, 283.

Dr. Dombrowski testified that, in his expert opinion, none of the controlled substance prescriptions detailed in the Government's case were issued for a legitimate medical purpose in the normal course of a professional practice. *Id.* at 286.

The Government's expert witness presented as a qualified, measured, knowledgeable expert, with no indications of any agenda beyond a dispassionate evaluation of the facts applied to the applicable standard. His testimony was persuasive, and in this case, his opinions are entitled to controlling weight.

The Respondent's Case

The Respondent's case consisted exclusively of his own testimony.[34] He testified that he currently maintains a private internal medicine practice that treats physical and mental health issues in what he characterizes as ''an underprivileged and lower socioeconomic population of the Richmond area, and particularly the inner city [of] Richmond.'' Tr. 353–54. The Respondent reckons that he is treating twenty to thirty percent of his private practice patients with opioids. *Id.* at 353–56.

In addition to the Respondent's private practice, he testified that he also works at two rehabilitation hospitals run by Encompass,[35] which he describes as ''a national corporation that is running inpatient rehabilitation hospitals as well as outpatient home health agencies.'' *Id.* at 365. The Respondent explained that in his hospital practice he manages the post-acute care of patients discharged from acute care facilities. *Id.* The Respondent related that the hospital aspect of his practice involves pain management to the extent he fills in for staff physiatrists when they are unavailable.[36] *Id.* at 369. According to the Respondent, between his private practice and hospital responsibilities, he is currently at work seven days a week. *Id.* at 368.

The Respondent remembered the TFO and remembered his interactions with him as patient Scott Davis. *Id.* at 376, 378–79. In that regard, the Respondent testified that he was unable to specifically recall whether he conducted a straight-leg raise on the patient, but was of the opinion that he would have, because it is his custom to do so. *Id.* at 381. The Respondent related that he observed the patient walk approximately thirty to forty feet inside the office on his way out, and specifically recalled directing him to office staff to guide him on procuring an x-ray. *Id.* at 381–82. He testified that he assessed the amount of Percocet the TFO disclosed as previously prescribed as a ''large dosage.'' *Id.* at 378. The Respondent described himself as being ''cognizant of [his patients'] financial struggles'' and attributed his decision to prescribe pain medication without reviewing imaging as justified by his desire ''to help a construction worker get through the day without having to lose his job.'' *Id.* at 383; *see also id.* at 426–27. He also noted, that in his opinion, the risks associated with the tramadol he prescribed to the TFO are curtailed by the drug's ''very low addictive potential.'' *Id.* at 383. It was this same low-addictive-risk estimation that also persuaded the Respondent to discount the TFO's admission that he had procured drugs illegally through his friend and girlfriend. *Id.* at 384. When prompted by his counsel, the Respondent expressed recognition that this was an errant course of action, because ''I have to be very strict with the DEA rules,'' and if asked to do so again, the Respondent represented that he ''will wholeheartedly counsel them for a long time.'' *Id.*

The Respondent acknowledged that, after listening to the testimony of the Government's expert, his medical examination of the TFO was not as thorough as it should have been, and that under the circumstances, his prescribing of Ativan, and combining medications as he did, was a mistake. *Id.* at 384–85, 387. The Respondent represented that he ''take[s] responsibility.'' *Id.* at 385. During his testimony, he provided assurances that he has (after practicing medicine for approximately seventeen years) recently taken continuing medical education courses[37] so that he now understands the basic elements for a rudimentary physical examination. *Id.* at 384–85.

The Respondent's limited confessions of error notwithstanding, the issue of

[33] Gov't Ex. 16.

[34] The Respondent's CV was received into the record without objection. Resp't Ex. 1; Tr. 352.

[35] The Respondent testified that he has worked at Encompass hospitals for about three years. Tr. 371.

[36] The Respondent offered that a post-surgery hip fracture patient is a common example of where he would regularly provide pain management and prescribe pain medications, such as tramadol, oxycodone, or hydrocodone. Tr. 369.

[37] Resp't Exs. 2–5.

whether he comprehends and accepts that he was wrong presents as entirely unclear on this record. He took issue with the TFO's recollection that he palpated his back for one-to-two seconds,[38] and maintained that it was really a six-to-seven second evolution. *Id.* at 386. The Respondent also quibbled with the time spent with the patient during UC Visit #3, pushing back on the testimony that it was only two minutes, suggesting that it may have been three. *Id.* at 388–89. The Respondent explained that he prescribed Ativan because he recalled a reference to anxiety on the TFO's intake form.[39] *Id.* at 387. More fundamentally, when asked if he issued the prescriptions to the TFO for a legitimate medical purpose, all ambiguity fled him, and he responded with an unequivocal ''I surely did. There was nothing illegitimate about it.'' *Id.* at 427. Additionally, even though the evidence reflected that the exams memorialized in his progress notes never occurred during any of the UC Visits, the Respondent would only offer, ''I'm not sure, I may not have [conducted those exams],'' and, ''I may have, I may not have. I was on autopilot and . . . there may be errors in the documentation.'' *Id.* at 430, 432, 433. The Respondent would not concede that notes reflecting examinations clearly shown as fictional by the UC Visit recordings were in fact false, offering ''I am not sure if it is or not'' and ''I cannot be conclusive about it.'' *Id.* at 432–34. The strongest admission on this issue that he could muster during his testimony was the possibility of an ''error in documentation.'' *Id.* at 433. Indeed, the Respondent insisted that each charged prescription was issued for a legitimate medical purpose because ''I do not issue prescriptions for illegitimate medical purposes,'' and clarified that he has ''no doubts about it.'' *Id.* at 427–28. Likewise, the Respondent was equally committed to the proposition that every one of the charged prescriptions was issued in the usual course of professional practice, asserting that he was ''[a]bsolutely acting in the course of [his] medical practice.'' *Id.* at 429.

