James L. Hooper, 76 FR 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR 27,617.

According to Florida statute, ''It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy: (a) Which is not registered under the provisions of this chapter.'' Fla. Stat. Ann. 465.015(1). Further, ''the practice of the profession of pharmacy'' definition ''includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug[3] . . . .'' Fla. Stat. Ann. 465.003(13) (West, 2021).

Here, the undisputed evidence in the record is that Applicant currently lacks authority to operate a pharmacy in Florida. As already discussed, a pharmacy must be a licensed to dispense a medicinal drug, including a controlled substance, in Florida. Thus, because Applicant lacks authority to practice pharmacy in Florida and, therefore, is not authorized to dispense controlled substances in Florida, Applicant is not eligible to receive a DEA registration. Accordingly, I will order that Applicant's application for a DEA registration be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby order that the pending application for a Certificate of Registration, Control Number W16006664A, submitted by Tel-Pharmacy, is denied, as well as any other pending application of Tel-Pharmacy for additional registration in Florida. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–00956 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–09–P

[3] ''Medicinal Drugs'' or ''Drugs'' means ''those substances or preparations commonly known as 'prescription' or 'legend' drugs which are required by federal or state law to be dispensed only on a prescription . . . .'' Fla. Stat. Ann. 465.003(8).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–08]

AARRIC, Inc. d/b/a at Cost RX; Decision and Order

On January 3, 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 AARRIC, Inc. d/b/a AT COST RX (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FA2125640 (hereinafter, registration or COR) 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 November 16–20, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference.*[A] On April 7, 2021, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On

*[A] [This footnote has been relocated from RD n.5.] At all times prior to and during the hearing, the Respondent was represented by multiple, able counsel. The Respondent's (then) counsels raised no issue during the proceedings or in the Respondent's closing brief regarding the fairness of the proceedings. The day after its closing brief was filed, the Respondent sought to discharge its lawyers and opted to have itself represented by its (non-lawyer) owner. ALJ Ex. 56. Acting as a non-attorney representative (*see* 21 CFR 1316.50), the Respondent's owner moved to disqualify the Government's expert and to recuse me [the Chief ALJ]. ALJ Exs. 57, 58, 61. These motions have been disposed of in separate orders issued contemporaneously with this recommended decision. ALJ Exs. 67, 68. A joint motion to be excused from further representation of the Respondent (ALJ Ex. 60) filed by his lawyers (at the request of the tribunal) was granted for the reasons stated therein. ALJ Ex. 62.

[I agree with the Chief ALJ's procedural rulings in this case, including his dismissal of Respondent's two recusal motions. In these motions, Respondent argued that the Chief ALJ ''den[ied] Respondent [the] right to a fair trial'' by ''creat[ing] an atmosphere of prejudice and lack of impartiality.'' ALJ Ex. 57, at 3. Respondent further argued that the Chief ALJ ''morphed [the Government's case] into a plausible case'' by ''w[earing] the hat of the Government's lawyer during most of the witness examination.'' *Id.* at 2. Respondent's motions reference portions of the record where the Chief ALJ assisted the Government in authenticating documents and questioning its witnesses. Although Respondent acknowledged that ALJs are permitted to question witnesses, Respondent argues that the Chief ALJ used his questioning authority to buttress the Government's case and ''patch[ ] up areas where there were obvious gaps in the Government's case,'' while not ''provid[ing] the same helping hand to Respondent when Respondent was attempting to authenticate documents that Respondent believes were critical to its defense. *Id.* at 5, 10. Additionally, Respondent alleged that it was inappropriate for the Chief ALJ to ask Respondent's representative, Dr. Howard, whether he agreed with certain testimony by Respondent's expert, because it ''placed . . . Dr. Howard in an awkward position to have to incriminate his own expert just to appease the ALJ.'' *Id.* at 26, 30.

I find that Respondent's recusal motions are without merit. As the Chief ALJ stated in his neutral and carefully-reasoned dismissal order, Respondent—the proponent of the recusal motion—has the burden of demonstrating that the Chief ALJ exhibited a ''deep-seated favoritism or antagonism that would make fair judgment impossible.'' Order Denying the Respondent's Recusal Motions, at 6. Respondent did not identify any evidence of favoritism or antagonism, much less the type of deep-seated favoritism or antagonism that would make fair judgment impossible. Rather, Respondent identified instances where the Chief ALJ was exercising his discretionary authority to regulate the hearing, by asking clarifying questions of counsel and witnesses and issuing evidentiary rulings. *See* Order, at 7 (citing 5 U.S.C. 556(c)(5); 21 CFR 1316.52(e)). Courts have uniformly held that judicial rulings issued during the course of litigation rarely constitute evidence of cognizable bias. *Id.* (citing *Liteky* v. *United States,* 510 U.S. 540, 555 (1994), *Hamm* v. *Members of Bd. of Regents,* 708 F.2d 647, 651 (11th Cir. 1983), *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,958–59 (2010)). Additionally, as the Chief ALJ highlighted in his dismissal order, the Chief ALJ frequently clarified the record for Respondent's benefit and overwhelmingly issued evidentiary rulings in Respondent's favor. *Id.* at 8–9. Furthermore, Respondent's recusal motions were untimely, which is an independent basis for their dismissal. *Id.* at 7, 15–16.

Beyond the substantive and procedural defects of Respondent's recusal motions, the motions convey a contemptuous tone towards the Chief ALJ, which supports my decision that Respondent's registration is inconsistent with the public interest. Respondent was particularly outraged that the Chief ALJ questioned Respondent's representative about whether he agreed with the Respondent's expert's expressions of hostility towards DEA as a regulator. Based on Respondent's attitude towards DEA and the Chief ALJ, I find it unlikely that Respondent would modify its behavior and become a law-abiding, cooperative registrant. Certainly, Respondent's focus on repudiating the Chief ALJ rather than acknowledging its own misconduct shows that it falls far short of the ''true remorse'' that is required when a registrant has committed acts that are inconsistent with the public interest. *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011).

For the same reasons stated above, I find that Respondent's Exceptions to ALJ's Denial of Respondent's Motions for Recusal and Request for Expedited Ruling on the Order Denying Recusal are without merit. ALJ Ex. 69 (dated April 27, 2021).]

December 15, 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 Respondent's Exceptions without merit and I adopt the ALJ's Recommended Decision with minor modifications, as noted herein. I have addressed each of Respondent's Exceptions and I issue my final Order in this case following the Recommended Decision.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *B 1 2 3

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

The Allegations

The Government alleges that the Respondent Pharmacy's COR should be revoked because on numerous occasions between February 2018 and September 2019, it repeatedly dispensed prescriptions to ten patients (collectively, the Ten Patients) [4] without addressing or resolving factual *indicia* (*i.e.,* ''red flags'') of potential drug diversion and in contravention of its corresponding responsibility to ensure the prescriptions were issued for a legitimate medical purpose. ALJ Ex. 1 at 2.

The Evidence

The Stipulations

The parties entered into factual stipulations prior to the litigation of this matter, which were accepted by the tribunal.[5] By virtue of those stipulations, the following factual matters are deemed conclusively established in this case:

1. The Respondent is registered with DEA to handle controlled substances in Schedules II through V under DEA COR No. FA2125640 at 16970 San Carlos Boulevard, Suite 110, Fort Myers, Florida 33908.

2. DEA COR No. FA2125640 will expire by its own terms on June 30, 2022.

3. DEA lists Adderall (amphetamine–dextroamphetamine mixture) as a Schedule II controlled substance under 21 CFR 1308.12(d)(1).

4. DEA lists Ambien (zolpidem tartrate) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(57).[6]

5. DEA lists Ativan (lorazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(32).

6. DEA lists hydromorphone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vii).

7. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(12).

8. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15).

9. DEA lists MS Contin (morphine sulfate extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(ix).

10. DEA lists Norco (hydrocodone–acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vi).

11. DEA lists oxycodone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiv).

12. DEA lists Percocet (oxycodone–acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiv).

13. DEA lists Restoril (temazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(53).

14. DEA lists Soma (carisoprodol) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(7).

15. DEA lists Valium (diazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(17).

16. DEA lists Xanax (alprazolam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(2).

17. Between February 19, 2018, and at least September 2, 2019, the Respondent filled at least 21 prescriptions for *Patient JA* for 90–120 units of hydromorphone 8 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug dispensed	Prescription No.
2/19/2018	112 units of hydromorphone 8 mg	535081
3/19/2018	112 units of hydromorphone 8 mg	535597
4/16/2018	120 units of hydromorphone 8 mg	536108
5/14/2018	120 units of hydromorphone 8 mg	536635
6/11/2018	120 units of hydromorphone 8 mg	537027
7/10/2018	120 units of hydromorphone 8 mg	537292
8/7/2018	120 units of hydromorphone 8 mg	537539
9/4/2018	120 units of hydromorphone 8 mg	537922
10/2/2018	120 units of hydromorphone 8 mg	538321
10/30/2018	120 units of hydromorphone 8 mg	538758
11/26/2018	120 units of hydromorphone 8 mg	539235
12/21/2018	120 units of hydromorphone 8 mg	539671
1/21/2019	120 units of hydromorphone 8 mg	540097
2/18/2019	120 units of hydromorphone 8 mg	540569
3/18/2019	120 units of hydromorphone 8 mg	541028
4/15/2019	120 units of hydromorphone 8 mg	541503
5/13/2019	105 units of hydromorphone 8 mg	541983
6/10/2019	90 units of hydromorphone 8 mg	542444
7/8/2019	90 units of hydromorphone 8 mg	542892
8/5/2019	90 units of hydromorphone 8 mg	543372
9/2/2019	90 units of hydromorphone 8 mg	543802

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

[1] [Footnote relocated, *see infra* n. *M.]

[2] [Footnote relocated, *see supra* n.*A.]

[3] [Omitted for brevity.]

[4] In this recommended decision, initials have been substituted for the names of the Respondent's customer-patients to preserve their personally identifiable information. The Ten Patients include Patients JA, EA, SD, LH, DH, DK, JM, ST, JW, and CW.

[5] ALJ Ex. 38.

[6] Multiple incorrect citations set forth in the proposed stipulations propounded by the parties have been corrected in this RD to reflect the current regulatory designation.

18. Patient JA paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

19. Between September 19, 2018, and at least September 16, 2019, the Respondent filled at least 42 prescriptions for *Patient EA* for 28 units of MS Contin 30 mg, 120 units of oxycodone 30 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
9/19/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538184–538186
10/17/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538570–538572
11/15/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539086–539088
12/13/2018	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539524–539525; 539527
1/9/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539931–539932; 539935
2/5/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540377–540378; 540381
3/4/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540812–540814
4/1/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541310–541311; 541314
4/24/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541726–541728
5/22/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542191; 542193–542194
6/25/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542751–542753
7/24/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543220–543221; 543223
8/20/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543644–543646
9/16/2019	28 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	544051–544053

20. Patient EA paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

21. Between February 20, 2018, and at least September 4, 2019, the Respondent filled at least 56 prescriptions for *Patient SD* for 21–30 units of MS Contin 30 mg, 60 units of MS Contin 60 mg, 92–135 units of oxycodone 30 mg, 30 units of Xanax 0.5 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/20/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	535123–535125
3/21/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	535637–535638; 535643
4/17/2018	60 units of MS Contin 60 mg; 135 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536133–536135
5/15/2018	30 units of Xanax 1 mg	536670
8/9/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	537591–537592; 537606
9/7/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	538017–538019
10/4/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538376–538377; 538379
10/31/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	538811–538813
11/7/2018	92 units of oxycodone 30 mg	538974
11/27/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539262; 539264–539265
12/24/2018	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539680–539682
1/22/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540132–540134
2/19/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540597–540598; 540600
3/18/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541054; 541056–541057
4/15/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541524; 541526–541527
5/13/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542001–542003
6/11/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542498–542500
7/8/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	542917–542919
8/6/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	543410–543412
9/4/2019	30 units of MS Contin 30 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 0.5 mg	543858–543860

22. Patient SD paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent on or after April 16, 2018.

23. Between March 6, 2018, and at least September 11, 2019, the Respondent filled at least 34 prescriptions for *Patient LH* for 28–60 units of MS Contin 30 mg and 120–140 units of oxycodone 30 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/6/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	535451–535452
4/3/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	535887–535888
5/8/2018	60 units of MS Contin 30 mg; and 140 units of oxycodone 30 mg	536542–536543
8/28/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	537859–537860
10/10/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	538473–538474
11/7/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	538955–538956
12/5/2018	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	539397–539398
1/3/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	539816–539817
1/30/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	540243–540244
2/27/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	540720–540721
3/27/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	541246–541247
4/24/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	541706–541707

Fill date	Drug(s) dispensed	Prescription Nos.
5/22/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	542196–542197
6/19/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	542646–542647
7/17/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543112–543113
8/14/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543557–543558
9/11/2019	28 units of MS Contin 30 mg; and 120 units of oxycodone 30 mg	543979; 543982

24. Patient LH paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

25. Between March 8, 2018, and at least September 11, 2019, the Respondent filled at least 59 prescriptions for *Patient DH* for 60 units of MS Contin 30 mg, 120 units of hydromorphone 8 mg, and 60 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/8/2018	60 units of MS Contin 30 mg	535478
3/13/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	535525–535526
4/10/2018	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536047; 536050; 536053
5/8/2018	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536566–536567; 536571
6/5/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	536993–536994
6/15/2018	60 units of MS Contin 30 mg	537081
7/4/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537254; 537257
7/13/2018	60 units of MS Contin 30 mg	537339
7/31/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537486; 537489
8/28/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	537853; 537857
8/31/2018	60 units of MS Contin 30 mg	537906
9/25/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538255; 538258
10/5/2018	60 units of MS Contin 30 mg	538386
10/23/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538663; 538666
11/2/2018	60 units of MS Contin 30 mg	538879
11/20/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539162; 539165
12/3/2018	60 units of MS Contin 30 mg	539350
12/18/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539596; 539599
12/31/2018	60 units of MS Contin 30 mg	539743
1/15/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540031; 540035
1/28/2019	60 units of MS Contin 30 mg	540191
2/12/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540467; 540473
2/25/2019	60 units of MS Contin 30 mg	540670
3/11/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	540938–540939
3/25/2019	60 units of MS Contin 30 mg	541179
4/8/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541428–541429
4/22/2019	60 units of MS Contin 30 mg	541661
5/6/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541914–541915
5/20/2019	60 units of MS Contin 30 mg	542133
6/3/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542349; 542358
6/17/2019	60 units of MS Contin 30 mg	542587
7/1/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542839–542840
7/15/2019	60 units of MS Contin 30 mg	543059
7/29/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	543275–543276
8/12/2019	60 units of MS Contin 30 mg	543489
8/26/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	543703–543704
9/11/2019	60 units of MS Contin 30 mg	543975

26. Patient DH paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent.

27. Between February 16, 2018, and at least September 12, 2019, the Respondent filled at least 59 prescriptions for *Patient DK* for 60 units of MS Contin 30 mg, 60 units of MS Contin 60 mg, 90–120 units of hydromorphone 8 mg, 90 units of Xanax 0.5 mg, 60 units of Xanax 1 mg, and 35–60 units of Soma 350 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; 60 units of Xanax 1 mg; and 60 units of Soma 350 mg.	535071–535074
3/14/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 35 units of Soma 350 mg	535552; 535557–535558
3/16/2018	60 units of Xanax 1 mg	535590
5/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	536704; 536707–536708
5/18/2018	60 units of Soma 350 mg	536732
6/13/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Soma 350 mg	537054–537056
6/20/2018	60 units of Xanax 1 mg	537145

Fill date	Drug(s) dispensed	Prescription Nos.
7/11/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	537307–537309
8/8/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	537565–537566; 537568
9/18/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	538219–538221
10/17/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	538548–538550
11/16/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539113; 539115–539116
12/14/2018	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539557–539558; 539560
1/11/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	539990–539991; 539993
2/13/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	540509–540510; 540512
3/12/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	540971; 540977–540978
4/11/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	541496; 541498; 541500
5/9/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	541975–541977
6/6/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	542430–542431; 542433
7/5/2019	60 units of MS Contin 60 mg; 120 units of hydromorphone 8 mg; and 60 units of Xanax 1 mg	542882–542883; 542889
8/13/2019	60 units of MS Contin 30 mg	543528
8/30/2019	90 units of hydromorphone 8 mg; and 90 units of Xanax 0.5 mg	543798; 543800
9/12/2019	60 units of MS Contin 30 mg	544003

28. Patient DK paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

29. Between February 28, 2018, and at least September 17, 2019, the Respondent filled at least 78 prescriptions for *Patient JM* for 60 units of MS Contin 30 mg, 120 units of hydromorphone 8 mg, 60 units of Restoril 15 mg, 30 units of Restoril 30 mg, and 60 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/28/2018	30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	535267; 535269
3/5/2018	120 units of hydromorphone 8 mg	535393
3/9/2018	60 units of MS Contin 30 mg	535492
3/28/2018	30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	535799–535800
4/2/2018	120 units of hydromorphone 8 mg	535842
4/9/2018	60 units of MS Contin 30 mg	536038
5/1/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	536422; 536424–536425
5/8/2018	60 units of MS Contin 30 mg	536574
5/29/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	536909–536911
6/4/2018	60 units of MS Contin 30 mg	536967
6/26/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537182–537183; 537189
7/5/2018	60 units of MS Contin 30 mg	537266
7/24/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537451; 537452; 537455
8/1/2018	60 units of MS Contin 30 mg	537508
8/21/2018	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	537773; 537778–537779
8/31/2018	60 units of MS Contin 30 mg	537909
9/18/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538160; 538162
9/24/2018	30 units of Restoril 30 mg	538235
9/28/2018	60 units of MS Contin 30 mg	538302
10/17/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	538541; 538543
10/26/2018	60 units of MS Contin 30 mg; and 30 units of Restoril 30 mg	538728; 538730
11/13/2018	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	539024; 539026
11/26/2018	60 units of MS Contin 30 mg; and 30 units of Restoril 30 mg	539245; 539247
1/9/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg.	539924–539925; 539927–539928
2/6/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg.	540415; 540417; 540419–540420
3/7/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 60 units of Restoril 15 mg; and 60 units of Xanax 2 mg.	540900–540903
4/3/2019	60 units of MS Contin 30 mg; 120 units of hydromorphone 8 mg; 60 units of Restoril 15 mg; and 60 units of Xanax 2 mg.	541355–541358
4/30/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	541815–541816
5/3/2019	60 units of MS Contin 30 mg	541878
5/28/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	542248–542249; 542252
5/30/2019	60 units of MS Contin 30 mg	542315
6/25/2019	120 units of hydromorphone 8 mg; and 60 units of Xanax 2 mg	542726; 542729
6/27/2019	60 units of MS Contin 30 mg	542801
7/23/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	543189–543190; 543194
7/25/2019	60 units of MS Contin 30 mg	543238
8/20/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	543628–543630
8/23/2019	60 units of MS Contin 30 mg	543696
9/17/2019	120 units of hydromorphone 8 mg; 30 units of Restoril 30 mg; and 60 units of Xanax 2 mg	544074–544076

30. Patient JM paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

31. Between March 7, 2018, and at least August 21, 2019, the Respondent filled at least 40 prescriptions for *Patient ST* for 60 units of MS Contin 60 mg and 150 units of oxycodone 30 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
3/7/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	535465–535466
4/4/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	535928–535929
5/2/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	536448–536449
5/30/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	536925; 536934
6/27/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537209–537210
7/25/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537471–537472
8/22/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	537781–537782
9/19/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	538182–538183
10/17/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	538555–538556
11/14/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539062–539063
12/12/2018	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539505–539506
1/9/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	539913–539914
2/6/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	540400–540401
3/7/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	540894–540895
4/3/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	541363–541364
5/1/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	541831–541832
5/29/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	542282–542283
6/26/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	542762–542763
7/24/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	543217–543218
8/21/2019	60 units of MS Contin 60 mg; and 150 units of oxycodone 30 mg	543650–543651

32. Patient ST paid cash for all of the above-listed prescriptions for controlled substances that he filled with the Respondent on or after April 4, 2018.

33. Between April 19, 2018, and at least May 2, 2019, the Respondent filled at least 30 prescriptions for *Patient JW* for 28–90 units of methadone 10 mg, 112–120 units of oxycodone 30 mg, and 30 units of Xanax 1 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
4/19/2018	90 units of methadone 10 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536190–536191; 536194
5/23/2018	90 units of methadone 10 mg; 120 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	536860–536862
8/29/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	537877–537878; 537881
11/12/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539000–539002
12/11/2018	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539482–539484
1/8/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	539875; 539877–539878
2/6/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540394; 540397–540398
3/7/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	540886–540888
4/3/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541369–541370; 541374
5/2/2019	28 units of methadone 10 mg; 112 units of oxycodone 30 mg; and 30 units of Xanax 1 mg	541863–541865

34. Patient JW paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

35. Between February 26, 2018, and at least August 28, 2019, the Respondent filled at least 33 prescriptions for *Patient CW* for 30 units of methadone 5 mg, 30–60 units of methadone 10 mg, 90–120 units of hydromorphone 8 mg, 30 units of Xanax 0.5 mg, 30 units of Xanax 1 mg, and 90 units of Xanax 2 mg. These prescriptions were filled on or about the following specific occasions:

Fill date	Drug(s) dispensed	Prescription Nos.
2/26/2018	90 units of hydromorphone 8 mg	535206
3/26/2018	90 units of hydromorphone 8 mg	535720
4/23/2018	90 units of hydromorphone 8 mg	536247
5/21/2018	90 units of hydromorphone 8 mg	536776
7/24/2018	60 units of methadone 10 mg; 120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	537446–537448
8/24/2018	30 units of methadone 5 mg	537818
9/25/2018	30 units of methadone 10 mg; 120 units of hydromorphone 8 mg; and 90 units of Xanax 2 mg	538259; 538261; 538266
10/23/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	538675–538676
10/24/2018	30 units of Xanax 1 mg	538714
11/19/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	539145–539146
11/20/2018	30 units of Xanax 0.5 mg	539154
12/17/2018	30 units of methadone 10 mg; and 120 units of hydromorphone 8 mg	539591–539592
1/15/2019	30 units of methadone 5 mg; and 120 units of hydromorphone 8 mg	540015–540016
2/19/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	540583; 540585
3/19/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	541065; 541069
4/16/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	541548–541549

Fill date	Drug(s) dispensed	Prescription Nos.
6/4/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	542374–542375
7/31/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	543329–543330
8/28/2019	120 units of hydromorphone 8 mg; and 30 units of Xanax 1 mg	543773–543774

36. Patient CW paid cash for all of the above-listed prescriptions for controlled substances that she filled with the Respondent.