In addressing the boost in tramadol that occurred unsolicited at the conclusion of UC Visit #3, the Respondent explained the increase by saying that he ''became a bit more comfortable with the patient,'' because he was not seeking early refills and he ''felt that [the TFO] was not diverting any—there was no signs of diversion—no signs of doctor shopping.'' *Id.* at 391–92; *see also id.* at 393–94. The Respondent's basis for concluding that the patient was not doctor shopping was based on his review of PMP data. *Id.* at 392. Interestingly, a review of PMP data would have also informed the Respondent that the prescriptions he issued to the TFO were never actually dispensed, but the Respondent testified that doctor shopping was essentially his exclusive focus in reviewing PMP data.[40] The Respondent ascribed his discounting of the information about the no-fills based on his view that pharmacies, particularly ''outlying pharmacies,'' [41] frequently do not enter dispensing data into the PMP. *Id.* at 393. He testified that he declined to follow up on this potential anomaly because ''[i]t's very time-consuming.'' *Id.* at 395. Thus, the Respondent by his own admission ascribed confidence in the PMP insofar as it reflected no other prescribers, but none to the extent that the prescribed medications were not being filled. *Id.* at 393–95.

On the issue of remedial steps, the Respondent testified that he has completed numerous continuing medical education courses (hereinafter, CME) aimed at improving his controlled substance prescribing practices, and that some of the courses provided him with valuable information. Resp't Exs. 2–5; Tr. 384–85, 398–415. The Respondent testified that the CME he completed was done online with a quiz administered at the conclusion. Tr. 414–21. The Respondent also offered the corrective action plan (hereinafter, CAP) that he had apparently filed with the Agency in accordance with 21 U.S.C. 824(c)(3). Resp't Ex. 8; Tr. 421–22. The CAP modestly proposes that the Respondent will take two specified CMEs (and such other additional CMEs which may be designated by DEA). Resp't Ex. 8. The CAP further proposes that the Respondent is willing to undergo a period of ''partial suspension'' of his COR pending completion of these CMEs that will restrict him to prescribing under Schedules IV and V. *Id.*

The Respondent testified that these proceedings have emotionally affected him in a way that is more grave than the COVID–19 epidemic. Tr. 424. His sleeping has been affected and he describes himself as being ''anxious all the time.'' *Id.* The Respondent offered assurances that he ''will not prescribe until [he] ha[s] the data,'' and that although ''[i]n the past, in [his] practice, [he] used to cut people breaks. [He] will not do that anymore, [he]'ll be 100 percent by the book and by the rules.'' *Id.* at 424–25. The Respondent then proposed the novel argument that he had no intention of ever even using his COR to prescribe controlled substances (*i.e.,* to conduct the regulated activity that is authorized by a DEA registration), but that he merely wanted to maintain his registered status to assist him in securing employment. *Id.* at 425–26.

It is beyond argument that the Respondent is the witness with the most at stake in these proceedings, and thus, is the witness with the greatest pressures to influence his perspective and testimony. However, even apart from these considerations, there was much in the Respondent's presentation that devalued his credibility and the force that can be attached to his testimony. When faced with examinations that he noted in his progress notes, which he plainly saw did not take place in the UC Visit videos, the Respondent was unwilling to admit what his eyes could scarcely deny: He did not perform the examinations he documented. *Id.* at 432–33. Even after agreeing with much of Dr. Dombrowski's testimony, the Respondent relentlessly adhered to his position that his prescriptions were issued for a legitimate medical purpose and in the usual course of a professional medical practice. *Id.* at 427–29. His unambiguous commitments to prescribe within the applicable standard of care in the future were matched with his equally unambiguous commitment to never prescribe again so long as the Agency maintains him in status so that he can secure medical employment. *Id.* at 424–26. The only thing that appeared sure about the Respondent's testimony was an apparent commitment to saying anything under oath that might induce the Agency to continue him in status. That is not to say that the Respondent's testimony was completely bereft of any reliability. Indeed, there were biographical and other elements of his testimony that can be credited, but

[38] Tr. 81–82, 90–91, 133.

[39] Gov't Ex. 1, at 7.

[40] The Respondent also sought support in reports he obtained from the PMP administrators regarding the relative percentage of his controlled substance prescribing compared to his peers. Resp't Ex. 7; Tr. 362–64. However, the value of this evidence was mortally undermined by the designation on the printout that the Respondent was being compared to geriatric medicine practitioners. Resp't Ex. 7; Tr. 434–35. The Respondent theorized that his PMP designation may have been a residual effect from a time when he did a lot of work in nursing homes. Tr. 436. Dr. Dombrowski persuasively testified that because physicians treating geriatric patients tend to prescribe higher amounts of pain medication due to the chronic problems associated with age, the comparison of geriatric practice with the Respondent's practice is not a relevant one. Tr. 440–41. Accordingly, this evidence is of negligible value in these proceedings.

[41] There was no indication in the record that the TFO would have been utilizing an ''outlying pharmacy,'' or what geographic location constituted a pharmacy to be ''outlying.''

where (as happened not infrequently here) his testimony stands in conflict with other reliable evidence of record, it must be viewed with great caution and skepticism.

Other facts required for a disposition of the present case are set forth in the balance of this decision.

The Analysis

Public Interest Determination: The Standard

Under 21 U.S.C. 824(a)(4), the Agency may revoke the DEA registration of a registrant if the registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Congress has circumscribed the definition of public interest in this context by directing consideration of the following factors:

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

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

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, 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 to be considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's DEA registration should be revoked. *Id.; see Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; 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 . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In adjudicating a revocation of a DEA registration, the DEA has the burden of proving that the requirements for the revocation it seeks are satisfied. 21 CFR 1301.44(e). Where the Government has met this burden by making a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Further, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *accord Krishna-Iyer,* 74 FR at 464 n.8. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38,363, 38,364, 38,385 (2013).

Normal hardships to the registrant, and even to the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. *See Linda Sue Cheek, M.D.,* 76 FR 66,972, 66,972–73 (2011); *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,757 (2009). Further, the Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66,138, 66,140, 66,145, 66,148 (2010); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009); *Krishna-Iyer,* 74 FR at 463; *Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078 (2009); *Med. Shoppe-Jonesborough,* 73 FR at 387.