The Government's Case *[C]

In addition to its reliance on the agreed factual stipulations reached by the parties in this case, the Government presented its case through the testimony of a DEA Diversion Investigator and an expert pharmacy witness.

Diversion Investigator

The Government presented the testimony of a DEA Diversion Investigator (DI). DI testified that, as of the date of the hearing, he has been a DI for approximately three years and is currently stationed at the Miami field office. Tr. 19. The investigation that culminated in the present administrative charges was initiated by DI's predecessor, DI 2. Tr. 22. Upon DI 2's retirement from DEA, DI assumed responsibility as the lead DEA investigator on the case and inherited both open and closed evidence requests, as well as the balance of the investigative case file. Tr. 22–23. According to DI, the Respondent became the focus of DEA's attention after an on-site inspection by DEA in 2015. Tr. 24. DI's testimony was also used to authenticate a number of Government Exhibits, consisting of documents obtained during the course of the investigation. Tr. 31, 35, 38, 40–41, 46, 48–49, 62, 65, 67, 76, 79–80, 109–10, 364.

DI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. As a successor investigator, he demonstrated candor in teasing out which aspects of the investigation were initiated/controlled by him, and which aspects were inherited. Where he was unsure of an answer, he presented a good-faith effort but made no attempt to supply a convenient contrivance. The testimony of this witness, viewed *in toto,* was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

Dr. Tracey Schossow, Pharm.D.

The Government presented the expert testimony of Dr. Tracey Schossow. Dr. Schossow's *curriculum vitae* (CV) [7] reflects that she received a Doctorate in Pharmacy in 2001, has practiced,[8] managed, consulted, trained, and taught pharmacy for twenty-six years in a variety of settings, and even authored the pharmacy portion of a manual for a hospice company. Tr. 135, 155; Gov't Ex. 17. In fact, the witness testified that her introduction to the pharmacy profession commenced with work as a pharmacy technician in her father's independent pharmacy back in 1982. Tr. 136.

In the midst of a largely uneventful presentation, there arose a bizarre twist of events that bears special mention. During a cross-examination conducted by the Respondent's (then) counsel, Dr. Schossow [testified] that she was familiar with the composition of the Florida Board of Pharmacy, and volunteered that ''It's made up of pharmacists. I sat on the Board one time so—a long time ago.'' Tr. 455. Since neither Dr. Schossow's CV,[9] nor her direct testimony regarding her qualifications, reflected past employment as a Board member, [this testimony was unexpected. On cross examination, Respondent's counsel followed up on this issue with Dr. Schossow, and they had the following exchange:

Q: I understood you to say that you sat on the Board of Pharmacy for a period of time? Is that right?

A: When I first graduated from pharmacy school, yes. I was—this was a long time ago. I don't know if it was—I don't remember the position, exactly. It wasn't, like,—I wasn't the head of the Board, or anything like that. But I did sit on the Board in the meetings.

Q: Okay. And did you vote and participate in the process?

A: I participated in the process, but I didn't have any voting—I didn't do any voting.

Q: Okay. So, what you're talking about is, maybe, internship-type position with the board of pharmacy?

A: I don't recall the exact title of it. It was not an intern position. I was a licensed pharmacist at the time.

Q: All right. And so, this was, when? After you received your initial degree as a registered pharmacist, or during your Pharm D program?

A: No, it was after I received my initial pharmacy degree back in '94.

Tr. 546–47. Dr. Schossow then confirmed that she ''wasn't sitting on the board'' and ''didn't have a title like that,'' but she did participate. *Id.* at 547. She continued, ''It was a long time ago, so I do not recall the official, whatever I was doing at that time.'' *Id.* As discussed in more detail below, this testimony was inconsistent and confusing.

Dr. Schossow also testified that she could not recall particular sources that she reviewed prior to her testimony in this case, but stated that she is constantly reviewing a variety of information from legal sources, federal guidelines, as well as clinical data and studies to stay current on the applicable standard of care for Florida pharmacists.[10] Tr. 152–53, 163; *see also id.* at 193. Dr. Schossow also volunteered that she ''also had a lot of patients in the community arrested for opioid and other controlled substance fraud and abuse.'' [11] Tr. 137. The witness testified that she has also served as a pharmacy expert reviewer in federal agency cases involving controlled substances [12] and has been recognized as an expert witness on multiple occasions in administrative enforcement cases. Tr. 145–47. Dr. Schossow was tendered [13] and, over the Respondent's

*[C] Throughout the Chief ALJ's description of both the Government's Case and the Respondent's Case, I have made some minor adjustments to the wording where noted for brevity and for clarity and to reflect more of my style. I agree with the Chief ALJ on the astute points that he made and I have left in the content.

[7] Gov't Ex. 17.

[8] Dr. Schossow testified that she has practiced as a clinical pharmacist and a retail pharmacist. Tr. 145. In her words, ''a retail pharmacist does most of the actual dispensing of the medications into the bottles, versus a clinical pharmacist is more involved with the patient and the doctor, working more closely with them, usually offering recommendations on managing the patient.'' *Id.* The witness testified that she practiced retail pharmacy for about twelve years. *Id.*

[9] Gov't Ex. 17.

[10] The witness testified that the Florida requirement for continuing education is limited to one hour every two years. Tr. 197.

[11] This portion of the witness's testimony was objected to as irrelevant by the Respondent's counsel, and the tribunal subsequently sustained the objection. Thus, while no part of this statement will be considered to the detriment of the Respondent, it does present some potential insight into the mindset of the Government's expert. Its consideration is limited to that narrow point.

[12] Dr. Schossow testified that she has been compensated for her professional work as an expert, including by DEA in this case. Tr. 530. She also testified that although thus far her expert opinion has been exclusively sought by DEA, she would be willing to ''give [her] opinion to anybody who asks [her] regarding pharmacy.'' Tr. 162–63.

[13] Tr. 149.

objection, was accepted as an expert witness in the standard of care for Florida pharmacists and pharmacy practice in the State of Florida. Tr. 166–67.

According to Dr. Schossow, the applicable standard of care for dispensing controlled substances in Florida requires a pharmacist to evaluate every prescription presented by a patient.[14] Tr. 168–69. Dr. Schossow encapsulated her view of applicable statutes governing state corresponding responsibility in Florida as follows:

> [T]he responsibility of a [Florida] pharmacist is to ensure the safety and efficacy of the therapy for that person and also to protect that person in regards to safety for the patient and the community. It's very clear.

Tr. 171. Less helpfully, at another point in her testimony, the witness defined the applicable standard of care as ''[w]hat usually a normal pharmacist would do in a pharmacy or how they would practice the profession of pharmacy.'' Tr. 181; *see also id.* at 336.

According to the Government's expert, in evaluating a prescription, a Florida pharmacist is required to perform a drug utilization review (DUR),[15] which is a process by which a pharmacist analyzes a prescription to check for red flags signaling a potential diversion issue, and to ''assure that the prescription is for a legitimate medical purpose.'' Tr. 169; *see id.* at 189–90. Dr. Schossow defined a red flag as ''something on the prescription that alerts the pharmacist that the prescription may be being diverted or abused and that the pharmacist must do their due diligence to determine whether that red flag can be cleared or not.'' Tr. 189–90. When a pharmacist[16] is faced with a red flag, the red flag must be addressed and documented. Tr. 189–90, 198. Documented findings can be recorded on the prescription itself, within a patient profile, or in a note section of a pharmacy software program. Tr. 177. The witness opined that a lack of documentation indicates that the required analysis of a red flag was not performed by the dispensing pharmacist. Tr. 199–200. The witness conceded that she did not know whether any of the red flags she identified were actually analyzed and resolved by the Respondent,[17] but she made her opinion clear that a deficit in the adequacy of the documentation setting forth the pharmacist's DUR analysis brings a dispensing event below the Florida minimum standard of care, and that the DUR analysis can be set forth on the prescription itself or in a pharmacy's electronic records. Tr. 177, 740. According to Dr. Schossow, the mere existence of a red flag, in and of itself, does not always prohibit a pharmacist from filing a prescription;[18] it was her view that upon sufficient documented analysis, all red flags are potentially resolvable. Tr. 237. The Government's expert clarified early in her testimony that she was restricting her opinions to the minimum Florida standard of care, and not elucidating on best practices in the field of pharmacy. Tr. 175–76.

The Government's expert testified that she reviewed prescriptions and patient profiles corresponding to the Ten Patients[19] and determined that dispensing events depicted in those profiles and records presented numerous red flags, with no documented indications on the part of the Respondent of any attempts to resolve those red flags prior to filling the prescriptions in accordance with the standard of care for a Florida pharmacist. Tr. 431. One such red flag identified by the witness through the Respondent's paperwork was present in dispensing events where controlled substances were filled in high-risk combinations[20] that significantly elevate the risk for such things as central nervous system (CNS)/respiratory depression, overdose, coma, and death. Gov't Exs. 6, 7, 9–11, 13, 14, 22, 23, 25–27, 29; Tr. 215–16, 218–21; Stip. 33 (Patient JW); Tr. 268–69; Stip. 19 (Patient EA); Tr. 287–91, 294–95; Stip. 21 (Patient SD); Tr. 309–12; Stip. 25 (Patient DH);[21] Tr. 321–26; Stip. 27 (Patient DK);[22] Tr. 330–32; Stip. 29 (Patient JM);[23] Tr. 243–45; Stip. 35 (Patient CW). According to Dr. Schossow, under the Florida standard of care, filling these prescriptions would require documented *indicia* that the pharmacist reviewed the patient's history, reviewed the patient's information on the Electronic-Florida Online Reporting of Controlled Substance Evaluation database (E–FORCSE),[24] spoke with the doctor, spoke with the prescriber, inquired about the patient treatment plan, discussed function improvement of the patient, and discussed whether the patient had been apprised of the associated risks.[25] Tr. 204, 213–14, 216. The witness explained that there was no indication in the Respondent's records that the documentation requirement had been completed or addressed for the high-risk combination red flags that she identified. Gov't Exs. 6, 7, 9–11, 13–15, 22, 23, 25–27, 29, 32;[26] Tr. 240–41, 424–25 (Patient JW); Tr. 286, 371–75 (Patient EA); Tr. 295–300, 375–78 (Patient SD); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH);[27] Tr. 329–30,

[14] Throughout her testimony, the witness would refer to various Florida statutes that, according to her, inform her opinion on the standard of care for a Florida pharmacist. In evaluating the role of an expert witness in the pharmacy context, the Agency has held that a pharmacy expert is ''not [expected to be] an expert in the details of state law, but she is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in her state, whether that is derived from state law, mandatory training, standards of care or otherwise.'' *Suntree Pharmacy,* 85 FR 73,753, 73,772 (2020).

[15] During her testimony, the witness used the term ''DUR'' interchangeably to mean the process of a drug review, as well as for a finding made during the review that would warrant further review (*i.e.,* a red flag); this was confusing and unhelpful. *See, e.g.,* Tr. 187–88.

[16] It is Dr. Schossow's view that a diversion red flag may only be resolved by a pharmacist, never a pharmacy technician. Tr. 200.

[17] Tr. 446.

[18] Tr. 198.

[19] Patients JA, EA, SD, LH, DH, DK, JM, ST, JW, and CW.

[20] Dr. Schossow identified combinations of opioids and benzodiazepines that, when taken together, can potentially result in a dangerous suppression of the central nervous system. Tr. 204.

[21] Dr. Schossow testified that her opinion would not be altered by a brief temporal break such as two weeks between the in-conflict medications. Tr. 318.

[22] Dr. Schossow testified that her opinion was not altered by the fact that the prescriptions in conflict were not dispensed on the same day. Tr. 324.

[23] Dr. Schossow testified that her opinion was not altered by the fact that the prescriptions in conflict were dispensed several days apart. Tr. 338.

[24] E–FORCSE is the prescription drug monitoring program (PDMP or PMP) maintained by the State of Florida.

[25] The Government's expert also referenced guidelines (CDC Guidelines) issued on March 18, 2016 by the Centers for Disease Control and Prevention (CDC) regarding morphine equivalent dosages (MMEs). Tr. 205–06. The CDC Guidelines were the subject of official notice during the proceedings. ALJ Ex. 39. While the CDC Guidelines were the subject of some level of pre-hearing notice by the Government, ALJ Ex. 4 at 23, there was no specific notice that an MME at any particular level, standing on its own, constitutes a red flag requiring action by a pharmacy registrant. During her testimony, Dr. Schossow accepted the proposition that the CDC Guidelines were issued primarily to guide prescribers, not pharmacies. Tr. 503–04.

[26] During the hearing, Proposed Government Exhibit 16 was initially offered in the form of a compact disc and admitted with the condition that the Government provide a hard-copy version of the subset of pages that it seeks to rely upon. ALJ Ex. 44. After the hearing, the Government discovered that the relevant information within Proposed Government Exhibit 16 was also contained within Government Exhibit 32, and subsequently withdrew Proposed Government Exhibit 16. ALJ Ex. 47.

[27] Although the Respondent pharmacy's notes did reflect that its personnel conducted a conversation with the prescriber, the Government's expert held the view that the documentation was so lacking in detail that the applicable standard was not met. Tr. 387–95. Dr. Schossow was steadfast in her opinion that the level of documentation was wanting, but was unable or unwilling to specify any sort of a generic standard as to what the level of documentation needs to be to pass muster. *Id.*

409–13 (Patient DK); Tr. 346–47, 425–30 (Patient CW). Dr. Schossow's testimony regarding the absence of documentation also extended to Patient JM. Tr. 338–39, 413–16, 419–20; Gov't Exs. 11, 15, 27, 32. However, as highlighted in her testimony, the Respondent's records did contain notes documenting combination medication discussions between the pharmacy and Patient JM. Tr. 414–418, 471; Gov't Ex. 32 at 69. Specifically, the pharmacy notes include, *inter alia,* the following entries:

12/12/19 SPOKE TO MD OFFICE: PT HAS BIPOLAR SCHIZOPHRENIA/ANXIETY. MD IS AWARE OF COMBO DRUG (XANAX, TEMAZEPAM, HYDRO-MORPHONE, TIZANIDINE, MS CONTIN) NO SIGNS OF ABUSE. PT HAS BEEN ON MEDS SINCE 2010. PT HAS BUILT UP TOLERANCE.

12/16/19 SPOKE TO MD OFFICE: ABOUT COMBINATION OF OXYCO-DONE, MS CONTIN, XANAX, TIZANI-DINE, TEMAZEMAM. MD IS AWARE PT HAS BIPOLAR MORBIDITY. STATES MONITORS PT FOR ABUSE. NO SIGNS OF REPIRATORY DEPRESSION. PT HAS BEEN ON MEDS FOR OVER 5 YEARS.

Gov't Ex. 32 at 69. Similarly, a pharmacy note regarding Patient CW provides:

12/18/19 SPOKE TO MD ABOUT COMBINATION OF HYDROMORPHONE/ ALPRAZOLAM. PT HAS NO SIGNS OF SIQUALE. NO SIGNS OF ABUSE PT HAS BEEN ON MEDS FOR SEVERAL YRS. OK TO FILL. . . .

Id. at 13. To be sure, on their face, these highlighted pharmacy notes are temporally outside the Government's allegations related to Patients JM [28] and CW,[29] but they clearly do appear to contain analysis regarding the combination prescribing issue and coordination with the prescriber. These notes demonstrate that at some point the Respondent did commence documenting conversations with the prescribers on this issue, [which is a positive development that indicates an attempt by Respondent's pharmacists to fulfill their corresponding responsibility and operate within the usual course of professional practice. However,] inasmuch as the documented resolutions are dated after the charged misconduct, they supply no defense to the registrant in this case.

In reviewing the prescriptions that were filled by the Respondent, Dr. Schossow also identified anomalies in regard to dosages of controlled substance prescriptions that raised red flags. Specifically, the witness explained that certain prescriptions did not ''make pharmacological sense'' [30] because of the dosing combinations of long-acting and short-acting opioids.[31] Gov't Exs. 6–9, 11, 12; Tr. 274–76, 281–83; Stip. 19 (Patient EA); Tr. 296–97; Stip. 21 (Patient SD); Tr. 302–05; Stip. 23 (Patient LH); [32] Tr. 315–16; Stip. 25 (Patient DH); [33] Tr. 333–34; Stip. 29 (Patient JM); Tr. 339–41; Stip. 31 (Patient ST). And for at least one patient, Dr. Schossow testified that there were instances of therapeutic duplication, [34] which also presented a dosage-anomaly red flag. Gov't Ex. 11; Tr. 335–38; Stip. 29 (Patient JM). The witness testified that to address a dosage-anomaly red flag, a Florida pharmacist acting within the standard of care is required to speak with the physician to discuss the potential dangers and the patient's treatment plan, and then document the conversation.[35] Tr. 284–855, 318, 336–37. Through her testimony, the witness explained that she saw no indication in her review of the Government exhibits that the Respondent resolved, addressed, or documented the dosage-anomaly red flags. Gov't Exs. 6–9, 11, 12, 15, 22–25, 27, 28, 32; Tr. 286, 371–75 (Patient EA); Tr. 298–300, 375–78 (Patient SD); Tr. 308, 378–80, 384 (Patient LH); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH); Tr. 338–39, 413–16, 419–20 (Patient JM); Tr. 342–43, 420–23 (Patient ST).

Dr. Schossow also testified that instances where customer-patients of the Respondent drove long distances to obtain and/or fill controlled substance prescriptions were red flags that must be addressed and resolved. Tr. 232–34; Gov't Exs. 5, 8, 10, 12, 13, 21, 24, 26, 28; Tr. 232–36 (Patient JW); Tr. 248–50 (Patient JA); Tr. 305–06 (Patient LH); Tr. 326–28 (Patient DK); Tr. 341–42 (Patient ST); ALJ Ex. 19, Attachs. A, C. [Dr. Schossow testified that] a patient driving long distances to fill a controlled substance prescription presents a red flag because of concerns ''for the safety of the patient'' as they could potentially be driving under the influence of controlled substances. Tr. 232–34. In order to address this long-distance red flag, a Florida pharmacist acting within the standard of care, at least according to Dr. Schossow, would need to question the patient on whether they were personally driving, question the prescriber on whether they ''discussed the dangers of the dosing of the medication in regards to operating a motor vehicle,'' [36] and then document the conversation/resolution.[37] Tr. 238–39; *see also id.* at 306–07, 328. [Omitted as superfluous. As discussed in more detail below, the Chief ALJ found that Dr. Schossow's testimony regarding the distance red flag was not convincing. I agree, and I do not give any weight to this testimony in my Decision. I have omitted portions of the RD's discussion of this red flag for brevity.]

Cash payments for controlled substances were also identified by Dr. Schossow as a red flag of potential diversion. Tr. 222–23, 457; Gov't Exs. 5–14, 21–29; Tr. 229–30; Stip. 34 (Patient JW); Tr. 242, 244; Stip. 18 (Patient JA); Tr. 269–70; Stip. 20 (Patient EA); Tr. 296–97; Stip. 22 (Patient SD); Tr. 305; Stip. 24 (Patient LH); Tr. 313; Stip. 26 (Patient DH); Tr. 326; Stip. 28 (Patient DK); Tr. 332–33; Stip. 30 (Patient JM); Tr. 341; Stip. 32 (Patient ST); Tr. 346; Stip. 36 (Patient CW). Dr. Schossow explained that an indication on a

[28] OSC/ISO Allegation 7.e charges that combination prescriptions between January 9, 2019 and August 23, 2019 were dispensed by the Respondent to Patient JM without documented evidence that the identified combination red flag was resolved. ALJ Ex. 1 ¶ 7.e.

[29] OSC/ISO Allegation 7.g charges that combination prescriptions between February 19, 2019 and August 28, 2019 were dispensed by the Respondent to Patient CW without documented evidence that the identified combination red flag was resolved. ALJ Ex. 1 ¶ 7.g.

[30] Tr. 281.

[31] Certain controlled substances are prescribed to be taken scheduled, in order to maintain the medication at a certain level in the body consistently. Tr. 275–76. While other controlled substances are prescribed to address breakthrough pain, or episodic pain, on an as-needed basis. Tr. 276–77. Here, Dr. Schossow testified that the Respondent was filling prescriptions where controlled substances that are usually prescribed for breakthrough pain were prescribed on a scheduled basis. Tr. 274–75.

[32] The witness was unmoved by the fact that the prescription sig was marked ''PRN,'' signifying that the medication was to be taken on an ''as needed'' basis. Tr. 302–03.