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–03 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481–82. While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys* v. *DEA,* 96 F.3d 658, 663 (3d Cir. 1996). The ultimate disposition of the case ''must be 'in accordance with' the weight of the evidence, not simply supported by enough evidence 'to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.' '' *Steadman,* 450 U.S. at 99 (quoting *Consolo* v. *FMC,* 303 U.S. 607, 620 (1966)).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past Agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008), *cert. denied,* 555 U.S. 1139 (2009); *cf. Dep't of Homeland Security* v. *Regents of Univ. of Cal.,* No. 18–587, 592 U.S. __, slip op. at 22–23 (June 18, 2020) (holding that an agency must carefully justify significant departures from prior policy where reliance interests are implicated). It is well settled that, because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *see Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Agency's final decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the

exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

Factors Two and Four: The Respondent's Experience Dispensing Controlled Substances and Compliance With Federal, State, and Local Law

The Government has founded its theory for sanction exclusively on Public Interest Factors Two and Four,[42] and it is under those two factors that the lion's share of the evidence of record relates.[43] In this case, the gravamen of the allegations in the OSC, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of his practice relative to prescribing controlled substances and acts allegedly committed in connection with that practice. Thus, it is analytically logical to consider Public Interest Factors Two and Four together. That being said, Factors Two and Four involve analysis of both common and distinct considerations.

The DEA regulations provide that to be effective, a prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). The Supreme Court has opined that, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006). Further, the Agency's authority to revoke a registration is not limited to instances where a practitioner has intentionally diverted controlled substances. *Bienvenido Tan,* 76 FR 17,673, 17,689 (2011); *see MacKay,* 75 FR at 49,974 n.35 (holding that revocation is not precluded merely because the conduct was ''unintentional, innocent, or devoid of improper motive'').

To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Controlled Substances Act (CSA)].'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' 21 CFR 1306.04(a).

The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17,541 (citing *Gonzales,* 546 U.S. at 274); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion). The prescription requirement likewise stands as a proscription against doctors ''peddling to patients who crave the drugs for those prohibited uses.'' *Aycock,* 74 FR at 17,541 (citing *Gonzales,* 546 U.S. at 274). A registered practitioner is authorized to dispense, which the CSA defines as ''to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.'' 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), cert. denied, 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the ''regulat[ion of] medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,'' *Gonzales,* 546 U.S. at 909–10, an evaluation of cognizant state standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,090 (2009); *Kamir Garces-Mejias,* M.D., 72 FR 54,931, 54,935 (2007); *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from engaging in unlawful prescribing. *Aycock,* 74 FR at 17,541. The analysis must be ''tethered securely'' to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain. *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner establish and maintain a *bona fide* doctor-patient relationship in order to act ''in the usual course of . . . professional practice and to issue a prescription for a legitimate medical purpose.'' *Mackay,* 75 FR at 49,973 (internal quotations omitted); *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA generally looks to state law to determine whether a *bona fide* doctor-patient relationship was established and maintained. *Stodola,* 74 FR at 20,731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54,935; *United Prescription Servs.,* 72 FR at 50407.

Here, the relevant provisions of state law largely mirror the CSA and its regulations where they do not go

[42] ALJ Ex. 19, at 29.

[43] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor One), but, aside from cases establishing a complete lack of state authority, the presence or absence of such a recommendation has not historically been a case-dispositive issue under the Agency's precedent. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,730 (2009); *Krishna-Iyer,* 74 FR at 461. Similarly, there is no record evidence of a conviction record relating to regulated activity (Factor Three). Even apart from the fact that the plain language of this factor does not appear to emphasize the absence of such a conviction record, myriad considerations are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities which lessen the logical impact of the absence of such a record. *See Robert L. Dougherty, M.D.,* 76 FR 16,823, 16,833 n.13 (2011); *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.''), *aff'd, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009). Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. Because the Government's allegations and evidence fit squarely within the parameters of Factors Two and Four and do not raise ''other conduct which may threaten the public health and safety,'' *see* 21 U.S.C. 823(f)(5), Factor Five militates neither for nor against the sanction sought by the Government in this case.

beyond it. *Compare* Va. Code Ann. § 54.1–3303(C) *with* 21 CFR 1304.06(a). Section 54.1–3303(A), like its CSA counterpart,[44] limits controlled substance prescribing to licensed practitioners. The Virginia Code also requires that a *bona fide* patient-practitioner relationship precede the issuing of all prescriptions (controlled and non-controlled)[45] in the state. Va. Code Ann. § 54.1–3303(B). The elements of a *bona fide* patient-practitioner relationship are spelled out in the code, and require that prior to prescribing, the practitioner must have:

(i) Obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner.

Id.

The Virginia Administrative Code provides further direction for practitioners prescribing opioids for chronic pain. 18 Va. Admin. Code § 85–21–60. Under this provision:

Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including: (1) The nature and intensity of the pain; (2) current and past treatments for pain; (3) underlying or coexisting diseases or conditions; (4) the effect of the pain on physical and psychological function, quality of life, and activities of daily living; (5) psychiatric, addiction, and substance misuse history of the patient and any family history of addiction or substance misuse; (6) a urine drug screen or serum medication level; (7) a query of the [PMP]; (8) an assessment of the patient's history and risk of substance misuse; and (9) a request for prior applicable records.

Va. Admin. Code § 85–21–60(A). Furthermore, prior to opioid drug treatment initiation, the prescribing doctor is required to counsel the patient on known risks and benefits of opioid therapy, patient responsibilities regarding storing and disposal, and a treatment exit strategy. *Id.*

The applicable Virginia Code provisions are completely consistent with the standards as outlined by the Government's expert, Dr. Dombrowski. Tr. 179, 183–88, 199, 211–12. Beyond the specified elements of the requisite relationship, history, examination, counseling, and follow-up care, Dr. Dombrowski explained that informed consent, exit strategy counseling, and adequate documentation also comprise vital parts of the prescribing standards in Virginia. Tr. 184–91. Beyond the Respondent's unsupported protestations that all of his controlled substance prescribing has been legal,[46] the testimony of the Government's expert stands uncontroverted on the present record. When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). There is no shortage of reliable expert knowledge in the present record, it is uncontroverted, and it is not favorable to the Respondent.

In reviewing the evidence of record (including the stipulations of the parties), and applying the consistent and unchallenged controlled substance prescribing standards applicable in Virginia, the evidence preponderantly establishes the Respondent's registration and practitioner status, as well as the Government's allegations that he prescribed controlled substances to the TFO during the course of four undercover visits. Accordingly, OSC allegations 3, 6, 7, 8, 9, 11, 12, 15, 16, 19, and 20 are SUSTAINED.