[33] Regarding Patient DH, Dr. Schossow's opinion is that to resolve an identified dosing red flag within the standard of care, a Florida pharmacy registrant would be required to demonstrate documented ''careful justification of why [the patient] would need so much [medicine] or the attempt of trying to lower it to a safer dose with the physician.'' Tr. 409. [The Chief ALJ determined that the standard outlined by Dr. Schossow was too onerous to impose on pharmacists. However,] there is a sufficient lack of documentation in this case that it is not necessary to reach the issue of whether Dr. Schossow's elevated standard of documentation delivered here meets or exceeds the required threshold. [Respondent's failure to document any resolution of this red flag was outside the usual course of professional practice, and a violation of its corresponding responsibility.]

[34] The witness defined therapeutic duplication as when two controlled substances that act pharmacologically the same are prescribed together. Tr. 335–36.

[35] [Omitted for clarity].

[36] Tr. 307.

[37] In one particular note for Patient LH, the Respondent wrote that the patient lived in Naples, Florida. Tr. 380; Gov't Ex. 32 at 80. The witness testified that this type of notation is insufficient and that the standard of care requires communication and documentation regarding whether the patient is actually driving. Tr. 380.

particular prescription of ''cash'' means that the price of the prescription was not ''charged to an insurance company, or worker's comp.'' [38] Tr. 222–23. The Government's expert explained that, in her opinion, if a patient did pay in ''cash'' that she would assume the patient had insurance but was choosing not to utilize their insurance; a scheme she explained, in her experience, is practiced by drug diverters.[39] Tr. 223–28. Dr. Schossow admitted that she could not know for certain whether a patient had insurance or not simply by seeing the notation ''cash'' on a prescription. Tr. 226. The witness also acknowledged that where a pharmacy is out of network, the customer patient can submit the insurance reimbursement claim to the insurer. Tr. 537. According to Dr. Schossow, in order to resolve a cash red flag, within the standard of care, a Florida pharmacist is required to ask the prescribing physician whether the patient has insurance and document the finding.[40] Tr. 228–29, 239, 306. A notation by the pharmacy staff that a customer-patient did not have insurance coverage [41] was, in Dr. Schossow's view, insufficient to resolve the red flag of cash payment. Tr. 367, 374, 428. Even a case where the registrant pharmacy documented that it was not contracted with the customer-patient's insurance carrier was insufficient to satisfy the standard outlined by Dr. Schossow based on her expressed innate suspicion of a customer who would not, on that occasion, seek out a different pharmacy that accepted the prescription coverage benefit.[42] Tr. 411. [Omitted for brevity. The Chief ALJ found that Dr. Shossow's testimony about this red flag was not convincing and that her standard for resolving this red flag was too burdensome and illogical to set the minimum standard of care in Florida. The Chief ALJ did not sustain the Government's allegations regarding this red flag, and the Government took Exception to this finding. As discussed below, I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest. [43] [44] [45] [46] [47] [48] [49] [50]

Overall, Dr. Schossow's testimony, although not without its warts, was generally authoritative and amply supported by the admitted evidence of record. While her overall presentation was generally objective, her [testimony that she] ''had a lot of patients in the community arrested for opioid and other controlled substance fraud and abuse,'' [51] and her underlying assumption that customer-patients should be assumed to be abusers [52] (although she had no information that this may have been the case regarding any of the Ten Patients), [53] were certainly concerning aspects of her testimony. [It was also concerning that Dr. Schossow testified that] she had been a member of the Florida Board of Pharmacy and then denied that this was ever the case. [Omitted for brevity. I agree with the Chief ALJ that this testimony was confusing, but there is insufficient evidence on the record about how the Board operates and what role Dr. Schossow was referring to that would permit me to ascribe any level of intent to Dr. Schossow regarding this statement. Based on my review of the record, I did not discern any intent to mislead the Tribunal, but certainly at least her initial statement gave an incorrect impression and I consider this statement in the same manner as the Chief ALJ did below.]

Dr. Schossow's testimony also contained isolated occasions where she arguably presented as confusing,[54] defensive, even bordering on evasive, [55] and the ''on-the-Board''/''not-on-the-Board'' feature was [confusing], but she has no objective stake in the outcome of the proceedings, and there is nothing present in the record or her testimony that would mortally undermine her credibility and reliability. On those points where her testimony was found reliable and persuasive in this RD, the witness provided sufficient, detailed, cogent support for her views. Of the two experts who testified in these proceedings, her shortcomings notwithstanding, she is the more reliable and persuasive, and where her testimony was at variance with the Respondent's expert, it is Dr. Schossow's opinion which will be relied upon.

The Respondent's Case [*D]

The Respondent's case consisted of testimony from the Respondent's owner and an expert witness.

Dr. Daniel E. Buffington, Pharm.D.

The Respondent presented the testimony of Dr. Daniel Buffington, Pharm.D. Dr. Buffington's CV [56] reflects that he earned his Doctorate in Pharmacy in 1987, completed a pharmacy residency in 1988, and concluded a pharmacy fellowship in 1989 that focused on pharmacy practice and clinical pharmacology. Tr. 792–94; Resp't Ex. 12. The witness testified that he has held a faculty position at the University of South Florida, Colleges of Medicine and Pharmacy since the early 1990s, along with various other academic appointments and positions where he has taught a myriad of topics regarding pharmacotherapy and clinical pharmacology. Tr. 792, 794–95. Dr. Buffington explained that, although he is not licensed as a consultant

[38] During the course of his testimony on the issue, the Respondent's owner testified that ''cash'' can mean currency, a credit card, or a check. Tr. 635.

[39] The Government presented no evidence that any of the Ten Patients were or are drug diverters. This assumption played no role in the Government's noticed theory of its case. ALJ Ex. 1.

[40] According to Dr. Schossow, a notation that simply states that the patient does not have insurance is insufficient to meet the standard of care in Florida. Tr. 374. Dr. Schossow explained that even where a prescription contains such a notation, it is incumbent upon the pharmacist to contact the prescriber to ensure a true lack of insurance, Tr. 374, but conceded that ''many'' of the prescriptions she reviewed in this case did have an indication from the prescriber that the customer-patient was uninsured, Tr. 471. Thus, by Dr. Schossow's view, even where the pharmacy has apparently determined that the customer-patient is without prescription insurance coverage and documented that conclusion on the relevant scrip, the additional step of contacting the *prescriber* and documenting the results of that conversation are required to meet the minimum standard of care in Florida. As discussed, *infra,* this makes no sense.

[41] *See, e.g.,* Gov't Ex. 32 at 13 (pharmacy note entered outside the charged conduct period reflecting the Respondent's conclusion that Patient CW paid cash because she did not have insurance).

[42] [Footnote omitted where text was deleted.]

[43] [Footnote omitted where text was deleted.]

[44] [Footnote omitted where text was deleted.]

[45] [Footnote omitted where text was deleted.]

[46] [Footnote omitted where text was deleted.]

[47] [Footnote omitted where text was deleted.]

[48] [Footnote omitted where text was deleted.]

[49] [Footnote omitted where text was deleted.]

[50] [Footnote omitted where text was deleted.]

[51] Tr. 137.

[52] Tr. 368.

[53] Tr. 444–45.

[54] *See, e.g.,* Tr. 399–408. The witness volunteered that the pharmacy notes she was reviewing on the stand were not the same as the notes she reviewed prior to her testimony. *Id.* This anomaly was never cogently explained by the witness. [Omitted for brevity. I agree with the Chief ALJ that there was no ''cognizable prejudice to the interests of justice or the Respondent's case'' from Dr. Schossow's confusion about which notes she reviewed before the hearing, because Dr. Schossow was clear during her testimony about what materials she reviewed and how she formed her opinions.]

[55] *See, e.g.,* Tr. 243–44 (multiple attempts taken to get the witness to state that the paperwork she examined did not have any indication as to whether the customer-patients had insurance with prescription drug coverage); Tr. 291–93 (significant equivocation on whether identified red flags are resolvable, and if yes, how so); Tr. 448–49 (significant equivocation on answering whether, during her analysis, she had identified violations beyond failure to document red flag resolutions); Tr. 451–52 (significant equivocation in addressing the straightforward question of whether she had ever read the footnotes, any of the footnotes, in a specified guidance document issued by the CDC).

[*D] Throughout the Respondent's case, I have made some minor adjustments to the wording where noted for brevity and for clarity and to reflect more of my style. *See supra* n. *C.

[56] Resp't Ex. 12.

pharmacist in Florida,[57] his pharmacy background has included some consultation, clinical research, and pharmacy work as both a clinical and retail pharmacist. Tr. 796–97. His current business, Clinical Pharmacology Services ''is a licensed pharmacy [that] also provides direct patient consultation, manages clinical research trials, and provides drug information support for health systems, medical practices, but also forensics for law enforcement, government agencies.''[58] Tr. 796. The witness testified that he has also served as an expert in numerous state and federal cases and has participated on panels relative to Florida legislative initiatives regarding administrative code provisions. Tr. 814–15. Dr. Buffington was tendered[59] and, without objection from the Government, accepted[60] as an expert witness in Florida pharmacy practice under Florida and federal standards, and the standard of care for pharmacists practicing in the state of Florida.[61] Tr. 813.

According to Dr. Buffington, under the applicable standard of care for dispensing controlled substances in Florida, a pharmacist is expected to assess every new and refill prescription presented to them by a patient.[62] Tr. 823. Dr. Buffington summarized his view of applicable statutes governing the standard in Florida as follows:

> [T]he pharmacist as the specialist in this area of pharmacology and drug-related issues is expected, per Florida Board of Pharmacy and regulations, to do [sic] on each new and refill prescription, to evaluate, prior to dispensing, seven key criterions that look at common drug-related problems. Some of those may be drug interactions or duplications in therapy, dosing, drug allegories, wide variety.

Tr. 823. Regarding the issue of documentation, the witness holds the view that there is essentially no requirement that a pharmacist document any analysis employed for resolving any red flag issue that arises relative to potential controlled substance diversion so long as the medication is ultimately dispensed. According to Dr. Buffington, the Florida state standard of care is also apparently dependent upon whichever commercial software system any pharmacy elects to purchase and utilize. The colloquy between the Respondent's counsel and its expert is [notable]:

> Q. Does the standard of care in Florida require that a pharmacist document, at all, resolution of any issues by the prospective drug utilization review?
>
> A. No, sir. It's the pharmacist's individual prerogative and up to their system. In some cases, their pharmacy software system may afford some of that by process. Others, there's data entry fields. It doesn't have to be solely contained in the pharmacy software. It can be in secondary software. It can be hand-written. It can be maintained in a variety of ways. They leave that up to the personal judgment and prerogative and systems at each pharmacy.

Tr. 823–24. When asked to clarify if the standard really depends on something as subjective and unregulated as what commercial software is employed by individual pharmacies, the [Respondent's expert testified]:

> No, sir. I'm saying it's up to the pharmacist as to which method, or collective methods, they wish to document. There is no format. There is no content-specific requirements with which a pharmacist has to document the addressing of those issues.

Tr. 824. By this view, a pharmacy that elects to purchase a substandard software system apparently can generate a lower standard of care than a pharmacy that acquires a more vigilant system. By this same reasoning, a pharmacy could even potentially escape regulatory scrutiny by the acquisition of a subpar software system. Suffice it to say that the notion that state and federal regulators intended to design a system that creates a perverse incentive to deploy bad software to dodge responsibility is unpersuasive. When asked again for clarification, the Respondent's expert, after some [discussion] about whether DURs and red flags[63] are homonyms, stated his opinion:

> [T]here is no requirement for the documentation of red flags, or DURs, in the State of Florida. There is opportunity to document. There is a requirement, or a duty, to address those items. The—the—the DURs. There is no Florida-based, or DEA-based recognition for documenting red flags.

Tr. 825.

The Respondent's expert later clarified that while processing a DUR, that even when a pharmacist encounters a potential red flag issue through its software, if ''it didn't need resolved, there's no need to record it.'' Tr. 913. Documentation, according to Dr. Buffington, is only required ''[i]f there's something to resolve.'' Tr. 914. When asked if a heightened level of suspicion that supported a decision to decline to dispense would ever merit some level of documentation, Dr. Buffington [testified]: ''Well, first of all, I'm going to work through whatever that question or suspicion is, and *it's not going to be documented—or, it's not going to be dispensed*.'' Tr. 917 (emphasis supplied). Following this approach, a pharmacist can subjectively determine that there is no issue to be resolved, document nothing, and be within the Florida standard of care. And since nothing is documented, the only correct assumption available to regulators, according to the Respondent's expert's view, is that everything was correctly assessed and resolved. [Omitted.] Thus, according to Dr. Buffington, there is no requirement under the applicable standard of care to document any resolution regarding any indication of diversion on the part of any patient or prescriber, no matter how egregious or how potentially dangerous, so long as the decision was ultimately made to dispense.

Dr. Buffington [also testified that the phrase] ''if it wasn't documented, it wasn't done'' has no application to a pharmacy's obligation to document the resolution of red flags because there is no obligation to document the resolution of red flags.[64] Tr. 825–26. [Dr.

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[57] Tr. 793.

[58] Dr. Buffington explained that his work includes consulting with retail pharmacies regarding their compliance with relevant Florida law provisions. Tr. 816.

[59] Tr. 799–800.

[60] During *voir dire,* the witness was combative and evasive even in answering straightforward questions regarding his qualifications. *See, e.g.,* Tr. 805–09.

[61] Tr. 799.

[62] The witness testified that in preparation for his testimony he reviewed relevant Florida administrative code sections. Tr. 815. In evaluating the role of an expert witness in the pharmacy context, the Agency has held that a pharmacy expert is ''not [expected to be] an expert in the details of state law, but [ ]he is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in [his] state, whether that is derived from state law, mandatory training, standards of care or otherwise.'' *Suntree Pharmacy,* 85 FR 73,772.

[63] In fact, the Respondent's expert communicated a certain hostility to even the concept of red flags, pointing out during his testimony that red flags is ''a colloquial term,'' Tr. 832, and in the guidance issued by Florida and DEA ''there are no definitions of red flags, nor is there any published requirement that guides pharmacy practice on what, and how, to document those,'' Tr. 825. At another point in his testimony, the witness stated he would not document the resolution of a controlled substance red flag because he ''can't find a consistent definition of that colloquial term.'' Tr. 936–37. This proposition [is inconsistent with] many years of Agency adjudication addressing red flags of potential diversion [supported by credible expert testimony] and longstanding acceptance of the term. *See, e.g., Suntree Pharmacy,* 85 FR 73,769 (''When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription.'') (collecting cases); *Morning Star Pharmacy & Medical Supply 1,* 85 FR 51,045, 51,060 (2020) (same).

[64] The witness was unpersuaded by the argument that without adequate documentation another pharmacist encountering the same customer-patient would be without knowledge of a red flag determination made by a predecessor pharmacist or be able to pass down information to a successor pharmacist. Tr. 960–61.

Buffington testified that pharmacists are not obligated] to document the resolution of any controlled substance red flag because he ''can't find a consistent definition of that colloquial term.'' Tr. 936–37; *see also id.* at 940, 945. The witness suggested that requiring a level of documentation beyond this minimalist view would require the use of ''court reporters in the pharmacy.'' Tr. 939. [Omitted for brevity.] For, as Dr. Buffington reasoned, it is the pharmacist alone who exercises ''professional prerogative,'' and as he, himself put it, ''someone else not understanding the core facts of [his] job doesn't make what [he's] doing incorrect.'' Tr. 915–16

Dr. Buffington [offered an interpretation of Florida law that was not persuasive. Tr. 826–27, 924 (discussing subsection (3)(a) of rule 64B16–27.831 of the Florida Administrative Code (Florida Pharmacy Standards Statute or FPSS).] Subsection (3)(a) of the FPSS lists steps to be taken by a pharmacist before *declining* to dispense a controlled medication. Fla. Admin. Code Ann. r. 64B16–27.831(3)(a). The FPSS requires a pharmacist to reach out to the patient and prescriber, or check E–FORCSE in place of either (but not both) of those contacts prior to *declining* to dispense a controlled substance. *Id.* r. 64B16–27.831(3)(a), (b). [Although Dr. Buffington agrees that a pharmacist must document his decision to *decline* to fill a prescription, *see* Tr. 827, he does not believe that a Florida pharmacist has a] duty to evaluate the validity of the prescription or to document his/her analysis or findings [if the pharmacist ultimately fills the prescription.] There is no exposure so long as he/she dispenses the drugs. [This testimony is inconsistent with the] FPSS and other provisions of Florida law. The FPSS specifically instructs:

> There are *circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance;* however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

Id. r. 64B16–27.831(2) (emphasis supplied). It is clear that in its description of ''circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance,'' the Florida legislature was referring to what has been ubiquitously referred to by DEA, the regulated community, and the industry, as a red flag of potential diversion. Upon encountering one of these, the FPSS directs pharmacy practitioners to consult with the prescribers, patients, and/or E–FORCSE. The opening section of the FPSS instructs that ''[p]harmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the [controlled substance] prescription.'' *Id.* r. 64B16–27.831. Thus, upon encountering a ''circumstance that may cause a pharmacist to question the validity of a prescription for a controlled substance'' [65] (*i.e.,* a red flag of potential diversion), a pharmacist must reach out to either the prescriber or the patient, and where appropriate, in place of one of those two sources (but not both) the pharmacist may resolve a red flag by utilizing E–FORCSE. *Id.* The Florida legislature has also directed that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' Fla. Admin. Code Ann. r. 64B16–27.800(2) (Florida Pharmacy Patient Record Statute or FPPRS). The FPPRS also directs pharmacists to create a record of ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* r. 64B16–27.800(1)(f). Hence, contrary to Dr. Buffington's view, under Florida law and the applicable standard of care, a pharmacist who encounters a red flag is required, before resolving the red flag [and filling the prescription], to contact the prescriber and/or patient and is required to document both of those interactions.[66] [*E]

Contrary to Dr. Buffington's testimony that [it should be assumed that a pharmacist has resolved any potential red flags if he decides to fill the prescription], the Agency has made it clear that it is unwilling to credit ''[*p*]*ost hoc* written or oral justifications'' for actions taken as a registrant that were not documented, *George Pursley, M.D.,* 85 FR 80,162, 80,171 n.28 (2020); *see Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019). In fact, the Agency has accepted the premise that ''it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution in any manner . . . .'' *Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31,310, 31,335 (2016). [Omitted for brevity].

Dr. Buffington also testified that filling combination prescriptions of higher dosages of short-acting medications and lower dosages of long-acting medications does not fall below the standard of care.[67] Tr. 877. Likewise, the witness rejected medication combinations referred to as ''cocktails'' as a red flag, stating that ''[e]very patient who has multiple drugs in their regiment is a cocktail [sic].'' Tr. 955. The witness opined that simultaneously dispensing such combinations (either opioids and benzodiazepines, or opioids, benzodiazepines, and muscle relaxers) ''[a]bsolutely [does] not'' fall below the applicable standard of care for Florida pharmacists. Tr. 863–64. Dr. Buffington explained that the presentation of such controlled substance combinations is ''not a potential issue, the fact that it may have been flagged in a DUR, unless the patient is experiencing complications.'' Tr. 865. This view is not only inconsistent with the opinion of Dr. Schossow, but also the view of the Agency, which has sustained cocktail combinations as red flags of potential diversion requiring documented resolution. *See, e.g., Suntree Pharmacy,* 85 FR 73,756 (acknowledging that DEA ''has long discussed cocktails'' as a red

[65] *Id.* r. 64B16–27.831(2).

[66] Dr. Buffington's opinion that there is no requirement for a Florida pharmacist to consult with prescribers regarding the existence of a clinical plan, tapering, or titration (Tr. 828) [is also not credible].

[*E] The Chief ALJ's interpretation that Florida law requires pharmacists to document the resolution of red flags is supported by a plain language reading of the various provisions of the Florida Administrative Code and by credible expert testimony about the importance of documentation in Florida. I agree with the Chief ALJ's interpretation, and I agree with his conclusion that Respondent violated Florida law by failing to document the resolution of red flags. However, my Decision does not rely on any interpretation of Florida law, because, in failing to document the resolution of red flags, Respondent violated federal law in addition to state law. Dr. Schossow offered credible expert testimony that failing to document red flag resolution is outside the usual course of professional practice in Florida. Although Dr. Buffington offered conflicting testimony that documentation is not required in the usual course of professional practice, I agree with the Chief ALJ that Dr. Schossow's testimony regarding documentation requirements was considerably more credible. Thus, as discussed in more detail *infra,* I find that Respondent repeatedly violated federal law by filling numerous prescriptions outside the usual course of professional practice without adequately addressing, resolving, or documenting red flags in violation of its corresponding responsibility. *See* 21 CFR 1306.04(a) and 1306.06. Respondent's violations of federal law serve as an independent basis for my conclusion that Respondent's registration is inconsistent with the public interest and that revocation is the appropriate remedy in this case.

[67] The witness reasoned that such occurrences can happen because ''[y]ou build a therapeutic regimen that meets that patient's specific needs and lifestyle.'' Tr. 876. ''[Y]ou don't see that and assume that it's somehow indicative of inappropriate patient care.'' Tr. 878.

flag issue). Furthermore, Dr. Schossow's view of the appropriate uses of immediate-release and extended-release medications is more persuasive than Dr. Buffington's summary dismissal of the issue.

The witness was likewise dismissive in considering the applicability of the CDC Guidelines issued in 2016 regarding controlled substance dispensing. Dr. Buffington testified that the CDC Guidelines had no impact on the standard of care for pharmacists practicing in Florida. Tr. 819, 907–08. According to the Respondent's expert, the CDC Guidelines amount only to a ''recommendation to help educate physicians,'' and a mere ''guideline, or recommendation.'' Tr. 820; *see also id.* at 903 (''Typically all guidelines are recommendations, or instructional for—they're not thresholds or limitations on practitioners.'').

[However,] the CDC Guidelines reveal considerable specificity in their guidance to prescribers (and by extension, to pharmacists [filling prescriber's prescriptions]), including advisals to commence opioids at the ''lowest effective dosage,'' preferences for immediate-release over extended-release opioids at the commencement of opioids as a pain treatment modality, specific guidance regarding MME levels exceeding 50, and a preference for ''[n]onpharmacologic therapy and nonopioid pharmacologic therapy'' for chronic pain. ALJ Ex. 39, Attach. A at 16. Although the issue in this case is whether a particular prescription raises a red flag of potential diversion, Dr. Buffington altered the subject into whether the CDC Guidelines imposed a ''hard stop, hard block, or change'' on prescribers,[68] which [is not relevant to the Government's allegations. Although Dr. Buffington is correct that the CDC Guidelines do not impose a ''hard stop,'' the Guidelines issue clear guidance to medical professionals about prescribing high dosages of opioids:]

> Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

ALJ Ex. 39, Attach. A at 16. At another point in his testimony, Dr. Buffington allowed that the CDC Guidelines advise practitioners to ''use caution if [they]'re getting to 90 [MME], or be very clear that [they] understand and have a rationale for doing that.'' Tr. 908. Whatever be the limits of the finer points of the CDC's guidance, to dismiss an encountered titration that exceeds 90 MME/day as an insignificant non-issue to pharmacy practice is not a fair inference that can or should be drawn by the plain language of the CDC Guidelines. Neither is the subsequent policy clarification[69] (CDC Clarification) issued by the CDC particularly supportive of Dr. Buffington's premise that it was issued to address ''key areas where the [CDC] realized people, or courts, may be misrepresenting the [CDC G]uidelines as a fixed or regulatory threshold.'' Tr. 830–31. The principal focus of the CDC Clarification was focused on ensuring that practitioners did not read the CDC Guidelines as supporting dangerous, sudden, and drastic discontinuations of opioid therapy to the detriment of patients. ALJ Ex. 39, Attach. B at 1–2. There is nothing in the plain language of the document that runs counter to identifying a red flag of potential diversion under the appropriate circumstances based in some part on high opioid dosages.

The witness was similarly dismissive in addressing a warning[70] issued by the U.S. Food and Drug Administration (FDA) concerning the extreme dangers posed by combining opioids and benzodiazepines (the Black Box Warning). ALJ Ex. 39, Attach. C. The Respondent's expert acknowledged that a black box warning connotes a ''heightened level of warning,'' that should inform a pharmacist's decision making, but insisted (despite the FDA's decision to issue the warning) that it contained no new information and was merely an advisal to prescribers that these ''very low incident'' complications could occur. Tr. 909. Although in its drug safety communication setting for the Black Box Warning, the FDA refers to black box warnings as its ''strongest warnings,''[71] the Respondent's expert [did not consider the warning to be notable, and further testified that ''the combined use of the two [medications] presents no complication or problem for healthcare professionals specifically in chronic pain . . . .'']. Tr. 909, 959. This view arguably stands in some tension with the plain language contained in the Black Box Warning:

> *Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate.* If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. *Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants,* including alcohol.

ALJ Ex. 39, Attach. C at 1 (emphasis supplied). Although Dr. Buffington reads the Black Box Warning as an authorization to continue to use (not limit) this combination,[72] the FDA apparently holds the view that health care officials should limit the combined prescribing of opioids and benzodiazepines to situations where other treatment options are inadequate. *Id.* Notwithstanding this limitation (couched in directive, not passive language), Dr. Buffington's position is apparently that the ''avoid'' aspect of the warning should be deemphasized over a recognition that the two medications can be prescribed together. In any event, the Government never argued that the combination is *per se* prohibited, but rather that the combination raises a dispensing red flag that requires documented resolution to meet the standard of care. [Relocated]

In specifically addressing cash red flags, the Respondent's expert opined that ''the method of payment is somewhat irrelevant'' and that the standard of care ''[a]bsolutely [does] not'' require pharmacists to investigate the rationale for a customer-patient utilizing cash payments or insurance. Tr. 833–34; *see also id.* at 953. Dr. Buffington reasoned that pharmacists ''have that capacity to understand that patients' payment methods often ebb and flow based on [insurance] coverage. . . . There are just so many variables that there is no predictive validity, or use, of presuming cash payment to be a problem.''[73] Tr. 833. Regarding the position of the Government's expert that a pharmacy is required to contact a prescriber to confirm prescription coverage details, Dr. Buffington persuasively testified that a ''medical benefit does not always coincide with a drug-spend benefit.'' Tr. 834. While this perspective is reasonable, declaring cash as *never* a relevant consideration [is not balanced and not credible]. The view of the Respondent's expert that cash is always patently irrelevant to the evaluation of dispensing events is in considerable

[68] Tr. 830, 862–64.

[69] ALJ Ex. 39, Attach. B.

[70] Also known as a boxed warning.

[71] ALJ Ex. 39, Attach. C at 1.

[72] Tr. 909.

[73] Dr. Buffington reasonably opined that requiring a pharmacy registrant to reach out to a physician's office to investigate a patient's insurance coverage is idiosyncratic because the insurance coverages are different. Tr. 834.

tension with the Agency's view based on credible expert testimony. *See, e.g., Suntree Pharmacy,* 85 FR 73,757 n.13 (sustaining ALJ's finding based on credible expert testimony ''that cash is a red flag in combination with other red flags''); *Pharmacy Doctors Enters.,* 83 FR 10,876, 10,891 (2018) (same). As can fairly be stated about other aspects of Dr. Buffington's presentation, he was inconsistent regarding this issue. At another point in his testimony the witness seemed to nominally retreat from this absolutist opinion and suggested that cash could indeed potentially be a red flag. Tr. 955. This was confusing. As discussed elsewhere in this recommended decision, although the rationale of the Government's case for cash as a red flag in the present case (*to wit,* the pharmacy must call the doctor regarding pharmacy insurance coverage) was unpersuasive, [I also decline to credit Dr. Buffington's testimony that cash payments are never a red flag.[74] *See infra* for further discussion of cash payments. Omitted for brevity].

The Respondent's expert similarly dismissed any considerations of long travel distances as a potential red flag. When asked whether distance could be a potential red flag, his response was ''[a]bsolutely not.'' Tr. 948. Beyond his eminently valid point that a pharmacist possesses no capacity to limit the driving habits of its customer-patients beyond recommendations,[75] Dr. Buffington was unequivocal in his rejection of the whole concept, declaring:

> There's no logical rationale, or supportable—and certainly no regulatory—oversight over that. You could live in the [Florida] Keys and fill in the [Florida] Panhandle. You could fill at a pharmacy you prefer, or have worked with, where you lived previously. One that's—there are just so many variables, from your home, your office, your doctor's office—it's purely your choice as a consumer. There's no predictive validity that where—in fact, you can fill out-of-state. There's not a problem for your prescription. So, there is just no utility in attempting to use that as a metric.

Tr. 834–35. The witness opined that ''distance is of no predictive value in and of itself . . . .'' Tr. 949. [He testified that he was not obligated] to document a distance red flag, adding ''I have no obligation to take someone else's variable and write something down.''[76] Tr. 951. Certainly, Dr. Buffington's broad denunciation of distance as a red flag is directly contrary to [prior Agency decisions based on credible expert testimony]. *See, e.g., Heavenly Care Pharmacy,* 85 FR 53,402, 53,417 (2020) (recognizing based on credible expert testimony long distance as a valid red flag); *Pharmacy Doctors Enters.,* 83 FR 10,885 (same); *Hills Pharmacy, LLC,* 81 FR 49,816, 49,839 (2016); *Holiday CVS, L.L.C.,* 77 FR 62,316, 62,321–22 (2012) (same); *E. Main St. Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (same). [Omitted for brevity.] As was not uncommon throughout the course of his presentation, Dr. Buffington produced an answer favorable to the Respondent by changing the question. When *asked* if distance could support a diversion red flag (*i.e.,* an issue to be resolved prior to dispensing), the witness *answered* the question of whether such an issue was potentially *resolvable,* which was a premise that comprised no part of the Government's case. [Omitted for brevity.] Although the rationale employed by the Government's expert (motor safety) was unpersuasive in this case, the categorical dismissal of distance as a red flag under all circumstances detracted from the reliability that should be afforded to Dr. Buffington's testimony.

The witness similarly transposed the issue of illogical medication dosing combinations as a red flag. When queried on the subject, Dr. Buffington [changed] the issue into whether such dosing variations between extended-release and short-acting medications were inappropriate under *all* circumstances, which was [not the Government's or Dr. Schossow's theory]. Tr. 877–81. The issue in the case is whether the Respondent pharmacy was presented with a red flag that required follow-up, resolution, and documentation. Like most red flags, the question presented may be (and often is) subject to resolution. Dr. Buffington's view on the issue of illogical medication dosing is divergent from that of Dr. Schossow, but the Government expert's testimony on this issue was better explained, more persuasive, less evasive, and more reliable.

[The Chief ALJ questioned the credibility of Dr. Buffington's testimony that he performs physical examinations on pharmacy customers. Tr. 920–21. I agree that this testimony was unusual, but I have omitted the discussion as it does not ultimately impact my Decision.]

The Respondent's expert testified that he reviewed the relevant documents[77] for the Ten Patients from the Respondent pharmacy and testified that the Respondent's controlled substance dispensing did, in his opinion, meet the standard of care in Florida for each of the prescriptions at issue in this matter. Tr. 845, 850–51, 859, 881. Dr. Buffington testified that he saw no deviation from the standard of care on the part of the Respondent in terms of over-utilization and under-utilization,[78] therapeutic duplication,[79] drug-disease interactions, drug-drug interactions,[80] drug dosages or treatment,[81] drug-allergy interactions, and clinical abuse and misuse.[82] Tr. 845, 854, 863, 865, 868–69.[83] Although it was never

[74] [Omitted.]

[75] Tr. 873.

[76] After repeatedly [testifying that distance was not] a potential red flag issue, the witness testified that he ''already said it could'' be a red flag. Tr. 952. At another point in his testimony, the witness, in response to a direct query of whether distance could ever be a red flag, [testified]: ''It could, but I've already stated we already have methods for dealing with that, and I wouldn't call it a red flag.'' *Id.* at 954. [Omitted for brevity.] The inconsistencies further denigrated any ability to credit Dr. Buffington's opinions.

[77] Dr. Buffington testified that, in addition to the Government Exhibits, he also reviewed Proposed Respondent Exhibits that were not offered or admitted during the course of the hearing. Tr. 845, 880.

[78] The witness testified that this is ''a patient-specific issue.'' Tr. 852. This is another instance where the witness replaced the issue posed with one that [he preferred to discuss]. When asked about under-utilization, something that could potentially be a red flag of abuse requiring resolution, the witness substituted his analysis that the CDC Guidelines placed no hard cap on MME levels, Tr. 853–57, which was not among the Government's theories. The issue in the case was never whether a prescriber can elect to use his/her professional judgment, but whether a particular dosage strength can raise a potential red flag requiring inquiry, resolution, and documentation. The witness's responses on this issue were also (as many other answers were) seemingly dependent upon the limits of the commercial software purchased by an individual pharmacy, which, as discussed in detail, *supra,* cannot serve as a reasonable, objective yardstick for whether a DEA pharmacy registrant has met the applicable standard of care.

[79] The witness defined therapeutic duplication as when two medications of the same class, or two medications with the same pharmacologic effect, are prescribed together. Tr. 854–55.

[80] Dr. Buffington explained that when a pharmacist encounters a drug-drug interaction, they are ''looking for predominantly metabolism, secondarily effects as to whether or not that potential for conflict is going to either create an adverse side-effect or potentially, some medications may bind to the other'' rendering it therapeutically useless. Tr. 861.

[81] This specific category was explained by the witness to typically be presented as a miss-fill on the part of the pharmacist or a scrivener's error on the part of the prescriber. Tr. 868.

[82] Dr. Buffington differentiated between abuse and misuse by explaining that ''abuse could have the ill intent to produce some effect . . . that that medication has,'' while ''[m]isuse may in fact be that the individual is not taking the medication properly, so poor compliance.'' Tr. 870.

[83] Regarding Patient JM, Dr. Buffington testified that the customer-patient receiving Restoril and Xanax at the same time ''would not present a problem that needed resolved, unless, in fact, in the dialogue and counseling with that patient, you've identified a clinical concern where the patient is expressing they're not getting therapeutic benefit or possibly too much therapeutic benefit.'' Tr. 856.

entirely explained how he reached this supposition, Dr. Buffington testified that it was his understanding that each of the prescribers associated with the Ten Patients was a pain management specialist. Tr. 867. Whether this was the case or not, or how heavily this factor may have weighed into his metric, this assumption appears to have [impacted] his analysis. For each category, Dr. Buffington testified that a showing or ''hit'' of one of these categories simply requires an evaluation on whether the patient is experiencing complications or side-effects, and the absence of complications or side-effects means the ''hit'' does not rise to the level of a clinical problem. Tr. 855–58, 860, 862–63, 865, 870. The witness testified that ''[t]hese are categories that the Board of Pharmacy is saying you should evaluate these issues [sic] and determine in your professional judgment if there is something to avoid or resolve and that's the issue.'' Tr. 862. When Dr. Buffington was asked whether the presence of an opioid and a benzodiazepine would present a drug-drug interaction DUR, he replied in the following confusing way:

> No. Because those two are used routinely together. Now, could you—in other words there's no certainty that that software system is going to flag the two of those—that's something that the practitioner will understand. It may, based on the vendor who made the software or the pharmacy who added an additional manual edit to be part of that process, but none of these are hard stops with any regulatory oversight.

Tr. 862. In specifically addressing duplicate therapy in regards to Patient JM, Dr. Buffington provided, ''The mere presence of the two together do[es] not create the red flag. It's as though someone is creating or propagating the fact that if the two appear, materialize in the same regiment that it is wrong. It is not wrong unless problems ensue . . . .'' Tr. 968–69. The witness consistently alluded to a high level of deference and prerogative left, at least in his view, exclusively (and apparently un-reviewably) to the dispensing pharmacist, when he explained that for any of the categories, documentation is required only if an issue is identified (by the pharmacist). Tr. 866.

As discussed, *supra,* a recurrent theme in the testimony of this witness was to eschew the issue at hand and substitute an issue he would prefer to address. At one point during his testimony, the witness was asked whether ''patient questionnaires that were presented by [the Respondent] to new patrons . . . [is] something that [pharmacies are] required to maintain by any statute or regulation.'' Tr. 851–52. Dr. Buffington's answer was ''No, just routine practice.'' Tr. 852. Unanswered by the expert here is whether patient questionnaires are required to meet the applicable standard of care as subsumed by both federal and state statutes and regulations, and/or whether the ''routine practice'' employed by Florida pharmacies in his estimation comprises any portion of the applicable standard of care. Similarly, when asked whether there is a requirement for Florida pharmacists to document resolution of over-utilization, under-utilization, therapeutic duplication, and drug-disease contraindications, the witness's answer again injected an intentional level of equivocation:

> Only if you in the course of, normal course of your practice identified there was an issue, a clinical presentation, a concern, something that might be hindering medication compliance and the likes, then, upon recognizing those, if it's a concern during your evaluation, then you could take the steps to avoid and resolve the problem.

Tr. 866. The framework of the witness's answer here, like many of his answers, was unhelpful, and seemingly deliberately so. A red flag indicating a potential diversion issue *is* ''a concern'' or ''an issue,'' or even ''something that might be hindering medication compliance and the likes.'' [84] Thus, the interpretation that nothing is required of the pharmacist upon encountering a red flag creates an unhelpful level of a sort of plausible deniability. Another example of this is apparent in the witness's explanation of subsection (1)(g) of rule 64B16–27.810 of the Florida Administrative Code (Florida DUR Statute), which requires the identification of ''[c]linical abuse/misuse.'' Although the statute supplies no limitation regarding the nature of clinical abuse/misuse, the Respondent's expert explained this aspect of the operation of the Florida DUR Statute in this circuitous manner:

> That means if you've identified as a practitioner that the patient is abusing or misusing the medication, and we state it that way for very specific reasons, abuse could have the ill intent to produce some effect, some main effect or side-effect, that the medication has. Misuse may in fact be that the individual is not taking the medication properly, so poor compliance.

Tr. 869–70. When juxtaposed, Dr. Buffington's dismissal of almost all red flags of potential diversion as nonissues with the pragmatic operation of his interpretation of the Florida DUR Statute is quite interesting. There are virtually no red flags that can or should motivate the pharmacist to resolve prior to dispensing a controlled substance (as opposed to declining to do so), so to the extent the pharmacist intends to fill the prescription, there is no need to contact the prescriber or discuss any issues with the patient.[85] Thus, there is no real way (perhaps short of some extreme demonstration of intoxication or other drug-seeking behavior exhibited by a customer-patient which is observed and conveyed to the pharmacist by pharmacy staff, or other equally unlikely scenario) for the pharmacist to identify abuse or misuse. The pharmacist's obligation under the Florida DUR Statute is [minimized to virtually no obligation, under Dr. Buffington's view].[86] Under an interpretation where there is no obligation to do anything beyond inexorably dispensing medications (with as substandard a software system as can be found), the pharmacy registrant [does not have a meaningful role of oversight]. [Omitted for brevity.]

In opining that the Respondent met its corresponding responsibility, the witness stated that ''corresponding responsibility is specific to that if either party, the prescriber, or the dispenser, knowingly fills a medication that is illegitimate; I saw no evidence that there was any illegitimate medications, prescriptions that were filled in this case.'' Tr. 881. Dr. Buffington made it clear that the decisions made by the pharmacist, in his view, are not amenable to review by others. To the witness, a controlled substance

[84] Tr. 866.

[85] Dr. Buffington restricts a pharmacist's obligation to ''doing a valid check on the legitimacy of the prescription in terms of having done your homework and understanding the prescriber, having done your homework and understanding the patient . . . .'' Tr. 867. There was no clarification from the witness as to what objective steps could or must be invested in ''understanding'' the patient and prescriber, or what any of that means. At another point in his testimony, the Respondent's expert explained his view that validating a prescription would include an evaluation of the scrip, the completeness of the scrip, the prescriber's authority, and whatever evaluation steps are included in the pharmacy software. Tr. 909–10. When pressed upon the issue of whether risk plays a role in the assessment, Dr. Buffington stated that ''every medication has risk'' and based his answer, not on whether a red flag is triggered by the level of risk, but whether a risk, standing alone, constitutes ''a preclusion,'' which he naturally answered in the negative. Tr. 911–12. The issue with red flags in this case, as alleged by the Government, never included a hard preclusion component, but only whether the evidence demonstrated unresolved red flags of potential diversion which remained unresolved and undocumented prior to dispensing.

[86] In responding to a hypothetical, the Respondent's expert [testified] that even if newly-issued CDC guidelines indicated that a medication at a particular dosage level could result in physical harm to the patient, he would continue to dispense based on nothing more than the prescriber's unexplained insistence. Tr. 905.

prescription becomes invalid, potentially unfillable, only when there is a ''[k]nowing that the patient was using the product inappropriately—they were abusing. Knowing that the patient was going to be handed the prescription but was misusing.'' Tr. 914. Interestingly, Dr. Buffington explained that the concept of knowing is based purely on ''professional prerogative,'' [87] that the dispensing pharmacist is ''the one that has to discern if [they] know, or have reason to know—not a third party who's evaluating that.'' Tr. 917. The witness's standard strikes as an unreviewable judgment call on the part of the dispensing pharmacist. [Dr. Buffington appears to believe] that every pharmacy registrant is possessed of essentially un-regulatable, unreviewable authority. [This position is inconsistent with the] highly-regulated field such as pharmacy and the dispensing of controlled substances.

When questioned on an objective component of the concept of knowing, Dr. Buffington explained that, in his opinion, ''[t]he Florida Board of Pharmacy defines that.'' Tr. 921. Dr. Buffington suggested at one point in his testimony that the state standard of care bears no correlation to the regulatory administration of a DEA registration. Tr. 922–23. When pressed on whether his opinion would change to any extent if the Agency had interpreted knowing in a certain way, Dr. Buffington discounted DEA's authority in this way:

> Well they don't have—the DEA doesn't have the training or the expertise, and has never provided a valid instrument that is predictively—with predictive valid—validity—that demonstrates the method they would use to discern that.

Tr. 928.

[The Chief ALJ found that Dr. Buffington was hostile to DEA as a regulator, based on Dr. Buffington's testimony that he does not believe that DEA regulations or Agency decisions inform pharmacy practice in Florida, or that Agency decisions ''even translate[] to something that is enforceable.'' Tr. 930, 947, 983. I agree with the Chief ALJ that this testimony is legally incorrect to the extent that it implies that DEA has no relevance to a pharmacist's corresponding responsibility in dispensing controlled substances. Because of DEA's role in ensuring that controlled substances are distributed only through lawful channels, and its authority to revoke or suspend DEA registrations, it is incumbent on pharmacies to be familiar with DEA decisions and create pharmacy policies that ensure that pharmacists are fulfilling their corresponding responsibility. *See Suntree Pharmacy,* 85 FR 73,753, 73,770 (2020); *see also S&S Pharmacy, Inc.,* 46 FR 13,051, 13,052 (1981). DEA publishes final orders in administrative proceedings involving doctors, pharmacies, and other DEA registrants, which provide final adjudications on the public record of DEA's expectations for current and prospective members of the registrant community regarding their obligations under the CSA, in particular how the provisions of the CSA are adjudicated in enforcement actions.] [Omitted for brevity.]