The OSC in this case also alleges that the Respondent engaged in unprofessional conduct as that term is defined in the Virginia Code.[47] ALJ Ex. 1, at ¶¶ 10, 14, 18, 22. [Specifically, the OSC alleges violations of four subsections of Va. Code Ann. § 54.1–2915. ALJ Ex. 1 at ¶ 5.c (stating that ''Va. Code Ann. § 54.1–2915(A) defin[es] unprofessional conduct as including, among other things: [3] '[i]ntentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients;' [12] '[c]onducting his practice in a manner contrary to the standards of ethics of his branch of the healing arts;' [*I] [13] '[c]onducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public;' and [17] '[v]iolating any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing, or administration of drugs''); *id.* at ¶¶ 6 (stating that Respondent issued four prescriptions in violation of ''federal and Virginia law noted in paragraphs 4–5, above'').[*J] I find that Respondent violated subsections three and thirteen, based on Dr. Dombrowski's testimony confirming that Respondent engaged in conduct that was likely to injure Patient SD, as well as Dr. Dombrowski's testimony that Respondent committed numerous treatment failures that led to the prescribing of controlled substances outside of the applicable standard of

[44] 21 U.S.C. 802(21), 823(f).

[45] Regarding the prescribing of controlled substances, the Virginia Code specifically requires compliance with federal telemedicine provisions which do not impact the current proceedings. Va. Code Ann. § 54.1–3303(B).

[46] Tr. 427–29.

[47] [Footnote omitted.]

[*I] Although Dr. Dombrowski testified that Respondent did not comply with ethical standards, *see* Tr. 287, the Government did not notify Respondent of this testimony in the OSC or in its prehearing statements. Therefore, I do not consider the Government's allegations with respect to subsection twelve in my public interest analysis.

[*J] I find that the OSC provided adequate notice of the Virginia Code subsections that the Government charged Respondent with having violated. Although the Chief ALJ did not sustain these allegations based in part, because there were ''multiple potential factual scenarios [ ] available under a single statutory scheme,'' and the Government did not sufficiently specify the application of the facts to the alleged violations, *see* RD, at 30, upon further review, I find that the Government quoted from four subsections of Va. Code Ann. § 54.1–2915(A) in paragraph five, and then identified the prescriptions in paragraph six that violated the state laws enumerated in paragraph five. *See* OSC, at ¶¶ 5.c, 6. The Government afforded Respondent the opportunity to prepare a defense by identifying each subsection of the Virginia Code at issue, and by providing a factual basis for its allegations that Respondent could have harmed or injured a patient. *See, e.g.,* OSC, at 5–7 (noting that Respondent prescribed opioids and benzodiazepines concurrently, and that the concurrent prescribing of these drugs ''poses a significant risk of addiction or other adverse consequences''); Gov't Prehearing, at 19, 22, 25 (same); *id.* at 14 (stating that Dr. Dombrowski was expected to testify that ''Respondent's actions put Patient S.D. at risk for harm, including addiction or other adverse medical outcomes;'') *see also Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996) (''[T]he parameters of the hearing are determined by the prehearing statements.''). Although I agree that the charging documents would have benefited from further explanation, I find that the prehearing statement and the OSC together provided adequate notice in order for the Respondent to ''be timely informed of . . . the matters of fact and law asserted.'' 5 U.S.C. 554(b)(3); *see also* 21 CFR 1301.37(c) (requiring that the OSC ''contain a statement of the legal basis for [a] hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted''). Previous Agency Decisions have stated that ''[t]he primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.'' *Wesley Pope, M.D.,* 82 FR 14,944, 14,947 (2017) (internal citation omitted). Because I have found that these allegations were adequately noticed, I have added this section addressing these allegations.

care in Virginia and not for a legitimate medical purpose. Tr. 286; *see also, e.g., id.* at 207–11.*K Additionally, I find that Respondent violated subsection seventeen based on my finding above that Respondent violated state and federal law. Therefore, OSC allegations 10, 14, 18, and 22 are SUSTAINED.][48] [49]

In the OSC, the Government also charged the Respondent with an additional violation of state law in asserting that the Respondent was in violation of the Virginia Code for failing to prescribe naloxone [50] (the Virginia Naloxone Regulation). ALJ Ex. 1 at ¶¶ 13, 17, 21. This is a novel charge for this tribunal.[51] The Virginia Naloxone Regulation, in pertinent part, states that when initiating opioid treatment, a practitioner shall ''[p]rescribe naloxone for any patient when risk factors of overdose, substance abuse, doses in excess of 120 [morphine milligram equivalent] per day, or concomitant benzodiazepine[s] are present.'' 18 Va. Admin. Code § 85–21–70(B)(3).*L

An analysis of the relative merits of this novel allegation are best considered within the framework of Public Interest Factor Four (compliance with applicable state laws relating to controlled substances). 21 U.S.C. 823(f)(4). The actions of a regulatory agency must bear a rational relationship to the purposes of the statute it is charged with enforcing. *See Judulang* v. *Holder,* 556 U.S. 42, 63 (2011) (invalidating Board of Immigration Appeals decision making practice where the ''rule [was] unmoored from the purposes and concerns of the immigration laws''). [Consequently, when the Agency has analyzed whether state law violations are relevant to its Factor Four analysis, it has considered whether those state laws have a rational relationship to the core purposes of the CSA in preventing drug abuse and diversion.]*M *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,900 (2018) [(stating that the state law provisions at issue ''go to the heart of the controlled substance anti-diversion mission—drug abuse prevention and control'')].*N *O

[As explained above, my consideration of a violation of a state law under Factor Four must bear a rational relationship to a core purpose of the CSA, as does my consideration of all the public interest factors. *See Judulang* v. *Holder,* 556 U.S. at 63. Additionally, the language of Factor Four requires that the state law be ''relat[ed] to controlled substances.'' These two concepts are easily conflated, but they are importantly distinct. In this case, I find that Respondent's violation of the Virginia Naloxone Regulation [52] bears a rational relationship to a core purpose of the CSA such that it is appropriate for me to consider it under Factor Four, and also that the state regulation is ''relat[ed] to controlled substances'' as the statute requires. 21 U.S.C. 823(a)(4). Respondent's failure to prescribe naloxone put Patient SD at risk for overdose or death resulting from concurrent opioid and benzodiazepine prescriptions.*P Thus, Respondent's violation of this regulation bears a rational relationship to the core purposes of the CSA of preventing the abuse of controlled substances and the adverse health consequences that might result from such abuse.

I have omitted the RD's discussion of the purpose of the Virginia Naloxone Regulation and its legislative history,

*K The RD states that ''DEA is without authority to hold that a registrant has committed unprofessional conduct regarding the practice of medicine, a clear function of the state's police powers.'' RD, at 30 (citing *Gonzales,* 546 U.S. at 274). While I agree with the Chief ALJ that findings on these matters often require expertise in assessing unprofessional conduct that the Agency lacks, the state law violations in this case were supported by the unrebutted testimony of a Virginia medical expert, Dr. Dombrowski. Dr. Dombrowski testified that Respondent prescribed a dangerous combination of controlled substances without ''engaging in any precautionary and follow-up steps,'' Tr. 239–44, 283, and he confirmed that Respondent's conduct was likely to cause injury to Patient SD. *Id.* at 286. Therefore, I find that Dr. Dombrowski's testimony provides a basis for sustaining these state law violations.

Although I am considering these additional allegations of violations of state law, they ultimately do not add substantially to my analysis under Factors Two and Four. I agree with the Chief ALJ that these violations further support my conclusion that Respondent's prescribing fell below the applicable standard of care in Virginia. *See* RD, at 31 n.49 (''[C]onduct which falls within a state's definition of unprofessional conduct (or is otherwise improper under state law), which supports the proposition that a practitioner's prescribing fell below the applicable standard of care (as is the case here), will generally be supportive of a finding that a registrant's controlled substance prescribing was in violation of the CSA.'').

[48] [Footnote omitted.]

[49] [Content of footnote discussed above, *see supra* n.*K.]

[50] [The RD took official notice, pursuant to 5 U.S.C. 556(e) and 21 CFR 1316.59(e), that naloxone was an opioid antagonist that is commonly used to counter the effects of an opioid overdose and/or adverse reaction. RD, at 31 n.50 (citing 81 FR 44,714 (2016)). The RD notified the parties that they may file objections to this official notice within fifteen calendar days from receipt of the RD. *Id.* Neither party filed objections, so I adopt the Chief ALJ's finding.]

[51] The Government's expert witness, Dr. Dombrowski, did not include the prescribing of naloxone within the elements required to satisfy the Virginia controlled substance prescribing standard of care.

*L Text deleted for consistency with my finding below that the violation of the Virginia Naloxone Regulation is sufficiently related to the CSA's core purposes to be considered under Factor Four.

*M Modified for clarification.

*N Citations omitted. I have also deleted text for consistency with my finding below that the violation of the Virginia Naloxone Regulation is sufficiently related to the CSA's core purposes to be considered under Factor Four.

*O We have previously identified the CSA's core purposes of preventing drug abuse and diversion by analyzing the statute's legislative history. *See, e.g., John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 n.K, M (2020); *Fred Samimi, M.D.,* 79 FR 18,698, 18,709–10 (2014). As further discussed herein, it is axiomatic that another core purpose of the CSA is to protect patients from the drug-related deaths and injuries that may result from drug abuse and diversion. This core purpose is evident in the CSA's legislative history and underlies the entire statute.

In 1984, Congress expanded DEA's authority to deny practitioners' applications for DEA registrations by adding the public interest factors to Section 823. Controlled Substances Penalties Amendments Act of 1984, Public Law 98–473, 511, 98 Stat. 1837, 2073 (1984) (codified at 21 U.S.C. 823(f)(1)–(5)). Prior to the addition of these public interest factors, DEA's grounds to deny a practitioner's application were limited. DEA was required to grant an application unless the applicant was not ''authorized to dispense . . . [controlled substances] under the law of the State in which they practice[d].'' Controlled Substances Act, Public Law 91–513, 303, 84 Stat. 1236, 1255 (1970) (codified at 21 U.S.C. 823(f)). The Senate Report explained that because of DEA's ''very limited'' grounds for denial, the Controlled Substances Act had not been very effective at addressing diversion at the practitioner level, where eighty to ninety percent of diversion occurs. Senate Report, at 261–62, 1984 U.S.C.C.A.N., at 3443–44. Thus, the public interest factors were added to ''strengthen the Government's authority to regulate controlled substances.'' Senate Report, at 262, 1984 U.S.C.C.A.N., at 3444.

The Senate Report observed that ''[i]t is estimated that between 60 and 70 percent of all drug-related deaths and injuries involve drugs that were originally part of the legitimate drug production and distribution chain.'' Senate Report, at 260, 1984 U.S.C.C.A.N., at 3442. The CSA seeks to prevent these drug-related deaths and injuries by ''maintaining . . . [a] 'closed' system at the practitioner level. Senate Report, at 262, 1984 U.S.C.C.A.N., at 3444. The CSA's focus on patient safety is evident in the Senate Report's discussion of the procedures for scheduling drugs. The Senate Report observes that it is important to have swift procedures for scheduling new drugs, because of the ''significant health problem[s]'' that may result when an ''as yet uncontrolled drug rapidly enters the illicit market.'' *Id.* Indeed, drugs are designated as controlled substances precisely because of their potential to harm patients. *See, e.g.,* Senate Report, at 261, 1984 U.S.C.C.A.N., at 3443 (noting that drugs are placed into one of five schedules ''based on the severity of the abuse potential of a particular drug, the extent to which it leads to physical or psychological dependence, and has an accepted medical use . . .''). Thus, at its core, the CSA seeks to protect patients from the adverse health consequences that may result from dangerous and addictive drugs. Therefore, as found below, my consideration under Factor Four of a state law violation that significantly increases the risk of these adverse consequences is related to a core purpose of the CSA.

[52] 18 Va. Admin. Code § 85–21–70(B)(3).