Overall, even setting aside the multiple inconsistencies, evasiveness, and views he espoused that are directly contrary to the Agency's prior decisions, Dr. Buffington's expressed antagonism for the regulatory authority vested in DEA and the Administrator undermines the weight that can be attached to his presentation. While there is no question that the witness's credentials were impressive, Dr. Buffington [presented as an advocate for Respondent rather than as an impartial expert]. That is not to say that Dr. Buffington is entirely unreliable. This witness is an experienced and well-credentialed professional. There were certainly aspects of his biographical information, the progress of his career, and even some testimony regarding dispensing in general that presented as sensible and consistent with the record. However, where Dr. Buffington's views conflict with the views expressed by Dr. Schossow, at least where her views have been deemed reliable and well-supported in this RD, it is her expert opinion that must be afforded greater weight.

Dr. Aaron Howard, Pharm.D.

The Respondent (while still represented by qualified counsel) presented the testimony of Dr. Aaron Howard, the owner and pharmacist-in-charge (PIC) of the Respondent pharmacy. The witness (Dr. Howard, the Respondent's owner, or the owner) testified that he received his Doctorate in Pharmacy in 2003 and has spent the vast majority of his career as a licensed pharmacist working as a retail pharmacist. Tr. 583–84. His experience consists of work in chain and independent pharmacies, work in a hospital pharmacy,[88] as well as opening and establishing various pharmacies (including the Respondent pharmacy in 2010). Tr. 584–89.

The Respondent, doing business under the name ''At Cost RX,'' is an independent pharmacy and the witness explained that its business model was designed ''to target patients who need prescription drugs who do not have insurance or are under insured.'' Tr. 589–90. Dr. Howard testified that the Respondent pharmacy operates a membership program wherein the majority of its customer-patients pay for their prescriptions in cash. Tr. 590–91. ''[T]hat's [its] whole niche.'' Tr. 591. According to Dr. Howard, upon paying a membership fee, a customer-patient can purchase medications at the Respondent pharmacy for prices below those found in chain pharmacies in the local area. Tr. 591. The discounted price is extended as a benefit of the membership. *Id.* The witness explained that the Respondent's discounted price system and business model is designed to target ''patients who are underserved or do[ ] not have insurance.'' Tr. 1212. The ''At Cost'' name of the pharmacy is designed to convey the Respondent's primary business objective of offering medications to its customer-patients at a discounted price. Tr. 1213. [However, there is] no evidence of record that any of the Ten Patients held memberships to this purported discount program, which renders the force of this evidence as only marginally relevant. While the Respondent employs multiple pharmacists, Dr. Howard testified that he is the owner and the only pharmacist in the organization that dispenses controlled substances. Tr. 605.

Dr. Howard outlined the Respondent's pre-dispensing processes, or drug utilization review (DUR). He testified that he is the person who conducts the DUR at the Respondent pharmacy, [89] that the procedure is conducted as the prescription is being processed, [90] and that these processes have been the subject of some level of evolution over time. Tr. 600. The owner testified that he places his initials on the prescription under review to signify that the DUR steps have been undertaken and completed. Tr. 735–37. Dr. Howard's depiction of the Respondent's DUR strikes as being strongly dependent upon queries generated by the commercial electronic software (RX30) utilized by the pharmacy.[91] Tr. 607–10, 711–13, 736, 758, 1201–02, 1213–14. The owner indicated that the RX30

[87] Tr. 915.

[88] The Respondent testified that in 2003 he worked as a clinical pharmacist at Jackson Memorial Hospital. Tr. 589.

[89] Tr. 710–11.

[90] Tr. 711.

[91] Dr. Howard testified that the Respondent pharmacy has been using RX30 software since 2010. Tr. 1169.

assists him in identifying red flags of over-utilization/under-utilization, therapeutic duplication, and drug-disease contraindication. Tr. 712. When a patient presents at the Respondent pharmacy with a controlled substance prescription, Dr. Howard testified that there are a number of steps that he progresses through to verify the validity of the prescription. Tr. 596. However, he testified that there was no set order for the functions to be completed and memorialized on the prescription.[92] Tr. 770. As initially explained by the witness, where he is unfamiliar with the prescriber, the verification process begins with consulting websites maintained by DEA and the state of Florida to ensure that the prescriber's state license and DEA registration are active and without discipline or restrictions.[93] Tr. 596–97, 600–01. The owner testified that he also reviews the specialty of the prescriber. Tr. 601.

The owner testified that he then converses with the customer-patient regarding ''basic elements, how long they've been taking the medication, why they're taking the medication, things of that nature.'' Tr. 597; *see id.* at 737. To ensure that the presented patient is the patient for whom the prescription was written, the Respondent requires the presenting patient to show a government-issued photo identification card.[94] Tr. 598–99, 737. The next step involves accessing E–FORCSE to ascertain when the patient last had a controlled substance prescription filled. Tr. 597, 736. The owner described the state E–FORCSE database as ''a great tool'' that he uses to look for evidence of patient doctor-shopping, duplicate or inappropriate therapy, as well as early refills, and that he notates the execution of a check of this system on the prescription itself.[95] Tr. 611–13. If a customer-patient is accepted by the Respondent, Dr. Howard explained that he/she will fill out a questionnaire, [96] which may prompt additional questions/conversation with the patient. Tr. 598. Strangely, although the witness claims the questionnaires have been used by the pharmacy since 2015 and are maintained indefinitely, [97] these documents were not produced by the Respondent when it was served with two successive DEA investigative subpoenas requiring, *inter alia,* production of:

> [C]omplete medication or patient medication records/profiles that the pharmacy maintains which documents any and all prescriptions filled by the pharmacy; any and all additional records documenting the steps taken to avoid or resolve any issues with the prescriptions presented by [the named customer-patients] pursuant to the requirements of the Florida Statutes and Florida Administrative Code 64B16–27.800 . . . and, any other documentation kept by the pharmacy in connection with the filling of prescriptions or providing medical treatment for these individuals, including but not limited to dispensing reports, billing records, [E–FORSCE] reports and medical records.

Gov't Ex. 2 at 1; *see* Gov't Ex. 18 at 1. That the Respondent made a choice to hold these documents back from investigators, even in the face of a subpoena, does not further the strength of its position, or its efforts to rely on these items during the course of the hearing. In fact, the adverse inference sought by the Government in this case [98] is appropriately taken here. The Agency has found it appropriate to take an adverse inference where a party has made a ''decision not to provide evidence within its control . . . .'' *Morning Star Pharmacy,* 85 FR 51,063 n.38; *see Pharmacy Doctors Enters.,* 83 FR 10,899. Accordingly, the decision to withhold the documents that were the subject of the subpoena gives rise to the inference (taken here) that the information therein would not be supportive of the Respondent's case; that is, that there was either no helpful documentation in those papers, or that the documentation reflected therein would be detrimental to the Respondent's case.

Although the owner testified that the Respondent's DUR protocol has no set order, [99] he also testified at one point that the last step in the verification process involves reaching out to the prescribing physician's office.[100] Tr. 598. Although, according to the owner, he routinely reaches out to prescribers, he conceded that he does not document the substance of those conversations. Tr. 602–03. He explained that because he is the only pharmacist at the Respondent pharmacy that dispenses controlled pain medication, he keeps this information in his head. Tr. 603–05. According to Dr. Howard, he discusses a wide range of information with the prescribing doctors, such as treatment plans, modifications, and red flags. Tr. 616. When pressed on the issue of whether anomalous information received from the prescriber ever raises a concern that triggers a decision to decline dispensing, the owner would only go so far as to say ''I have done that in the past,'' but he readily admitted that he keeps no list or other documentation concerning the occasions where that has occurred. Tr. 604–05. It is the owner's estimation that he has only run into a single prescriber that he would place in the category of suspicious to the point where the Respondent pharmacy would decline to dispense on his controlled substance prescriptions. Tr. 605. In further explaining the decision not to document prescriber concerns or keep a list of suspicious prescribers, the witness offered the following:

> No, I don't keep a list, you know, because that's an independent judgment call. You know, you can't—well, I've seen people who've gotten in trouble for saying I'm not going to fill this particular physician because of X, Y, Z. I don't think that's legal. I think you can subject yourself to legal ramifications, but my protocol, since I'm the only pharmacist there, if it's something that I don't agree with that has happened with that particular physician, I don't fill it. I don't keep a printout stating that I don't fill these particular physicians.

Tr. 604–05. Thus, the decision not to document or maintain a list of suspicious prescribers is based on the owner's concern that by documenting his analysis or the result of the pharmacy's regulatory obligation to exercise its corresponding responsibility (which he is legally obligated to do), he and/or his pharmacy would be vulnerable to some theoretical legal exposure.[101] This theoretical legal concern seems to be in some tension with the rational and non-theoretical concern that by failing to document the exercise of the pharmacy's

[92] When pressed on the steps taken in the Respondent's DUR protocol, the Respondent's owner/PIC was either unable or unwilling to explain whether the steps occur in a defined order. Tr. 1192–95. There was arguably an evasive quality to the testimonial exchange with questions answered with questions and where a clear message was conveyed that the witness was unwilling to be locked into a set order of steps in the DUR process. *Id.*

[93] After the initial check, the prescriber verification process is performed annually. Tr. 605–06. No documentation was offered to support this step. [Omitted for clarity].

[94] While Dr. Howard testified that he asks for a government photo ID to verify the identity of the customer-patient, he also volunteered that he does not know if this step is a state mandate. Tr. 599.

[95] The majority of these notations consisted of a check mark and ''PDMP'' or ''PMP.''

[96] Dr. Howard testified that the Respondent began utilizing questionnaires in 2015 and that copies of the questionnaires are maintained indefinitely at the pharmacy. Tr. 599–602, 1125.

[97] Tr. 599–602, 1125.

[98] ALJ Ex. 55 at 45.

[99] Tr. 770.

[100] At another point in his testimony, he testified that the last step was filling the prescription. Tr. 1193.

[101] No legal theory was ever offered by the Respondent to support this hypothetical concern of legal exposure for doing its job.

corresponding responsibility, the pharmacy would be subject to a sanction against its DEA registration.

According to the owner, the RX30 is useful in checking for medication conflicts, allergies, and some treatment concerns, which, unlike the corresponding responsibility outcomes and analyses, Dr. Howard claims he does document. Tr. 613–15. Further, the RX30 system automatically prints out some drug-specific information and cautionary information for each patient. Tr. 618–19. The owner testified that, in addition to the RX30-generated patient information, he interacts with and counsels ''each patient'' regularly, inquiring about side effects, efficacy, and observing any overt signs of mobility limitations. Tr. 619–20.

Regarding distance as a potential red flag, Dr. Howard testified that the extent of the Respondent's distance-curiosity extends only to the zip code supplied by the patient-customer. Tr. 635. The witness provided the following elaboration on the subject:

> I look at the patient's Florida ID and I look at the zip code. If it's within the same three-digit zip code of our location, then there's nothing for me to ask pertaining to the patient. If it doesn't, then what I do is I inquire what's the reason why they're coming to our pharmacy . . . [, to ascertain t]he specific reason why they would travel to our pharmacy[.] Is it because of the prices? Is it because, you know – that's pretty much it.

Tr. 635–36; *see also id.* at 738, 1173–74. Thus, it appears that the Respondent looks at the customer-patient's zip code,[102] and if the distance is outside the three digits of the pharmacy's location, the patient is asked whether it is the Respondent's (presumably discounted) prices that has attracted the person to make the trip.[103]

Dr. Howard presented some more specific testimony concerning the Ten Patients that are the subject of the OSC/ISO. He testified that he had some familiarity with Patient JA's medical conditions. Tr. 714–15. According to Dr. Howard he spoke to this patient every month, and discussed his ailments and medications with Patient JA's multiple treating physicians.[104] Tr. 714–716, 739, 750–51. The witness testified that through his review of a prescriber's note on the prescriptions,[105] he was aware that Patient JA had no insurance. Tr. 752–54. His representation of some patient familiarity notwithstanding, beyond being led through some of the Government-supplied prescriptions, the only litigation vehicle apparently available to discuss Patient JA's treatment was to have his (then) counsel repeatedly refresh his recollection by allowing him to peruse excluded/inadmissible pharmacy patient records as he was testifying by VTC.[106] Tr. 741–51, 755–57. Obviously, the weight that can be attached to testimony borne of the essentially ministerial act of a witness reading comments from documents that were insufficiently reliable to introduce into evidence is gravely diminished, but this evidentiary contrivance was endured at the hearing to afford the Respondent every possible measure of due process.[107]

Evidence was presented in like manner regarding his understanding of Patient EA. The Respondent's owner recalled that the customer-patient was overweight, complained of leg pain, worked as a shutter installer, and that he spoke with him monthly. Tr. 762–63. He also recalled having conversations with Patient EA's prescribing doctor. Tr. 772. The remainder of the details were furnished by refreshing the owner's recollection through Government-furnished prescriptions, OOR documents, and reviewing marks he testified that he had placed on dispensed prescriptions. Tr. 764–73, 777–90, 999–1006.

The testimony followed the same pattern regarding Patient SD. The witness testified that he conversed with this customer-patient monthly and communicated with the prescriber. Tr. 1007, 1014. The owner again tracked along with the markings on the prescriptions as a guide to the DUR (which he presented as always being completed), he examined the prescriptions supplied by the Government in its exhibits, and refreshed his recollection with OOR documents as before.[108] Tr. 1007–30.

The same general mechanics were again applied by the Respondent in addressing charged prescriptions regarding Patient LH. The witness testified that he also had monthly interactions with Patient LH, that he was familiar with his prescribing physician, that the handwritten markings on the Government-furnished prescriptions signified that he employed every step of the Respondent's DUR protocol, that he considered any and all red flags, and that he had them conclusively resolved by discussions with the customer-patient prior to dispensing. Tr. 1030–47. Regarding a drug-drug interaction flag that was presented in the OOR documents, and upon realizing that even the documents contained no articulated resolution, the witness [testified]: ''Yeah. I assessed it in my mind. There's no inter—there's no issue with him taking that medication.'' Tr. 1043. On the same red flag, when asked about how the issue was actually resolved, the witness merely added: ''The [RX30] system flags it. I flagged it in my mind that that's not a[n] issue.'' Tr. 1044. Upon a third effort to attempt to help the witness explain how the red flag might have been analyzed and resolved, the owner became visibly impatient and said ''Well I don't know how else to explain it.'' *Id.* [Omitted for brevity.] The rationale here is apparently that because he dispensed the medicine he must have resolved whatever red flags may have been connected with the transaction. Either the witness was

[102] Since no evidence was received regarding the significance of postal zip code digits, this process could not be the subject of any intelligent analysis on the issue of whether it rationally furthered the objective of identifying distance red flags concerning the customer-patients.

[103] [Omitted based on the Chief ALJ's finding that the Government did not adequately prove that long distances traveled were a red flag in this case.]

[104] The witness's memory was refreshed with an excluded exhibit (Resp't Ex. 1(ID) at 49) to relate the existence of a Patient JA questionnaire (and essentially read from it). Tr. 733–34.

[105] *See, e.g.,* Gov't Ex. 5 at 11.

[106] As discussed, *infra,* the Respondent initially offered into the record a set of Proposed Respondent Exhibits (Resp't Ex. 1(ID) at 41–90) that purportedly related to Patient JA. Although untimely, the Government's timeliness objections were overruled to afford the Respondent the maximum level of due process. Tr. 642–60. However, other fundamental issues regarding inadequate foundation and reliability precluded the admission of the tendered evidence as being sufficiently reliable to be considered in this adjudication. *See* 5 U.S.C. 556(d). It is telling that after the anomalies regarding Respondent Exhibit 1(ID) were discovered, the Respondent's (then) counsel did not seek to offer the balance of the Proposed Respondent Exhibits that related to the nine other charged customer-patients. It is reasonable to assume that the unoffered documents suffered from the same reliability issues, but as they were not offered, such an assumption or further discussion is not required. Instead, the balance of those unoffered and outside-of-record (OOR) documents were used by the Respondent to refresh the recollection of the owner for each of the Ten Patients.

[107] No attempt was made by the Respondent to seek to introduce any of the refreshing documents as past recollection recorded. *See* Fed. R. Evid. 803(5). Ironically, on the last day of his testimony, when asked about whether he even remembered his testimony being refreshed on the previous day, the owner snapped ''That was yesterday. I can't remember. What—I guess what's your question?'' and ''I don't recall yesterday, but whatever —.'' Tr. 1189. Suffice it to say that announcing under oath that he has no recollection of events occurring on the previous day is singularly unhelpful to the credibility of a witness asking the tribunal and the Agency to credit his recollection of events that occurred months and years prior.

[108] There was even a point during Dr. Howard's testimony where his counsel forgot to employ the contrivance of having his recollection refreshed and the process devolved to the witness simply reading content verbatim from the OOR documents pertaining to Patient SD into the record. Tr. 1025–27. Suffice it to say that this did not enhance the credibility and force of his testimony, or the weight to be accorded to it.

being truthful and his analysis was really no cognizable analysis, or the red flag was never really considered before the medication was dispensed. Neither scenario furthers the Respondent's interests in avoiding a registration sanction in this case. Even the subsequent leading, rehabilitation questions from the Respondent's counsel about whether he believes he ''[w]ould [ ] have filled the prescription if [the red flag] had not been resolved'' [109] [did not rehabilitate the witness on this issue].

The testimony of the Respondent's owner regarding Patient DH followed the same general configuration. There was some testimony regarding the customer-patient's diagnoses.[110] Tr. 1058. The witness's memory also was refreshed [111] using a patient questionnaire that was also not offered or admitted into the record. Tr. 1059–64. At one point during the witness's testimony about Patient DH he testified that he spoke to the prescriber to resolve a drug-drug red flag, then when pressed, retreated to the language of the refreshing document, and corrected his testimony to reflect that he only consulted with the patient on the issue. Tr. 1068–71. It is reasonable to infer that a recurring theme for this witness was to somehow ascertain the most advantageous answer, which often came from the refreshing documents.

The testimony was very much the same with respect to Patient JM. The owner averred that he saw the patient monthly, that he spoke with her prescribers, and while on the stand he had his recollection refreshed with OOR documents. Tr. 1102–35. The recognition of marks on prescriptions regarding Patient JM again allowed him to assure the tribunal that all appropriate steps were taken. Tr. 1118–19, 1129–35. One aspect that was unique to the witness's refreshed recollection regarding this patient is that, the testimony of the Government's expert notwithstanding, the owner insisted that prescribing two different benzodiazepines simultaneously to one patient is ''not a problem.'' Tr. 1111. The owner dismissed the entire issue this way: ''So I did hear previous testimony stating that that's an issue, it's absolutely incorrect.'' Tr. 1111–12. Simultaneous prescribing of multiple opioids received the same treatment from the owner. When asked if this practice raised a red flag, his answer was ''[a]bsolutely not.'' Tr. 1112. He saw no red flags that required resolution. Tr. 1116.

The owner's testimony regarding Patient JW was more of the same. He said he spoke to the patient once a month, spoke with his prescriber, and read off of a litany of OOR documents purportedly to tender a more refreshed recollection. Tr. 1139–50. Interestingly, the owner opined that the administration of methadone for pain is common. Tr. 1146. Whether through disinterest, witness fatigue, self-interest, or some other cause, when asked by counsel whether his testimony regarding the significance of the prescription annotations extended to all the prescriptions received in the record, the witness first said ''No it wouldn't,'' but upon being pointedly re-asked the same question by the Respondent's counsel, the witness then agreed that it would. Tr. 1148–49. This seeming recurrence of the witness's willingness to say whatever answer he believed would be most helpful to his cause was not a credibility-enhancing feature of his presentation. Sworn testimony where a witness definitively responds yes and then upon being abruptly asked the same question a second time responds no hardly presents a model for reliable evidence.

The same pattern persisted regarding the witness's testimony concerning Patient CW. More refreshing that followed seemingly rote assurances that the customer-patient was seen monthly, and a blanket statement that no concerns regarding the dispensing events were encountered.[112] Tr. 1151–64. Tellingly, when asked by the Respondent's counsel whether the owner specifically recalled any physical observations regarding Patient CW, the witness replied:

> Well, yeah. I mean, I've been knowing her for probably since 2012, so I can't remember like right off the top of my head, right now, as far as—I can't remember right of the top of my head. I'm not sure.

Tr. 1152. Thus, when first asked, the witness responded that he did recall some physical observations about the customer-patient, but then, apparently realizing that he might be called upon to relate some of those observations, reversed course and said he was not sure and could not remember them ''off the top of [his] head.'' *Id.* Prescribing multiple opioids simultaneously also was, in the opinion of the owner, undeserving of any particular heightened scrutiny. Tr. 1156. The witness's view of disregarding the Government expert's view regarding this red flag was merely that the patient-customer had ''been on pain management therapy for a very, very long time that I can remember . . . [for] a lot of different ailments . . . .'' *Id.* Thus, the owner's account presents a binary choice: Either there is no red flag inherent in prescribing multiple opioids and the Government's expert is wrong, or the mere fact that the patient has been receiving medications in the face of a long-term unresolved red flag of potential diversion is completely dissipated by the fact that the dispensing (from the Respondent pharmacy) has been conducted in this manner for a long time. Neither scenario is particularly persuasive. The testimony of the Government's expert regarding the validity of this multiple-opioid red flag is persuasive, and the fact that a red flag was ignored for a sustained period does not deprive the red flag of its soundness.