*P Respondent issued concurrent prescriptions to Patient SD for opioids and benzodiazepines on August 28, 2019; September 27, 2019; and November 5, 2019, but he failed to prescribe naloxone, as required by state law. Tr. 93–94, 101, 116; Gov't Ex. 5, 8, 11; 18 Va. Admin. Code § 85–21–70(B)(3) (requiring naloxone to be prescribed when opioids and benzodiazepines are prescribed concurrently).

because I have concluded that the regulation, as applied to the facts of this case, supplies a sufficient nexus to controlled substances to be appropriately considered under Factor Four. In analyzing the legislative intent of the state law, the RD was likely addressing a particular Agency decision, which stated that in determining whether a state law is ''related to controlled substances'' under Factor Four, ''the mere fact that a violation of a state rule occurs in the context of the dispensing of controlled substances does not necessarily mean that the violation has a sufficient nexus to the CSA's core purpose of preventing the diversion and abuse of controlled substances.'' *Fred Samimi, M.D.,* 79 FR 18,698, 18,710 (2014) (citing 21 U.S.C. 823(f)(4). As explained above, I concur that a violation of state law must have a rational relationship to the core purposes of the CSA in order for me to consider it under Factor Four; however, that important concept should not be conflated with whether the state law is ''relat[ed] to controlled substances'' as required by the statute, which is what seemed to happen when the former Administrator in *Samimi* cited to the *intent of the state law itself* as the basis for finding that the law in that case was not sufficiently *related to controlled substances. Id.* (finding that the particular state law's ''provisions [were] not directed at preventing diversion''). Nothing in the CSA itself nor its legislative history requires such a limited view of ''laws relating to controlled substances,'' and although these sentences in *Samimi* could be read to imply that the Agency would be required to assess the state law's purpose, I can find no reason to analyze the legislative intent of every state law alleged for consideration under Factor Four. *See* 21 U.S.C. 823(f)(4).

In fact, the Agency has—both prior to and subsequent to the *Samimi* decision—frequently considered violations of state statutes that are applicable to all medications, not just controlled substances, under Factor Four without analyzing the legislative intent of these statutes. *See, e.g., Joseph Gaudio, M.D.,* 74 FR 10,083, 10,091 (2009) (considering under Factor Four the respondent's violation of a state law that stated that it is ''unprofessional conduct'' for a physician to ''provid[e] treatment . . . via electronic or other means unless the licensee has performed a history and physical examination of the patient . . .''); *Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,768 (considering under Factor Four the respondent's violation of state laws stating that it is ''unprofessional conduct'' for a physician to fail to ''maintain adequate medical records'' and to ''prescrib[e] . . . a prescription medication . . . to a person unless the [physician] first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship''). The core purpose of these statutes may not be directed at preventing the abuse and diversion of controlled substances; however, when the state addresses prescribing that presents a risk of diversion or substance abuse, these are the statutes that are charged. For example, the Arizona Medical Board frequently cites violations of the state laws requiring physicians to maintain adequate medical records and perform physical examinations in disciplinary actions against physicians who are prescribing controlled substances without taking appropriate steps to prevent diversion.[*Q]

Therefore, a broad interpretation of ''laws relating to controlled substances'' in Section 823(f)(4) is consistent with previous Agency Decisions. It is also consistent with the Supreme Court's interpretation of the phrase ''relating to'' in other contexts. According to the Supreme Court, the phrase ''in relation to'' is to be interpreted expansively, and means ''with reference to'' or ''as regards.'' *Smith* v. *United States,* 508 U.S. 223, 237 (1993).[*R]

Thus, prior Agency Decisions and Supreme Court precedent support my conclusion that the Virginia Naloxone Regulation is related to controlled substances under Factor Four and that Respondent's violation of the regulation is relevant to my Factor Four analysis under the CSA.] [53] [54] [55] [*S]

Recommendation

The evidence of record preponderantly establishes that the Respondent has committed acts which render his continued registration inconsistent with the public interest. *See* 21 CFR 1301.44(e) (establishing the burden of proof in DEA administrative proceedings). Because the Government has met its burden in demonstrating that the revocation it seeks is authorized, to avoid sanction the Respondent must show that given the totality of the facts and circumstances revocation is not warranted. *See Med. Shoppe-Jonesborough,* 73 FR at 387. In order to rebut the Government's *prima facie* case, the Respondent must demonstrate

[*Q] *See Hippenmeyer,* 86 FR at 33,768 n.62 (citing, *e.g., In the Matter of Brian R. Briggs, M.D.,* No. MD–15–0164A, 2017 WL 554258 (Feb. 2, 2017) (issuing a Letter of Reprimand and placing respondent on probation for prescribing controlled substances to a live-in girlfriend—who was also receiving opioids from other providers—without maintaining medical records and without ''perform[ing] and document[ing] an appropriate physical and mental examination''); *In the Matter of Warren Moody, M.D.,* No. MD–07–0874A, 2007 WL 3375035 (Oct. 16, 2007) (summarily suspending physician's license for various forms of misconduct, including prescribing controlled substances to friends without maintaining medical records); *In the Matter of David Landau, M.D.,* No. MD–17–0777A, 2018 WL 2192279 (Apr. 16, 2018) (issuing a Letter of Reprimand against a physician for various forms of misconduct, including prescribing controlled substances to a friend without maintaining adequate medical records).

[*R] The *Smith* decision involved an offer to trade an automatic weapon for cocaine. 508 U.S. at 225. The decision addressed the question of whether the exchange of a firearm for cocaine constitutes using a firearm ''during and in relation to . . . [a] drug trafficking crime'' within the meaning of 18 U.S.C. 924(c)(1). *Id.* The Supreme Court's analysis cited prior Supreme Court and appellate court decisions interpreting the phrase ''in relation to'' and concluding that the phrase should be interpreted expansively. *Id.* at 237; *see, e.g., District of Columbia* v. *Greater Washington Board of Trade,* 506 U.S. 125, 129 (1992) (''We have repeatedly stated that a law 'relate[s] to' a covered employee benefit plan . . . 'if it has a connection with or reference to such a plan.' . . . This reading is true to the ordinary meaning of 'relate to' . . . and thus gives effect to the 'deliberately expansive' language chosen by Congress.''); *United States* v. *Harris,* 959 F.2d 246, 261 (D.C. Cir. 1992) (per curiam) (''The only limitation is that the guns be used ''in relation'' to the drug trafficking crime involved, which we think requires no more than the guns facilitate the predicate offense in some way.''); *United States* v. *Phelps,* 877 F.2d 28 (9th Cir. 1989) (concluding that the situation was ''unusual'' and not covered, the court stated that ''the phrase 'in relation to' is broad'').