The presentation pattern was substantially repeated regarding Patient DK. Tr. 1078–1101. The witness did convey some seemingly contemporaneous memory about Patient DK, remembering some particulars about her treatment and about the fact that (according to the owner) a caretaker regularly dropped her off to retrieve her medications. Tr. 1086–88. But the Respondent resorted to the same recollection refreshing regarding the significant particulars of the dispensing events. One feature of the owner's testimony regarding Patient DK was particularly telling. When directed to one of the Government-furnished prescriptions issued to this patient, the Respondent's counsel invited his attention to what appeared to be a seemingly commendable notation on the prescription that purportedly synopsized a conversation between the owner and Patient DK concerning her diagnoses, weight loss, and pain

[109] Tr. 1045.

[110] [Omitted for brevity.]

[111] Even though this process had repeated itself numerous times, when asked by his counsel whether he had ''an independent recollection of the flags that were raised and resolved with respect to the first set of prescriptions that [he had been asked] about with [Patient] DH,'' he answered that he did. Tr. 1066. Thus, it would have appeared that the witness's memory was not in need of refreshing. When asked about it, the witness then immediately said ''No, I don't recall.'' *Id.* Like many other features of this witness's testimony, this feature did not enhance the credibility of his presentation. This additional anomaly notwithstanding, the Respondent's counsel was permitted to continue to refresh the owner's recollection with excluded documentation to afford the Respondent the maximum margin of due process.

[112] The witness testified that he did see a PMP anomaly regarding a new prescriber, raising a conflict that he purportedly resolved through conversations with the customer-patient and the prescriber, some details of which were memorialized in a July 31, 2019 handwritten note on the applicable prescription. Tr. 1163–64; Gov't Ex. 29 at 5.

level.[113] Gov't Ex. 26 at 17–18. After identifying his handwriting, the witness [offered testimony that devalued the importance of documentation]:

> Q. Dr. Howard, can you please tell the tribunal what was the intent and purpose of the note that you placed on this particular prescription?
>
> A. Basically, to document the conversations between the patients more. With this situation, what occurred is the patient had been in the hospital for probably about three weeks from a serious infection and what happened was is [that] the physician reduced the dosage for the patient based upon her weight loss. So I counseled the patient and explained to her the reason why the physician reduced her medication based upon that issue. So that was the reason why I documented it, it's just an extra compliance step. This is something that pharmacists do all the time, never to—*never to thought to this point where you would have to do things like this,* but this is what we do.
>
> Q. I'm sorry, when you say you never thought you had to do things like this, what did you mean by this?
>
> A. Document to this extent. I mean it's just—*it's absolutely absurd* because you would be doing more documenting than dispensing medication if you go by some of the previous testimonies that I've heard, being a pharmacist.
>
> Q. Let me stop you there. . . .

Tr. 1095–96 (emphasis supplied). When invited multiple times (by the tribunal and the Respondent's counsel) to explain what he meant about the documentation being ''absurd,'' the Respondent's owner stuck to his guns on the issue. Tr. 1098–1100. The owner asked the tribunal whether he had ever worked in a pharmacy, and upon procuring a negative response, he offered the following:

> Okay. So if you've ever worked in a pharmacy, you have a lot of patient interaction between yourself and the patient. And you have conversations every month. If you were to document every conversation, every incident that you have with a particular patient, you would not be able to fill prescriptions.

Tr. 1098. When invited again to explain the part of the documentation obligation that he found ''absurd,'' the Respondent's owner doubled down, stating:

> Well, I mean I think it's absurd to the sense where from testimony that I've heard, previous testimony that I've heard on you call a physician every time you almost fill a prescription or if you know that particular patient, you know their illness. You've had interaction with that patient over the years. To call a physician, and you know the physician and you know the patient, on every prescription is absurd.

Tr. 1099. The only testimony the Respondent's owner ''heard'' during the hearing on this subject emanated from the Government's expert witness, but to remove any ambiguity on that front, the witness clarified that the testimony he was referring to as ''absurd'' was ''the expert witness for the DEA.'' Tr. 1100. Thus, the Respondent's owner was making it clear that the documentation requirements that underpin the standard of care are absurd in his view. [Omitted for brevity. I agree with the Chief ALJ that Respondent's statements as do not instill confidence in me that he will be compliant with the law in the future.]

At one point during the witness's testimony, the Government conducted a *voir dire* regarding screen shots of RX30 pages (the RX30 Screen Shots) regarding Patient JA that were purportedly generated in the ordinary course of business in the Respondent pharmacy at the time of the charged dispensing events.[114] Resp't Ex. 1(ID) at 55–90. Although the Government's timeliness objections were overruled, the Respondent, as the proponent of the evidence,[115] was ultimately unsuccessful in bearing its burden to establish admissibility. The Respondent's theory for admission of the RX30 Screen Shots was founded on the proposition that each tendered page was a screen shot of information created and inputted into the RX30 at the time of the dispensing event. Tr. 664–69. Dr. Howard testified that he created and prepared every one of the documents within the RX30 Screen Shots. Tr. 669, 686–88. At one point he testified that the data entries were made either by himself or the pharmacy staff. Tr. 665. He also (inconsistently) said that he inputted all data into the system himself. Tr. 688. However, the witness was unequivocal that the screen shots in question were made by him personally. Tr. 687–88. Yet, when Dr. Howard was asked to explain, if he truly made all the RX30 entries, why various RX30 screens contained the initials of pharmacy techs who work at his pharmacy, his answers were [inconsistent and confusing]. The witness first said that the tech initials could be explained by ''[i]t could've been a different screen that I had to open up, or something like that.'' Tr. 686. After an offer by Dr. Howard to ''clarify so I can let you understand,'' he explained the presence of various tech initials by saying, ''That means that when I was logged into the system, I was logged in under just my initials.'' *Id.* When asked why some of the initial fields were blank, the Respondent offered that this was ''[b]ecause I was logged into my system.'' Tr. 687. When pressed on this and given another opportunity to explain, the owner stated that the initials from various pharmacy technicians appeared on the screens on different pages

> [b]ecause I didn't generate them all in one day. I didn't sit there and go through these all in one day . . . . I just explained to you. Because when those would generate [sic], it was under that tech's—I guess, that computer.

Tr. 687. Whether the data was all inputted by Dr. Howard (as he said) or by Dr. Howard and pharmacy staff (which he also said), it is clear that this is yet another issue upon which Dr. Howard has provided inconsistent information under oath. Obviously, when taken together, none of these explanatory statements (made by a highly educated medical professional) made any sense whatsoever, raising the reasonable inference that he was being less than candid about the RX30 system, the identity of those who entered the data, and (most importantly) the integrity of the proffered evidence.

Although the overwhelming majority of the tendered RX30 Screen Shots had a ''Print'' option at the bottom of the page, the owner at one point testified that the pages could not, in fact, be printed. Tr. 672. Dr. Howard then stated that the pages could be printed so long as the print feature is accessed through the DUR screen related to a specific dispensing event. Tr. 672. He then reversed himself and adhered to his initial position that the screen could not be printed out. Tr. 673.

The majority of these pages contained options for a variety of actions, *to wit:* ''F1 Return,'' ''F3 Select,'' ''F5 Print,'' ''F8 Delete,'' and ''F9 Help.'' Resp't Ex. 1(ID) at 57–66, 68–90. Notwithstanding Dr. Howard's assurance that the pages could not be printed, the majority of the software pages he tendered for the

[113] The witness testified that the conversation with the customer-patient led to a resolved understanding of the prescriber's decision to titrate the customer-patient's medication downward. Tr. 1097.

[114] As it happens, these documents were not timely served on the tribunal or the Government, and the Government's timeliness objections were overruled to afford the Respondent the maximum level of due process. Tr. 642–60. However, other fundamental issues regarding foundation and reliability precluded the admission of the tendered evidence as being sufficiently reliable to be considered in this adjudication. *See* 5 U.S.C. 556(d). While the procedural timeliness objection could be (and was) overlooked by the tribunal in an effort to ensure the Respondent was able to present its case, the inherent unreliability of the tendered documents (as discussed, *infra*) prevented receipt into the record.

[115] *See* 5 U.S.C. 556(d). The untimely filing of the proposed evidence in the absence of any demonstration of good cause supplied good cause for the Government's at-hearing authenticity objection. *See* 21 CFR 1316.59(c).

record clearly contained a print option for the operator on the screen. Page 67 of the RX30 Screen Shots (Page 67) had no option to print, but unlike any of the other pages, this page had a ''F4 Save'' option, which was clearly highlighted. *Id.* at 67. It is not unreasonable to infer that the appearance of a ''Save'' option that was unique to a single page signals that as yet unsaved information was entered or altered into the database and that this changed information is now amenable to being saved. In the absence of any explanation by the owner (the purportedly most knowledgeable person at the hearing about the RX30 system) to the contrary, the preponderant evidence supports the proposition that Page 67 in the proffered exhibit depicts data that was altered or supplemented prior to the printing of the page, and not when the dispensing event occurred. Another feature that was remarkable about the RX30 Screen Shots is that, notwithstanding the Respondent's admission theory that these documents represent unadulterated screen shots that merely and reliably depict information stored in the RX30 system, the cursor is lit up on different fields depending on the page. *Id.* at 57, 63, 66, 68–90 (Intervention field), 58–62, 64–65 (Outcome field), 67 (Reason for Intervention field), 56 (Patient name field), 55 (a listed diagnosis within the International Classification of Diseases (ICD) field). When asked why the cursor was resting in different fields depending on the page, the owner dismissively declared that he did not know, that he had ''no clue,'' that he had ''no idea,'' and that ''[i]f you're trying to imply that I changed things, you're wrong.'' Tr. 675–78, 682–83. This was one of the points during the hearing where the witness's voice and demeanor reflected increasing agitation and volume as the inquiry progressed.

The witness insisted that he did not know where the cursor ordinarily populates and was unable to explain why it migrated to different places on the RX30 Screen Shots.[116] Tr. 671. Additionally, when asked why one of the pages contained text that bore a date about three and a half years beyond the dispensing event date,[117] the witness was unable to explain, but just kept repeating that he did not understand the question, and defensively asked ''what are you trying to say?'' Tr. 670–71, 679, 681–82.

Dr. Howard's contradictory and illogical statements, coupled with his dismissive declarations that he has no clue and no idea about how his own software system operates and why a host of anomalies were present in the tendered RX30 Screen Shots, were and are simply unpersuasive and detracted profoundly, not only from the Respondent's attempts to secure admission of the evidence, but more fundamentally from any credibility that could be accorded to the balance of his sworn testimony.

The dynamic regarding the RX30 notes is rendered worse by the fact that, as discussed, *supra,* these purportedly contemporaneously-created notes fit squarely within the parameters of the DEA's multiple subpoena demands for:

> [C]omplete medication or patient medication records/profiles that the pharmacy maintains which documents any and all prescriptions filled by the pharmacy; any and all additional records documenting the steps taken to avoid or resolve any issues with the prescriptions presented by [the named customer-patients] pursuant to the requirements of the Florida Statutes and Florida Administrative Code 64B16–27.800 . . . and, any other documentation kept by the pharmacy in connection with the filling of prescriptions or providing medical treatment for these individuals, including but not limited to dispensing reports, billing records, [E–FORSCE] reports and medical records.

Gov't Ex. 2 at 1; *see* Gov't Ex. 18 at 1. The Respondent's owner [testified that he was confused by what was required]. Tr. 1206–07. The Respondent's owner is and was a highly-educated, experienced registrant. The idea that this clear, directive language [was too confusing for him to comply with the subpoena was not credible]. Similarly unpersuasive was the Respondent's argument that the owner was unobligated to comply with the Government's multiple subpoenas because they were addressed to his counsel.[118] Tr. 1208. The issue here was not a subpoena enforcement technicality being litigated in a United States District Court. *See* 5 U.S.C. 555(d). The Respondent is engaged in a dangerous, highly-regulated activity, and it and its (then) counsel well understood the documents the regulator was seeking. Likewise, the owner's preliminary response to whether he produced the customer-patient questionnaires that evolved from ''I think, at that time I think it was [produced], I believe so,'' to a solid declaration that in the course of several seconds of testimony that he somehow became sure that the questionnaires were provided, was unconvincing to say the least. Tr. 1168–73. Similarly, when asked in what format the questionnaires were supplied to the Government, and if they were supplied in hard copy, the witness first said, ''I'm not sure. I would assume. Yeah, they were in hard—well I don't know if they were in hard copy, but I, I guess they were sent electronically.'' Tr. 1172. This was shortly followed up by this more definitive declaration: ''Electronically. We produced them electronically.'' Tr. 1173. This was immediately followed by the following statement:

> To be honest with you, I don't 100% know. I know that we provided them to you. You know, whatever question that you're trying to get at, I can tell you that we provided them to them, to you. Now the means that we provided it to you, I cannot remember, so I don't want to sit here and say something that I did or didn't do, when I totally don't remember. I can tell you we scanned them. They were in a binder, we scanned them in, and those were provided to you.

Id. [This testimony was inconsistent and not credible. Omitted for brevity.] The questionnaires and the RX30 notes were not produced when demanded. They were produced late and with anomalies in the RX30 notes that precluded a finding that they were reliable and may even possibly have been altered; and notwithstanding all that, the witness was still permitted to have his recollections refreshed by mostly reading the content of the unreliable, untimely-filed documents. The inconsistency of the owner's

[116] Notwithstanding his testimony that he inputted all the information into the RX30 system, the owner did not seem to understand much about how the system actually works; and his lack of understanding extended beyond cursors and printing. At another point in his testimony, Dr. Howard testified that he was unsure if the customer-patients were presented with counseling screens at the time of medication dispensing. Tr. 758–59. When asked about it, he simply said ''I'm not aware of how it works.'' Tr. 758. Ultimately, he gave up on explaining whether the RX30 had such a feature, and volunteered that he provides a hardcopy paper counseling election sheet to each patient. Tr. 759. But when asked where such hardcopy counseling sheets are maintained at the pharmacy, he was unable to supply a coherent response. When asked if the counseling sheets are kept in a binder, his answer was: ''Well, it's not a binder. We keep it sort of—well, yeah, it's a binder.'' Tr. 760. The same confusion permeated the owner's testimony about other systems that he would have been expected to be conversant in. When asked about whether and where patient questionnaires are maintained and for how long, he testified that they were stored at the pharmacy, and joked that they were maintained ''[a]s long as we don't lose them.'' Tr. 601–03. Inasmuch as he testified that he is the owner, PIC, and exclusive controlled substance dispensing pharmacist, his general lack of awareness about the automation system utilized by his pharmacy, and even other filing systems used there, is surprising. Irrespective of whether the witness was being intentionally evasive, or genuinely lacks a basis for understanding the pharmacy systems (automated and manual) operating under the pharmacy he owns and supervises, this feature of his presentation was unhelpful in meeting the Government's evidence.

[117] Resp't Ex. 1(ID) at 57.

[118] Tr. 1215.

answers, the structure of the Respondent's actions in subpoena (non)compliance, and the refreshing use of the documents essentially precluded reasonable reliance on these late-discovered items and ultimately hurt the credibility of the Respondent's case.

At another point in the owner's testimony, when asked the basic, straightforward question as to whether he ''would agree that there are red flags in pharmacy,'' the witness supplied the following convoluted response:

> Well if you want to deem it as a red flag, if you want to use the term red flag, that will be considered a red flag, or, if you check the PMP and you see that this patient that probably has a valid prescription but they went to two other physicians the day before, that's a red flag, for the same medication, those—if you wanna use the term red flag, that's a red flag.

Tr. 1182–83. While the witness did indicate that he would not dispense a prescription under the scenario his own reply created, his answer was [concerning in that he remains unwilling to acknowledge the importance, or even existence, of red flags. He dismissed the concept of a red flag] as a subjective exercise in whether the questioner (*i.e.,* DEA) ''want[s] to deem it as a red flag,'' whereby anything ''will be considered a red flag.'' Tr. 1182. [Omitted for brevity. I agree with the Chief ALJ that these statements do not instill confidence in me that Respondent will be compliant with the law in the future.]

The Respondent's owner supplied another insightful window into his true amenability to regulatory oversight at another point in his testimony. This exchange commenced with an inquiry regarding whether the questionnaires used by the pharmacy had seen any level of modification over time. The owner impatiently replied that the documents were modified in format for ''[t]he same reason why we're sitting here.'' Tr. 1185. When asked to explain, the witness [testified]:

> All the documentation and things that we try to do to satisfy the DEA, it still does not matter, all the documentation, all the compliance that we've done, to show regulatory agencies we go over and beyond to try to, to make sure that we do our part, it did not matter. It did not matter. . . . I said it does not matter to the regulatory agencies. It does not matter as far as how much compliance the pharmacy does. We [changed the questionnaire] as a compliance issue to make sure that we're trying to stay in compliance. We asked for guidance. We try our best to do what's right.

Tr. 1185–86. Thus, even in this case where the record shows that the Respondent's documentation was inadequate [and outside the usual course of professional practice], the owner's response is that he believes he has done enough and it does not matter what steps his pharmacy takes in the future. This is not the voice of a registrant seeking to come into compliance, but essentially one who is communicating that he is [frustrated] with the efforts already invested to try to meet the state standards for dispensing controlled substances. The owner's mindset remained consistent when asked about why the Respondent's patient questionnaires queried about distance. The witness did not indicate that distance could be an important red flag of potential diversion, but rather affirmed that the question was included ''[b]ecause that's one of the things that the DEA has been targeting, is patients traveling long distances.'' Tr. 1218. [Omitted for brevity.]

The witness was also unwilling to distance himself from Dr. Buffington's opinions that DEA has virtually no legitimate role in regulating the dispensing of controlled substances, notwithstanding invitations by the tribunal to do so in the best interests of his case. Tr. 1222–24. [The witness maintained throughout the hearing] that every single prescription that is the subject of these proceedings was dispensed correctly and with adequate documentation. Tr. 1224.

On the issue of credibility, Respondent's owner, Dr. Howard, has the most at stake in these proceedings, as the DEA registration that is the subject of this litigation concerns his pharmacy. Even beyond that, the testimony of this witness was often evasive, internally inconsistent, defensive, implausible, and sometimes even objectively hostile in tone.[119] As discussed in considerable detail, *supra,* during the course of his testimony, the witness [stated] that many of the efforts expended in the Respondent's dispensing practices were not geared toward identifying and targeting potential diversion, but to avoid professional scrutiny from DEA. [Additionally], the fact that the Respondent's owner declined to turn over subpoenaed documents until late in the proceedings, and sponsored documents that raised anomalies that were fatal to their reception into the record, further undermined his credibility, resulted in an adverse inference, and diluted the strength of his case. As discussed, *supra,* the Respondent's owner [declined] to distance himself from the testimony of its expert witness that DEA [does not have a significant role] in regulating pharmacy practice. To be sure, there were certain historical and/or biographical features of this witness's testimony that could be credited, but regrettably, the testimony presented by this witness cannot be afforded a positive credibility finding.

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

[119] Even beyond the words on the page of a sterile transcript (quite animated, even on their own in this case), the witness's tone and volume during his testimony was sometimes elevated and presented on multiple occasions as impatient and even visibly angry.

The Analysis

The Government seeks revocation based on its contention that the Respondent, through its pharmacists and employees, has committed acts that would render its continued registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The gravamen of the Government's allegations and evidence in this case focus on the Respondent's alleged (1) dereliction in the exercise of its corresponding responsibility in dispensing of controlled substance prescriptions and (2) violations of federal and state laws relating to controlled substances.

Public Interest Determination: The Standard

Under 21 U.S.C. 824(a)(4), the Agency may revoke the COR of a registrant if the registrant ''has committed such acts as would render [its] 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 COR 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) (citing *Morall,* 412 F.3d at 173–74), 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 the adjudication of a revocation of a DEA COR, 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, [a 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 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, 38385 (2013).

Normal hardships to the registrant, and even the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. *Heavenly Care Pharmacy,* 85 FR 53,402, 53,420 (2020) (principle conclusively applied to pharmacy registrants); *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 future misconduct will not occur. *Hoxie,* 419 F.3d at 483.[120]

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. 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) (citation omitted), 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). [Omitted for brevity.]

[Omitted for brevity.] 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, *see 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. *See* 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).

[120] The Agency has consistently adhered to this policy in its adjudications. *See, e.g., 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 463; *Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078 (2009); *Med. Shoppe-Jonesborough,* 73 FR 387.

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, and it is to those two factors that the evidence of record relates.[121]

Applying the record evidence to Factor Two (experience in dispensing controlled substances) in accordance with Agency precedent,[122] the Respondent is owned by Dr. Howard, and has been licensed in Florida since 2010. Tr. 584. No evidence was introduced regarding the length of time

[121] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor One). [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011) (''The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'').] The record likewise contains no evidence of a specific recommendation by competent state authority or any action from which its intent could be discerned. *See Jeanne E. Germeil, M.D.,* 85 FR 73,786, 73,799 (2020) (Agency recognizes that its prior final orders have considered this dichotomy of sources for Factor One consideration). The Agency has recognized that the failure by a state to affirmatively take action against a registrant ''carries minimal to no weight under Factor One.'' *Id.* 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 place emphasis on the absence of such a conviction record, the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities 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). The Agency has previously recognized the minimal impact of the absence of such a conviction in the Public Interest analysis. *Germeil,* 85 FR 73,799. Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. That 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,'' 21 U.S.C. 823(f)(5) (Factor Five) (emphasis supplied), likewise militates neither for nor against the sanction sought by the Government in this case.

[122] *JM Pharmacy Grp., Inc.,* 80 FR 28,667, 28,667 n.2 (2015); *Krishna-Iyer,* 74 FR 462.

that the Respondent pharmacy has been in operation or any basis upon which to characterize its level of compliance prior to the allegations that form the basis of this litigation.