The Supreme Court also cited a dictionary definition in its analysis. 508 U.S. at 237–38. It stated that ''[a]ccording to Webster's, 'in relation to' means 'with reference to' or 'as regards.' '' *Id.* at 237. It concluded, thus, that the phrase ''in relation to,'' at a minimum, ''clarifies that the firearm must have some purpose or effect with respect to the drug trafficking crime; its presence or involvement cannot be the result of accident or coincidence.'' *Id.* at 238. The Court also stated that ''the gun at least must 'facilitate[e], or ha[ve] the potential of facilitating,' the drug trafficking offense.'' *Id.*

[53] [Footnote omitted.]

[54] [Footnote omitted.]

[55] [Footnote omitted.]

[*S] 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 Virginia and in violation of state law. I, therefore, have concluded that Respondent engaged in misconduct which supports the revocation of his 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). At the time the Government issued the OSC, the Government had clear evidence that Respondent repeatedly issued prescriptions without having a sound rationale or legitimate medical purpose for doing so, which 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.*

not only an unequivocal acceptance of responsibility but also a demonstrable plan of action to avoid similar conduct in the future. *See Hassman,* 75 FR at 8236. He has accomplished neither objective.

Agency precedent is clear that a respondent must unequivocally admit fault as opposed to a ''generalized acceptance of responsibility.'' *The Medicine Shoppe,* 79 FR 59,504, 59,510 (2014); *see also Lon F. Alexander, M.D.,* 82 FR 49704, 49,728 (2017). To satisfy this burden, a respondent must ''show true remorse'' or an ''acknowledgment of wrongdoing.'' *Alexander,* 82 FR at 49,728 (citing *Michael S. Moore,* 76 FR 45,867, 45,877 (2011); *Wesley G. Harline,* 65 FR 5665, 5671 (2000)). The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Dougherty,* 76 FR at 16,834 (citing *Krishna-Iyer,* 74 FR at 464). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Jones Total Health Care Pharmacy, LLC* v. *DEA,* 881 F.3d 823, 830–31 (11th Cir. 2018); *MacKay,* 664 F.3d at 822; *Hoxie,* 419 F.3d at 483.

As discussed, *supra,* on the issue of remedial steps aimed at the avoidance of reoccurrence, the Respondent, in addition to promises that he will be compliant in the future, has submitted into evidence the CAP [56] he previously filed with the Agency, as well as several certificates showing completion from some CME courses that the Respondent completed online. Resp't Exs. 2–8; Tr. 414–21. The Respondent's CAP contains a somewhat minimalist proposal that he will take two specified CMEs (and other additional CMEs designated by DEA). Resp't Ex. 8. The CAP further proposes that the Respondent is willing to undergo a period of ''partial suspension'' of his COR pending completion of these CMEs that will restrict him to prescribing under Schedules IV and V. *Id.* In addition to these rather modest plans for remedial action, the Respondent (to the apparent surprise of everyone at the hearing) tendered a remarkable, novel, and illogical proposal. He offered that if the Agency would only grant him a registration to handle controlled substances, he would covenant never to actually use it. Tr. 425–26. The Respondent explained that he seeks the reinstatement and continuation of his COR, not to conduct the regulated activity it authorizes, but rather, because he considers it a necessary prerequisite to securing or continuing employment as a physician. *Id.*

Suffice it to say that the Respondent's remedial action plans are unimpressive at best, and in the case of his attempt to secure a non-functional COR, illogical and cynical, but inasmuch as the evidence of record fails to demonstrate an unequivocal acceptance of responsibility, the issue of remedial steps could hardly be considered as case dispositive. The Agency has consistently held that for either prong (acceptance of responsibility and remedial steps) to be considered in sanction amelioration, both prongs must have been established. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019); *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care,* 81 FR 79,188, 79,202–03 (2016); *Hassman,* 75 FR at 8236. If one prong is absent, the other becomes irrelevant. Both or neither has been the rule for many years. The Respondent quibbled on the precise amount of seconds devoted to palpations,[57] and refused to accept that examinations, which were documented in the paperwork but clearly absent from the UC Visit videotapes, did not take place.[58] As discussed in considerable detail, *supra,* even after sitting through the Government's evidence, the Respondent maintains that all of the controlled substance prescriptions he ever issued (including those issued during the four UC Visits established in these proceedings) were legitimate and within the usual course of a professional practice. Tr. 427–29. The Respondent presented as a practitioner who genuinely believes he did nothing really that wrong. As he described it, he ''used to cut people 'breaks,''' but ''will not do that anymore . . . .'' Tr. 424–25. The Respondent's closing brief representation that ''he has fully accepted responsibility . . .'' [59] is simply not supported by the record. Without plumbing the depths of what constitutes an unequivocal acceptance of responsibility, it is clear that a terse ''[yes], I do'' response to an inquiry from his counsel about whether he made ''a mistake'' by what he characterized as prescribing a ''low[-]addictive potential'' and low-overdose potential drug to the undercover patient so the hapless patient could ''get through the day and get through [his] work,'' [60] misses the mark.

While the transgressions alleged and proved here are serious and numerous, it is arguable that a true, unequivocal acceptance of responsibility, coupled with a thoughtful plan of remedial action could have gone a long way to supporting a creditable case for sanction lenity. Indeed, while true that the Agency's precedents hold the lack of an unambiguous acceptance of responsibility and a remedial action plan as a cold bar to the avoidance of a sanction,[61] the wisdom of the Agency's policy is vindicated in this case by the reality that the Respondent still believes that he has never issued a controlled substance prescription that was not legitimate and not within the usual course of a professional practice. The only potential he sees for error appears to be his innate kindness, which caused him to ''cut breaks'' to his fellow man. He was confronted with progress notes written in his own hand detailing the results of examinations that he never administered, yet he would not concede his mendacity. As highlighted by the Government in its closing brief,[62] the Respondent's generation of false chart information supports the fair inference that he was attempting to create a justification for controlled substance prescriptions he understood to be unsupportable under the law. *See Syed Jawed Akhter-Zaidi, M.D.,* 80 FR 42,963, 49,964 (2015) (holding that where a practitioner creates a false record when prescribing a controlled substance, there is a presumption that the practitioner [''falsified the records in order to justify the prescribing of controlled substances, and that in prescribing the controlled substances, Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose'']). He spent tiny minutes of time with the TFO before issuing controlled substances and dickered about the amount of seconds actually devoted to the interaction and the palpations. This is a man who believes he made no true mistakes. The Agency is thus faced with a choice of imposing a registration sanction or imposing none and therein creating a strong likelihood that it will be instituting new proceedings, charging the same conduct against the same doctor soon thereafter. To the extent the Respondent, after being present at this hearing, does not see that he was not acting as a reliable registrant, it is highly unlikely that he will see the light in a month, a week, or a day from an Agency action that affords him another chance. To be sure, the Respondent credibly testified that getting caught and being put into proceedings caused a certain degree of

[56] Resp't Ex. 8.