The lion's share of the evidence presented in this litigation is most readily considered under Factor Four (compliance with laws related to controlled substances). 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 CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Under the regulations, ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a). [Omitted.] *F

The pharmacy registrant's responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but rather, it is a *corresponding* one. 21 CFR 1306.04(a). The regulation does not require the pharmacist to practice medicine; it instead imposes the responsibility to decline to dispense based upon an order that purports to be a prescription, but may not be, because evidence (either apparent on the prescription or attendant to the presentation of that scrip) would lead a reasonable pharmacist to suspect that the practitioner issued the prescription outside the scope of legitimate medical practice. *E. Main St. Pharmacy,* 75 FR 66,149, 66,157 n.30 (2010). [Omitted.] *G

[According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

> An 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 filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing United *States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341 (citing *Med. Shoppe—Jonesborough,* 73 FR 384; *United Prescription Servs., Inc.,* 72 FR 50,397, 50,407–08 (2007); *EZRX, L.L.C.,* 69 FR 63,178, 63,181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61,613, 61,617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64,921, 64,924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR 63,181; *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR 62,341.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by filling prescriptions without addressing or resolving multiple red flags of abuse or diversion. Agency decisions have consistently found that prescriptions with the similar red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,898, *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash

*F Omitted to reduce repetition with added text. *See infra* n. *H.

*G Omitted to reduce repetition with added text. *See infra* n. *H.

payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Here, the Government established the presence of red flags on the prescriptions that Respondent pharmacy filled.][*H]

The Florida Administrative Code requires pharmacists to conduct a prospective drug use review for each ''new and refill prescription presented for dispensing'' and identify, *inter alia,* ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''[d]rug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code Ann. r. 64B16–27.810(1) (Florida DUR Statute). Under the Florida DUR Statute, if such a matter is identified, ''the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* r. 64B16–27.810(2). A patient record system is required to be maintained in order to ''provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.'' Fla. Admin. Code Ann. r. 64B16–27.800(1). Significantly, within the patient record, a ''pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain'' information including, *inter alia,* ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* In regard to controlled substance prescriptions, under the Florida Pharmacy Standards Statute, a pharmacist in Florida must ''exercise[e] sound professional judgment'' in filling controlled substance prescriptions and ''shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' Fla. Admin. Code Ann. r. 64B16–27.831. Specifically, ''when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.'' *Id.* r. 64B16–27.831(2). A valid prescription for a controlled substance is defined as one ''based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose,'' while an invalid prescription is one ''the pharmacist knows or has reason to know that . . . was not issued for a legitimate medical purpose.'' *Id.* r. 64B16–27.831(1)(a), (b). As discussed, *supra,* the concept of red flags is encapsulated in the FPSS as ''circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance.'' *Id.* r. 64B16–27.831(2). Upon encountering a ''circumstance that may cause a pharmacist to question the validity of a prescription for a controlled substance'' (*i.e.,* a red flag of potential diversion), a Florida pharmacist must reach out to either the prescriber or the patient; and where appropriate, in place of one of those two sources (but not both) the pharmacist may resolve a red flag by an E–FORCSE query. The Florida Pharmacy Patient Record Statute directs that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' Fla. Admin. Code Ann. r. 64B16–27.800(2). The FPPRS also directs pharmacists to create a record of ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* r. 64B16–27.800(1)(f). Accordingly the substance of the contacts initiated by a Florida pharmacist to resolve encountered red flags (which is required) must be documented.[*I] A failure to follow up on the red flags and the failure to document that follow-up falls below the applicable standard of care.

Here,[123] the Government has alleged and presented evidence that the

[*H] The supplemented text in this section clarifies my analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

[*I] As explained above, *see supra* n. *E, I agree with the Chief ALJ's conclusion that Florida law requires pharmacists to document their attempts to address and resolve red flags. However, my Decision does not rely on any interpretation of Florida law, because, in failing to document the resolution of red flags, Respondent violated federal law in addition to state law. *See* 21 CFR 1306.04(a) and 1306.06. Respondent's violations of federal law serve as an independent basis for my conclusion that Respondent's registration is inconsistent with the public interest and that revocation is the appropriate remedy in this case.

[123] As discussed, *supra,* the CSA authorizes the Agency to impose a sanction upon a finding that a registrant ''has committed such acts as would render [its] registration under [21 U.S.C. 823] inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Thus, for the Government to satisfy its *prima facie* burden, it must allege facts that, if sustained, would actually demonstrate that the registrant committed such acts as would render its registration inconsistent with the public interest. *See id.* Here, in a subset of allegations relating to the Ten Patients (the She-Opined Allegations), the Government does not allege actions, conduct, or omissions attributable to the Respondent, but rather conclusions or observations made by its own pharmacy expert. ALJ Ex. 1 ¶¶ 5, 6, 8, 9, 10, 11, 12, 13. The plain language of each of the She-Opined Allegations points merely to the fact that (at some unspecified point in time) the Government's expert concluded that certain matters were true. Even if preponderantly established by the evidence, the fact that the Government's expert held a point of view on a fact (in the past or at any time) cannot and does not constitute evidence (or, as more relevant here, an allegation) that the Respondent engaged in acts that are inconsistent with the public interest. However, while the drafting of the She-Opined Allegations is certainly suboptimal, it is clear that these issues were litigated by consent. *See Farmacia Yani,* 80 FR 29,053, 29,059 (2015); *Grider Drug #1 and Grider Drug #2,* 77 FR 44,070, 44,078 n.23 (2012). The parties mutually understood that they were litigating the issue of whether the controlled-substance dispensing issues set forth in a subset of those allegations depicted conduct that fell below the applicable standard. Additionally, this issue was not raised by the Respondent in its closing brief. *See* ALJ Ex. 54. This case raises no realistic notice issues, and the OSC/ISO language related to the opinions of the Government's expert will be treated here as surplusage that does not impact the validity of the charges or the findings. Accordingly, based on the conduct of the parties at the hearing, as well as their post-hearing briefs, the She-Opined Allegations will be considered as if the underlying actions are alleged, not as if the conclusions of the Government's expert (at some unspecified time) are the single issue (that is: As they were drafted and served on the Respondent and this tribunal). [Furthermore, it is noted that the OSC/ISO did include overarching acts or omissions in addition to the more-specific expert opinions. The OSC/ISO states that Respondent repeatedly filled prescriptions without addressing and resolving obvious red flags of drug abuse and diversion, which is conduct that constitutes ''acts [that] would render its registration . . . inconsistent with the public interest'' under the CSA. *See, e.g.,* OSC, at 2 (alleging that Respondent ''repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that prescriptions were issued for a legitimate medical purpose, in violation of federal and state law''); *id.* at 8 (''It is my preliminary finding that [Respondent] repeatedly dispensed controlled substances without attempting to address or resolve clear red flags of drug abuse or diversion, which is inconsistent with the public interest.''). Therefore, although I agree with the Chief ALJ that the drafting could be improved, I

Continued

Respondent pharmacy violated federal and state law relating to controlled substances and dispensed prescriptions in such a way that violated its corresponding responsibility to ensure that controlled substances are dispensed only upon an effective prescription by failing to recognize and resolve red flags of diversion prior to dispensing. *See* 21 CFR 1306.04(a). Specifically, the Government alleges that the Respondent violated laws applicable to the dispensing of controlled substances by dispensing multiple controlled substances to the Ten Patients in the face of unresolved red flags indicating possible or even likely diversion. ALJ Ex. 1. The exact allegations charge that the Respondent ignored red flags based on: (1) High-risk combinations of controlled medications; (2) dosage anomalies; (3) cash payments; and (4) long distances between customers, prescribers, and the registrant pharmacy.

The evidence of record demonstrates that on numerous occasions the Respondent pharmacy filled prescriptions in the face of unresolved high-risk combination red flags and dosage-anomaly red flags (*i.e.,* illogical dosing combinations of long-acting and short-acting opioids, and therapeutic duplication). Gov't Exs. 6–14, 22, 23, 25–27, 29; Tr. 215–16, 218–21; Stip. 33 (Patient JW); Tr. 268–69, 274–76, 281–83; Stip. 19 (Patient EA); Tr. 287–91, 294–97; Stip. 21 (Patient SD); Tr. 302–05; Stip. 23 (Patient LH); Tr. 309–12, 315–16; Stip. 25 (Patient DH); Tr. 321–26; Stip. 27 (Patient DK); Tr. 330–38; Stip. 29 (Patient JM); Tr. 339–41; Stip. 31 (Patient ST); Tr. 243–45; Stip. 35 (Patient CW). Dr. Schossow persuasively testified that these red flags require documented resolution in order for the Respondent pharmacy to comply with its corresponding responsibility.[124] Tr. 204, 213–14, 216, 284–855, 318, 336–37. However, such adequate documentation was not present here. Tr. 431; Gov't Exs. 6–15, 22–29, 32; Tr. 240–41, 424–25 (Patient JW); Tr. 286, 371–75 (Patient EA); Tr. 295–300, 375–78 (Patient SD); Tr. 308, 378–80, 384 (Patient LH); Tr. 319, 321, 385–88, 397–98, 408–09 (Patient DH); Tr. 329–30, 409–13 (Patient DK); Tr. 338–39, 413–16, 419–20 (Patient JM); Tr. 342–43, 420–23 (Patient ST); Tr. 346–47, 425–30 (Patient CW). The Respondent's countering argument that the relevant standard of care in Florida does not require documentation of the resolution of red flags is unsupported by the applicable statutes and unpersuasive on this record.[*J] In specifically addressing high-risk combinations of controlled substances and controlled substance prescriptions with dosage anomalies, the Respondent's owner calmly and repeatedly explained that such occurrences did not raise any concern in his mind because such types of prescriptions are ''common.'' Tr. 1018, 1025, 1056, 1087, 1112–13, 1131, 1146–47. The owner was firm in his belief that every prescription at issue was dispensed properly and that his documentation was adequate. Tr. 1224.

The evidence of record demonstrates that the Respondent has neglected its corresponding responsibility imposed by the CSA and the Florida Administrative Code. *See* 21 CFR 1306.04(a) (establishing corresponding responsibility under the Controlled Substances Act); *Liddy's Pharmacy,* 76 FR 48,895 (affirming that only lawful prescriptions may be dispensed); Fla. Admin. Code Ann. r. 64B16–27.831 (establishing corresponding responsibility under Florida state law). The Respondent, through its PIC/owner, was derelict in executing its corresponding responsibility by dispensing in the face of an unresolved reason to believe that these prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice. *Cf. Med. Shoppe-Jonesborough,* 73 FR 381 (requiring a pharmacist to refuse to fill such prescriptions); *Medic-Aid Pharmacy,* 55 FR 30,044. By dispensing these prescriptions despite knowing that they were potentially dangerous and failing to investigate further, the Respondent pharmacy failed to follow its legal responsibilities. *See Sun & Lake Pharmacy,* 76 FR 24,530 (stating that a pharmacist may not ''close his eyes and thereby avoid [actual] knowledge'' of possible abuse or diversion) (quoting *Bertolino,* 55 FR 4730).

[Omitted for clarity. The record evidence establishes that it was outside the usual course of professional practice for Respondent to dispense] the prescriptions detailed in the Government's evidence and agreed stipulations without resolving the red flags presented and documenting that resolution.[125] The red flags detailed above required the Respondent and its owner/PIC to question these prescriptions, and they did not. *See Bertolino,* 55 FR 4730 (requiring pharmacists to question prescriptions that present red flags for abuse or diversion). [Omitted for clarity.]

The Government has presented uncontroverted evidence that the Respondent pharmacy dispensed multiple controlled substances in the face of multiple red flags of potential diversion.

Accordingly, OSC/ISO Allegations 6, 7.a, 7.b, 7.c, 7.e, 7.f, and 7.g (pertaining to high-risk combinations) are *sustained.* For the allegation pertaining to Patient SD,[126] the record contains insufficient quantitative evidence to support the amount of alprazolam specified for the alleged amount of dispensing events.[127] Accordingly, OSC/ISO Allegation 7.d is *sustained in part* to the extent that the charge alleges ''a quantity of alprazolam,'' while the remaining alleged dosages/amounts within OSC/ISO Allegation 7.d are *sustained* as charged.

The record contains sufficient quantitative evidence to preponderantly sustain the ratio dosage anomaly (illogical dosing combinations of long-acting and short-acting opioids) allegations for Patients JM,[128] ST,[129] DH,[130] and EA [131] as charged. Accordingly, OSC/ISO Allegations 10.a, 10.b, 10.c, and 10.f are *sustained.* [Omitted.] [*K 132 133 134]

The Government alleges that on multiple occasions where the Respondent dispensed multiple

also agree with him that Respondent was adequately noticed of the allegations against it in this case.]

[124] Additionally, the Agency has consistently sustained allegations that centered around unresolved high-risk combination red flags. *See, e.g., Suntree Pharmacy,* 85 FR 73,770; *Pharmacy Doctors Enters.,* 83 FR 10,876, 10,898 (2018); *E. Main St. Pharmacy,* 75 FR 66,165.

[*J] As explained above, *see supra* ns. *E, *I, my Decision does not rely on any interpretation of Florida law.

[125] As discussed elsewhere in this RD, the allegations centered on distance and cash red flags cannot be sustained based on the underlying rationale supplied by the Government's expert.

[126] ALJ Ex. 1 ¶ 7.d.

[127] *See Gregg & Son Distribs.,* 74 FR 17517, 17517 n.1 (2009) (clarifying that ''it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding'').

[128] ALJ Ex. 1 ¶ 10.a.

[129] ALJ Ex. 1 ¶ 10.b.

[130] ALJ Ex. 1 ¶ 10.c.

[131] ALJ Ex. 1 ¶ 10.f.

[*K] The Chief ALJ did not sustain the Government's improper dosing allegations related to Patients SD and LH. RD, at 78–79. The Government took Exception to this finding. Gov't Exceptions, at 5–7. I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest.

[132] ALJ Ex. 1 ¶ 10.d.

[133] ALJ Ex. 1 ¶ 10.e.

[134] *See Gregg & Son Distributors,* 74 FR 17,517 n.1 (noting that ''it is the Government's obligation as part of its burden of proof . . . to sift through the records and highlight that information which is probative of the issues in the proceeding'').

benzodiazepines (therapeutic duplication) to Patient JM, it failed to address or resolve this red flag in a way that would have been required to stay within the standard of care. Dr. Schossow's expert opinion has been deemed persuasive on this issue. Accordingly, OSC/ISO Allegation 12 is *sustained*.

Although Dr. Schossow's expert opinion has been held generally reliable, her theory regarding the basis for the cash red flag (*to wit,* that [Respondent failed to adequately resolve the cash red flag], even where lack of insurance was specifically noted by the pharmacy staff) was too logically challenged to serve as a basis for sanction. Certainly the Agency has consistently sustained supported allegations that centered around unresolved cash red flags in the past. *See, e.g., Suntree Pharmacy,* 85 FR 73770; *Pharmacy Doctors Enters.,* 83 FR 10,891; *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–13 (2014); *Holiday CVS,* 77 FR 62,317–22. [Omitted for clarity.] As discussed elsewhere in this recommended decision, the red flag resolution proposed by the Government's expert, *to wit,* that a dispenser-registrant is required in all cases to contact a prescriber-registrant to ascertain whether the customer-patient had prescription drug coverage (a subject within the exclusive purview of the pharmacy), does not further the goal of minimizing the risk of diversion. [Omitted.] *[L]

Further, it is beyond argument that there has been a long uncontradicted history of the Agency sustaining allegations relating to unresolved long-distance red flags. *See, e.g., Heavenly Care Pharmacy,* 85 FR 53,417; *Suntree Pharmacy,* 85 FR 73,770; *Pharmacy Doctors Enters.,* 83 FR 10,885; *Hills Pharmacy,* 81 FR 49,839; *Holiday CVS,* 77 FR 62,317–22; *E. Main St. Pharmacy,* 75 FR 66,163–65. The basis of that history is rooted in expert testimony explaining the common-sense proposition that traveling a great distance to fill a prescription that could have been dispensed around the block from the customer-patient raises a reasonable suspicion that the customer-patient may have chosen the remotely-located pharmacy for an improper purpose (*e.g.,* to escape scrutiny from local, vigilant pharmacists, or to travel to a pharmacy believed to be less vigilant in its responsibilities). *See, e.g., Holiday CVS,* 77 FR 62,334. Under those circumstances, experts have testified that it is logical and required to explore and resolve the possibility that either the patient-customer is seeking to mask his/her diversion, or the pharmacy has been identified as an easy mark for improperly-authorized prescriptions. [Omitted for brevity.]

This case presents a somewhat divergent issue. As discussed, *supra,* there is no genuine question that the distances between the customer-patient, the correlating prescriber, and the Respondent pharmacy are sufficiently lengthy as to objectively raise a red flag requiring pre-dispensing analysis and documentation. The fly in the ointment here is the primary rationale presented by Dr. Schossow as underlying the red flag. According to the Government's expert, a remarkable travel distance raises a concern, not founded in concerns related to drug diversion, but rather because a customer-patient filling prescriptions for opioids and benzodiazepines presents ''the risk for getting into a motor vehicle accident, [and] fractures, even death, [ ] could potentially occur.'' Tr. 232 [However, the witness testified] that she had no information regarding whether any of the customers in question drove to the Respondent pharmacy. Tr. 545. In addressing a distance red flag related to one of the customer-patients, Dr. Schossow supplied the following opinion about why the red flag stood unresolved:

> [I]f you're specifically talking about the red flag of distance, that would be asking the patient if he is actually driving a motor vehicle these distances while he's on these medications, back and forth, this long distance. And that was not addressed in this [pharmacy] note.

Tr. 380. Stated differently, if the Respondent had documented a representation by the customer-patient that someone drove him to the pharmacy the dispensing event would have met Dr. Schossow's standard. Even when closely pressed on the issue, Dr. Schossow held her ground, explaining that to resolve a distance red flag, when encountered, would require no more than the pharmacist to procure a representation from the customer-patient that someone else was doing the driving to the pharmacy.[135] Tr. 237–39.

By the testimony of the Government's expert, the long-distance red flags in this case were not founded in controlled-substance diversion (which is the focus of this proceeding and which circumscribe the hardline limits of this Agency's jurisdiction); instead, the Government expert's explanation of long-distance red flags related to general patient safety concerns. Dr. Schossow's view paints safety with a broader brush than DEA's statutory authority allows.[136] Safer roads do not translate into lack of drug diversion, and more dangerous road conditions do not likewise translate into establishing the applicable dispensing standard for a DEA pharmacy registrant. This Agency is charged with administering the Controlled Substances Act, with no mandate to supervise highway and traffic safety. Accordingly, OSC/ISO Allegations 8.a, 8.b, 8.c, 8.d, 8.e,[137] and 8.f are *not sustained*.

The Government further alleges that the Respondent filled prescriptions for alprazolam to Patients JW, EA, and SD in amounts that presented a red flag (because the dosages were pharmacologically illogical) without attempting to address the red flag. However, the Government presented no evidence that this occurred (nor did it address the issue in its post-hearing brief);[138] thus, it appears the Government has abandoned these allegations, *see Pursley,* 85 FR 80,181–82, 80,185. Accordingly, OSC/ISO Allegation 11 is *not sustained*.

OSC/ISO Allegation 1 is *sustained* based on the evidence[139] and stipulations[140] of record.

*[L] Omitted. The Government has taken Exception to the RD's finding that allegation 13 was not sustained. Gov't Exceptions, at 1–5. I agree with the Chief ALJ that Dr. Schossow's method for resolving the red flag was logistically problematic. Still, I find that Dr. Schossow credibly testified that cash payments are a red flag that requires documented resolution. Ultimately, I find that it is unnecessary for me to reach this issue because there is substantial other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest.

[135] The witness also allowed that the existence and resolution of a distance red flag could be different if the pharmacy and the prescriber were collocated in the same building. Tr. 238. But even where the dispenser and prescriber were located miles away, Dr. Schossow kept her focus on whether the patient-customer was doing the driving. Tr. 239.

[136] *See Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (the setting of medical standards is a function of the police powers of a state, whereas DEA's authority under the CSA is limited to barring illicit drug dealing and trafficking as traditionally understood).

[137] While OSC/ISO Allegation 8.e charges the Respondent with dispensing controlled substances to Patient EA in the face of long-distance red flags, the Government presented no evidence on this issue during the hearing and did not address the issue in its post-hearing brief. Therefore, the Government has apparently abandoned OSC/ISO Allegation 8.e. *See George Pursley, M.D.,* 85 FR 80,162, 80,181–82, 80,185 (2020) (finding the Government abandoned allegation by not addressing it within its post-hearing brief).

[138] Again, *see Gregg & Son Distributors,* 74 FR 17,517 n.1 (clarifying that ''it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding'').

[139] Gov't Ex. 1.

[140] Stips. 1, 2.

[Accordingly, I find that Respondent has operated outside the usual course of professional practice (in violation of 21 CFR 1306.06 and Fla. Admin. Code Ann. r. 64B16–27.831 and in violation of its corresponding responsibility (in violation of 21 CFR 1306.04(a) and Fla. Admin. Code Ann. r. 64B16–27.831). I further find that the Government has made a *prima facie* case that the Respondent has committed acts which render its registration inconsistent with the public interest.] *[M] On consideration of the whole of the record, it is clear that Public Interest Factors Two and Four militate strongly in favor of the imposition of a registration sanction in this case.