[57] Tr. 388–89.

[58] Tr. 430–33.

[59] ALJ Ex. 20, at 15.

[60] *Id.*

[61] *Hassman,* 75 FR at 8236.

[62] ALJ Ex. 19, at 34.

emotional consternation,[63] but that is not the same as accepting responsibility, which is something he clearly is unwilling to do. On this point there is little room for logical, dispassionate dissent. Thus, in the face of a *prima facie* case, without the Respondent meeting the evidence with a convincing, unequivocal acceptance of responsibility and proposing thoughtful, concrete remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction. That a sanction is supported does not end the inquiry, however.

In determining whether and to what extent imposing a sanction is appropriate, consideration must also be given to the Agency's interest in both specific and general deterrence and the egregiousness of the offenses established by the Government's evidence. *Ruben,* 78 FR at 38,364, 38,385. Considerations of specific and general deterrence in this case militate in favor of revocation. As discussed, *supra,* the Respondent has made it clear that he feels that he was not so much wrong as misunderstood and, in a way, nitpicked. As discussed, *supra,* he feels his prescriptions were legitimate, if lenient. Tr. 424–425. Although he uttered words in support of regret, where a person does not accept as true the errors shown to him by hard evidence, the hopes of true future deterrence are diminished, and mortally so. The interests of specific deterrence, therefore, compel the imposition of a sanction.

Likewise, as the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR at 38,385. To continue the Respondent's registration privileges on the present record would send a message to the regulated community that it is acceptable to spend less than ten minutes, and sometimes less than two minutes with a patient, conduct no exams, document exams not conducted, procure neither prior records nor objective testing, prescribe dangerous controlled substances, increase the dosages without basis or regret, and continue to do so even in the face of information that the purported patient is not even filling the prescriptions. The interests of general deterrence militate powerfully in favor of a sanction on this record.

Regarding the egregiousness of the Respondent's conduct, as discussed, *supra,* the Respondent did virtually nothing to satisfy (or even further) his responsibilities as a DEA registrant on four occasions. He had no basis for a valid diagnosis, he had no prior medical records, called no prior treating physician, had no imaging, conducted no examination to speak of, doctored up phony examination results, ignored evidence that the prescriptions were not being filled by his purported patient, disregarded the gaps where the patient would have been without the medicine he was prescribing (even if it had been dispensed and taken as directed), and actually increased the dosage for no articulated reason beyond the fuzzy concept that he had an increased level of ''comfort[ ]'' [64] (based apparently on little more than the TFO's decision to keep coming back for more drugs). Even disregarding the very real likelihood that these four UC Visits presented a vivid snapshot of the Respondent's practice in general, the blithe manner in which he doled out controlled medicine to this undercover officer was nothing short of astonishing. The egregiousness of the established transgressions in this case, and the reckless abandon with which the Respondent ignored his obligations provides a unique window into the systemic gravity of the current opioid crisis.

A balancing of the statutory public interest factors, coupled with consideration of the Respondent's failure to meaningfully accept responsibility, the absence of record evidence of thoughtful and continuing remedial measures to guard against recurrence, and the Agency's interest in deterrence, supports the conclusion that this Respondent should not continue to be entrusted with a registration.

Accordingly, it is respectfully recommended that the Respondent's DEA COR should be REVOKED, and any pending applications for renewal should be DENIED.

Dated: August 20, 2020.

John J. Mulrooney, II,

U.S. Chief Administrative Law Judge.

[FR Doc. 2021–20247 Filed 9–17–21; 8:45 am]

BILLING CODE 4410–09–P

[63] Tr. 424.

[64] Tr. 391–94.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–31]

Lisa M. Jones, N.P.; Dismissal of Proceedings

I. Introduction

On June 28, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Lisa Mae Jones, N.P. (hereinafter, Applicant), of Mount Airy, North Carolina. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the denial of Applicant's application (Application No. W19018692M) for a DEA certificate of registration (hereinafter, North Carolina-based registration application) and ''any other applications for any other DEA registrations'' on the ground that she ''materially falsified'' her application ''in violation of 21 U.S.C. 824(a)(1) and 823(f).'' *Id.*

The substantive ground for the proceeding, as more specifically alleged in the OSC, is that Applicant's ''failure to disclose the disciplinary actions taken against . . . [her] nursing licenses (viz., the denial of . . . [her] application in Illinois and the fact that . . . [her] Tennessee and Iowa nursing licenses were placed on probation) constitutes material falsification of . . . [her] application for a DEA Certificate of Registration.'' *Id.* at 4.

The OSC notified Applicant of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 4 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to file a corrective action plan. OSC, at 5 (citing 21 U.S.C. 824(c)(2)(C)). Applicant requested a hearing. ALJX 2 (Request for Hearing dated July 22, 2019), ALJX 4 (Order for Prehearing Statements dated July 23, 2019), at 1 (stating that counsel for Applicant filed a hearing request on July 22, 2019).[1]

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to the Chief Administrative Law Judge (hereinafter, ALJ), John J. Mulrooney, II. The Chief ALJ noted thirteen stipulations agreed upon by the parties and ''conclusively accepted as fact in these proceedings.'' Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated November 21, 2019 (hereinafter, RD), at 4–5. The second and third stipulations state that Applicant ''is currently licensed in the State of North Carolina as a Nurse Practitioner under Approval No. 5011528'' and that her ''North Carolina Approval (license) expires by its own terms on May 31, 2020.'' *Id.* at 4.

[1] The Request for Hearing is stamped received on July 30, 2019.