[Sanction]

The evidence of record preponderantly establishes that the Respondent has committed acts which render its continued registration inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). Since the Government has met its burden [141] in demonstrating that the revocation it seeks is authorized, to avoid sanction, it becomes incumbent upon the Respondent to demonstrate that given the totality of the facts and circumstances revocation is not warranted. *See Med. Shoppe-Jonesborough,* 73 FR 387. That is, upon the preponderant establishment of the Government's *prima facie* case, the burden now shifts to the Respondent to show why it should continue to be entrusted with a DEA registration. *See Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,689 (2020); *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018).

Although by no means the only requirement, in order to rebut the Government's *prima facie* case, the Respondent must demonstrate both an unequivocal acceptance of responsibility and also a demonstrable plan of action to avoid similar conduct in the future. *See Hassman,* 75 FR 8236. While those two elements are key, the focus is, and must always be, rooted in a determination as to whether the Agency can have confidence that the Respondent can continue to be entrusted with the weighty and dangerous responsibilities of a registrant. *Cf. Khan-Jaffery, M.D.,* 85 FR 45,689; *Smith, M.D.,* 83 FR 18,910. While analytical frameworks applied to prior Agency actions provide useful guidance and helpful structure, such tools cannot distract the Agency from its critical mission to keep the public safe by only issuing and maintaining CORs in cases where the public is adequately protected. The central issue is whether, based on the evidence of record, including the Respondent's established misdeeds, the Agency can trust the Respondent with the authority to handle dangerous controlled substances. The Agency has provided the following framework for its analysis in this regard:

> The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction; as is whether the registrant's acceptance of responsibility is unequivocal.

Heavenly Care Pharmacy, 85 FR 53,420 (internal citations omitted).

Agency precedent is clear that a respondent must ''unequivocally admit fault'' as opposed to a ''generalized acceptance of responsibility.'' *The Medicine Shoppe,* 79 FR 59,510; *see also Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017). To satisfy this burden, the respondent must show ''true remorse'' or an ''acknowledgment of wrongdoing.'' *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011). The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Dougherty,* 76 FR 16,834 (citing *Krishna-Iyer,* 74 FR 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* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011); *Hoxie,* 419 F.3d at 483.

For both prongs (acceptance of responsibility and remedial steps), the Respondent [did not present any evidence]. Arguably, as discussed, *supra,* at some point (outside the timeframe of the allegations) the evidence of record showed that the Respondent did appear to commence at least some documentation of some conversations with prescribers and patients.[142] However, as discussed, *supra,* the Respondent's owner made his view unflinchingly clear that the documentation level required to dispense within the standard applicable in the State of Florida is ''absolutely absurd.'' Tr. 1096. The Respondent's owner, in the clearest terms possible, like the expert he called to meet the Government's evidence, has demonstrated active hostility to applying this standard in the past, in the present, and in the future, as well as his amenability to Agency oversight. Thus, the Respondent accepts responsibility on no level, much less unequivocally. A change in this attitude is unlikely. The view of the Respondent's owner/PIC is that no misconduct or deficits occurred, and to the extent that the Agency and its expert thinks otherwise, it is mistaken.

While the transgressions alleged and proved here are certainly serious, it is arguable that an acceptance of responsibility, coupled with a thoughtful plan of remedial action on the part of the Respondent pharmacy, would have had the potential for a creditable case for lenity. The errant dispensing events that were sustained involved areas of prescribing and dispensing that may well have been amenable to a convincing case that the Respondent's owner re-educated himself and now understood that follow-up and documentation are required to bring his pharmacy within the applicable standard. The Respondent pharmacy was clearly operating below an acceptable and safe standard, but it could not fairly be said that the pharmacy was a pill mill. On these facts, an unequivocal acceptance of responsibility and meaningful remedial steps could conceivably have supported a more moderate sanction. To the extent that the Respondent's owner had expressed some level of contrition coupled with an expression of some understanding of why his pharmacy was operating below the applicable standard, it could have achieved much in empowering the Agency to exercise some measure of lenity as a matter of discretion. But in view of the present record, considering what could have been on a different record is of minimal utility.

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*[M] For purposes of the imminent danger inquiry, my findings lead to the conclusion that Respondent has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Respondent dispensed controlled substance prescriptions outside the usual course of the professional practice established ''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.* There was ample evidence introduced to establish that Respondent, without first resolving red flags, repeatedly dispensed combinations of medications that posed serious risks to patients. Thus, I find that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger.

[141] *See* 21 CFR 1301.44(e).

[142] This is only an evidentiary observation, not a point propounded by the Respondent regarding remedial steps.

The Agency has frequently required unambiguous acceptance of responsibility and a remedial action plan as an essential component to avoid a sanction,[143] and in this case it is clear that the Respondent's owner, acknowledging no deficiencies, has no plan to conform his conduct whatsoever. In his view, he and his pharmacy did nothing wrong and would presumably make all the same choices if faced with the same facts tomorrow. The Agency is thus faced with a choice of imposing a registration sanction or imposing none and therein creating a virtual guarantee that it will be instituting new proceedings, charging the same conduct, on the day it issues its final order. 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 an acceptance of responsibility and proposing remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction.

Further, inasmuch as the evidence of record fails to demonstrate an unequivocal acceptance of responsibility, the issue of remedial steps becomes irrelevant. 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 8236. If one prong is absent, the other becomes irrelevant. Both or neither has been the rule for many years. The view of the Respondent's owner that nothing is wrong with his pharmacy has virtually precluded him from establishing remedial steps of any kind. As noted, *supra,* there was some indication of a sporadic, mildly increased level of documentation beyond the temporal range of the allegations, but these were not even proffered as remedial steps. Thus, in view of the *prima facie* case established by the Government's evidence, 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 38,364, 38,385. The issue of the egregiousness of the offense favors revocation. The Respondent dispensed many controlled substances for over a year without any regard for its obligations to identify blatant red flags of potential diversion. There was no indication during the hearing that the Respondent's owner did not understand his true obligations, only that he [resented those obligations.] The Respondent pharmacy [repeatedly dispensed controlled substances without appreciating that] further steps were required to resolve and document indications of potential diversion.

Considerations of specific and general deterrence in this case militate in favor of revocation. Through the testimony of its owner, [it was clear that the Respondent did not feel that it had acted improperly, did not have a fulsome understanding of the requirements for operating in the usual course of professional practice, and did not believe that any actions the Respondent might take to curtail diversion would matter to DEA]. The Respondent's owner and its expert witness [apparently believe] that DEA has no proper oversight role in the operation of the Respondent pharmacy and pharmacy practice in general.[144] The Respondent's owner [testified] that even the isolated instances of an increased level of documentation were effected, not in the interests of compliance with the applicable state standards, but to placate DEA. Tr. 1218–22, 1226–27. The Respondent's owner is not amenable to supervision by regulatory authorities, including DEA. He believes he is and has been correct, and it can be confidently assumed that the absence of a registration sanction will result in the continuation of business as usual at his pharmacy. Thus, the interests of specific deterrence, even standing alone, motivate powerfully in favor of the revocation of the Respondent's COR.

The interests of general deterrence compel a like result. 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 38,385. Where the record demonstrates that the Government has borne its burden and established that the Respondent has dispensed high numbers of controlled substances below the standard for over a year with no correction and no remorse, the unmistakable message to the regulated community would be that such conduct can be tried once (or more than once) with little or no consequence. Thus, on this record, the interests of general deterrence support the revocation sought by the Government.

Another factor that weighs significantly in favor of the revocation sanction sought by the Government is the profound lack of candor demonstrated by the Respondent's owner during his testimony and his actions during the investigation. In making the public interest determination, this Agency places great weight on a respondent's candor both during an investigation and during a subsequent proceeding. *Fred Samimi, M.D.,* 79 FR 18,698, 18,713 (2014); *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,004 (2010). As discussed at length, *supra,* during the investigation in this matter, the Respondent declined to forward a large swath of material specifically subpoenaed by DEA investigators, and during the hearing there were marked and profound adverse issues regarding the credibility of the owner's testimony. Hence, the issue of candor to the Agency, and candor to the tribunal, undermine the confidence that the Agency can have in the Respondent's continuation as a DEA registrant.

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

Dated: April 7, 2021
John H. Mulrooney, II
Chief Administrative Law Judge

The Respondent's Exceptions

On December 15, 2020, Respondent filed its exceptions to the Recommended Decision. DEA regulations require that Exceptions ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, Respondent's Exceptions not only fail to comply with this regulatory requirement, but they also lack evidentiary support in the Administrative Record. Several of

[143] *Hassman,* 75 FR 8236. [Edited the footnoted sentence for clarity.]

[144] As discussed, *supra,* the Respondent's owner received multiple unsubtle entreaties from the tribunal to distance himself from his expert's hostility to the exercise of regulatory authority by DEA, all of which were soundly declined. Tr. 1222–24.

Respondent's Exceptions also reflect a misunderstanding of the CSA and its implementing regulations. Additionally, some of Respondent's Exceptions repeat arguments that were already raised in Respondent's Posthearing Brief, or in prehearing or posthearing filings, and have been adequately addressed in the adopted Recommended Decision or in the Chief ALJ's orders. Therefore, I reject Respondent's Exceptions and adopt the Recommended Decision of the Chief ALJ as amended above.

Exception A

Respondent argues in its first Exception that the Government failed to demonstrate that Respondent's prescribing ''posed imminent harm to the public,'' and that the Chief ALJ ''departed from established standard'' by recommending that Respondent's registration be revoked without any evidence of public harm. Resp Exceptions, at 2–3. However, Respondent does not cite legal authority for the proposition that I must find evidence of diversion or harm before I may suspend or revoke a registration. Agency Decisions have found that DEA has the authority to revoke a DEA registration in the absence of evidence of diversion if the registrant's ''practices . . . create a substantial risk of diversion'' or even the ''opportunity for diversion.'' *See, e.g., Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,905 n.32 (2018) (citing *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,974 n.35 (2010). Further, DEA has held that ''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and could justify revocation or denial.'' *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601).

As discussed in more detail above, DEA is authorized to revoke a registration upon a finding that the registrant's registration is ''inconsistent with the public interest,'' based on a consideration of five enumerated factors, including the registrant's ''experience dispensing . . . controlled substances'' and the registrant's ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f). In this case, I find that the Government has met its burden of proving that Respondent's registration is inconsistent with the public interest by presenting evidence that Respondent repeatedly filled prescriptions that presented obvious and well-established red flags of drug abuse and diversion, in violation of federal and state law. Agency Decisions have consistently held that the repeated filling of prescriptions in violation of federal and state law constitutes acts that are inconsistent with the public interest, and establish grounds for DEA to revoke a registration. *See, e.g., Suntree Pharmacy,* 85 FR 73,776.

Moreover, Respondent's Exception conflates the legal standard for issuing an immediate suspension order under 21 U.S.C. 824(d) with the legal standard for revoking a registration under 21 U.S.C. 823(f). Before issuing an ISO, the Government must demonstrate that the registrant has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant,'' and that those failures have created 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.'' 21 U.S.C. 824(d) (emphasis added).*[N]As discussed in more detail above, *see supra* n.*M, I find that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger.

Exception B

Respondent next takes exception to the Chief ALJ's characterization of Dr. Schossow's expert testimony. Resp Exceptions, at 4–6. Respondent argues that Dr. Schossow's testimony should not be given any weight for several reasons. First, Respondent argues that Dr. Schossow cannot be trusted because she initially testified that she had sat on the Florida board of pharmacy in the 1990s, and later confirmed that she had not. Second, Respondent argues that Dr. Schossow's opinions were entitled to little weight because she did not speak to the physicians, pharmacists, and customers involved in Respondent's dispensing, and she had never been to Respondent pharmacy. Respondent identifies several additional concerns with Dr. Schossow's testimony, including that her opinions were illogical and based on speculation, that she did not identify any evidence that Respondent's customers were abusing controlled substances, and that she did not have adequate information to conclude whether there was imminent danger or public harm.

I agree with the Chief ALJ's assessment of Dr. Schossow's credibility,*[O] including his determination that Dr. Schossow's misstatement about the Florida board of pharmacy was not material. *See* ALJ Ex. 67 (Order Denying the Respondent's Motion to Disqualify Expert Witness). I also find that Dr. Schossow reviewed sufficient materials to provide relevant opinions on Respondent's compliance with the usual course of professional practice in Florida, and that her failure to speak to any of the involved pharmacists, physicians, or customers did not diminish the weight of her opinions. Dr. Schossow's opinions primarily focused on Respondent's failure to document a resolution of red flags of drug abuse and diversion. Respondent's failure to document was sufficient evidence that Respondent's dispensing was outside the usual course of professional practice, even without input from any of Respondent's pharmacists or customers, or the prescribing physicians.

Respondent's additional concerns about the allegedly illogical and inconsistent nature of Dr. Schossow's opinions are not adequately supported by citations to the record that would allow me to meaningfully respond. *See* 21 CFR 1316.66. As stated above, I agree with the Chief ALJ's credibility determinations and his analysis of Dr. Schossow's opinions. I find that the Chief ALJ thoroughly and neutrally analyzed Dr. Schossow's credibility and identified portions of her testimony that were illogical or internally inconsistent, and relied only on those portions that were logical and well-supported.

Finally, as stated above, Respondent does not cite legal authority for the proposition that I must find evidence of diversion or harm before I may suspend or revoke a registration. It is therefore irrelevant to my Decision whether the Government's expert believed that there was actual harm.

Exception C

Respondent next takes Exception to the Chief ALJ's questions to Respondent's representative, Dr.

*[N] In support of this argument, Respondent quotes from a West Virginia District Court order granting a pharmacy's motion to dissolve an immediate suspension order. The district court found that the Government had not adequately supported its imminent danger finding, because it had not ''demonstrat[ed] that actual or anticipated harm had occurred in patients.'' *Id.* (*citing Oakhill Hometown Pharmacy* v. *Uttam Dhillon,* 2:19–cv–00716, at 9). Respondent's reliance on this decision is misplaced, and it has no relevance to this proceeding. Respondent's legal course of action on this matter would have been to challenge the ISO in court. The subject of this proceeding is the revocation of Respondent's registration. I am finding in favor of revocation, and therefore, at the time that my order goes into effect, the immediate suspension will necessarily end.

*[O] 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, *Universal Camera Corp.,* 340 U.S. at 496, and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179.

Howard, about whether he agreed with certain testimony by Respondent's expert, Dr. Buffington. Resp Exceptions, at 6–8. Respondent believes that the Chief ALJ's questions to Dr. Howard misstated Dr. Buffington's opinions and that they put Dr. Howard in the uncomfortable position of deciding whether to agree with Dr. Buffington's opinions. *Id.*

As discussed in more detail above, ALJs have authority to regulate the administrative hearing, which includes asking clarifying questions of counsel and witnesses and issuing evidentiary rulings. *See supra* n. *A (citing 5 U.S.C. 556(c)(5); 21 CFR 1316.52(e)). In this case, the Chief ALJ was questioning Dr. Howard for Respondent's benefit in an attempt to ascertain whether Respondent shared Dr. Buffington's criticisms of—and hostility towards—DEA as a regulator. Respondent's attitude towards DEA, and appreciation for the requirements for operating in the usual course of professional practice, are relevant to DEA's determination as to Respondent's likelihood of future compliance in determining whether a sanction is appropriate.*P I therefore find that the Chief ALJ properly exercised his discretionary authority to regulate the hearing and that Respondent's Exception is without merit.

Exception D

Respondent next argues that the Chief ALJ improperly excluded Respondent's Second Supplemental Prehearing Statement (hereinafter, Second SPS), which was filed approximately five months after the deadline set by the Prehearing Ruling. Resp Exceptions, at 8–9. Respondent's Second SPS was also not accompanied by a motion for good cause, which is a prerequisite for a late-filed prehearing statement.*Q The Government filed a Motion to Strike (*see* ALJ Ex. 34), and Respondent replied to that motion (*see* ALJ Ex. 35), arguing that there should be no prejudice to the Government from the late filing. The Chief ALJ determined that Respondent had not provided any rationale or good cause for its late filing.*R Order Denying Respondent's Motion, at n. 3. As previously mentioned, the Chief ALJ has authority to regulate the hearing, which includes the authority to exclude evidence. 21 CFR 1316.52(e). I therefore defer to his decision to exclude Respondent's Second SPS.

I also find that there was no prejudice to the Respondent from the Chief ALJ's denial of its Second SPS. The Second SPS did not notice any new witnesses or testimony; it simply noticed Respondent's intention to amend ten of Respondent's previously-disclosed exhibits. Respondent stated that the amended exhibits contained additional ''[drug utilization review] data.'' *See* Second SPS, at 2. Although the Chief ALJ did not permit Respondent to amend these exhibits before the hearing, he allowed Respondent to attempt to authenticate the amended exhibits at the hearing ''to afford the Respondent the maximum level of due process.'' RD, at n. 106 (citing Tr. 642–60). Thus, the Chief ALJ essentially reversed his decision to deny the Second SPS by permitting the Respondent to offer the amended exhibits into evidence.

In the RD, the Chief ALJ referred to the amended exhibits as the outside-of-record (OOR) documents. *See* RD, at n. 106. Respondent attempted to admit one of the OOR documents at the hearing, but the Chief ALJ declined to admit it because there were ''fundamental issues regarding inadequate foundation and reliability.'' *Id.* Respondent did not offer the remaining OOR documents into the record after the first document was denied. *Id.* However, Respondent's counsel repeatedly refreshed Dr. Howard's recollection with the OOR documents, which gave Dr. Howard the opportunity to testify about any notations in the OOR documents that evidenced attempts by Respondent to conduct a drug utilization review. *See supra* Respondent's Case, Summary of Dr. Howard's Testimony.*S I find that Respondent was given ample opportunity at the hearing to provide the tribunal with all reliable evidence of its attempts to exercise due diligence efforts.

Respondent further argues that the Chief ALJ's decision to exclude the Second SPS was arbitrary in light of his decision to take official notice of an FDA black box warning that cautions against concurrent prescribing of opioids and benzodiazepines, which was not identified in the Government's prehearing filings. Resp Exceptions, at 8–9. However, on this issue, Respondent's counsel did not object to the official notice and agreed that there was no serious notice issue. *See* ALJ Ex. 39. I defer to the Chief ALJ's decision to take official notice of this document, which was an exercise of his authority to regulate the hearing. As stated above, courts have uniformly held that judicial rulings issued during the course of litigation rarely constitute evidence of cognizable bias. Order Denying the Respondent's Recusal Motions (citing *Liteky* v. *United States,* 510 U.S. 540, 555 (1994), *Hamm* v. *Members of Bd. of Regents,* 708 F.2d 647, 651 (11th Cir. 1983), *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,958–59 (2010)). Further, the contents of this document should not have been a surprise to Respondent, because this document is publicly available and widely known, and the Government had notified Respondent that its expert would testify about the dangers of prescribing opioids and benzodiazepines concurrently. *See e.g.,* ALJ Ex. 4 (Gov't Prehearing), at 20–21; *see also* OSC/ISO, at 3.

Exception E

Finally, Respondent argues that the Chief ALJ erred in finding that Dr. Howard's hearing testimony suffered from diminished credibility. Resp Exceptions, at 9–11. In support of this argument, Respondent cites to only one page of the transcript, where the Chief ALJ faulted Dr. Howard for failing to remember testimony from the day before. Resp Exceptions, at 9 (citing Tr. 53). Respondent's Exception fails because it does not ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. Respondent's Exception also

*P *See, e.g.,* Jayam Krishna-Iyer, 74 FR 459, 463 (2009) (stating that ''where a registrant has committed acts inconsistent with the public interest, the registrant must . . . demonstrate that [it] will not engage in future misconduct'') (quoting Medicine Shoppe, 73 FR 364, 387 (2008)); *see also Lisa Hamilton, N.P.,* 85 FR 71,465, 71,473 (2019) (observing, in determining that revocation was the appropriate remedy, that the respondent had ''demonstrated a general disdain for the charges against her and the situation in which she had found herself'').

*Q ALJ Ex. 36, at 2 (Order Denying the Respondent's Motion to File a Second Supplemental Prehearing Statement) (citing Prehearing Ruling, at 2; 21 CFR 1316.55 (stating that a prehearing ruling issued in an administrative enforcement action ''shall control the subsequent course of the hearing unless modified by a subsequent ruling'')).

*R Respondent disagrees with the Chief ALJ's determination that it did not provide good cause for the late filing. Resp Exceptions, at 8. Respondent argues that ''[t]here was good cause provided with the background setting of the pandemic that had caused the case to stay on hold for nearly a year,'' and ''[c]ounsel stated that there was no prejudice to the Government and that the pandemic and his recent notice of appearance in the case were the basis of the untimely Prehearing Statement.'' *Id.* However, the Chief ALJ was aware of the pandemic's impact on the litigation when he decided to exclude Respondent's Second SPS, and he determined that Respondent had not provided good cause. Order Denying Respondent's Motion, at 2–3.

*S As the RD observes, Respondent could have sought to introduce the OOR documents into the record as past recollection recorded, but declined to do so. *See* RD, at 107 (citing Fed. R. Evid. 803(5)).

fails because, after reviewing the entire record, I find that the Chief ALJ thoroughly and accurately analyzed Dr. Howard's credibility and his testimony, and I agree with his credibility findings.

I therefore reject Respondent's Exceptions and issue the following Order.

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. FA2125640 issued to AARRIC, Inc. 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 applications for renewal or modification of this registration, as well as any other pending application of AARRIC, Inc. for additional registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that any controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–00955 Filed 1–18–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until February 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act as Amended.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0001. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes STOP formula grantees (50 states, the District of Columbia and five territories (Guam, Puerto Rico, American Samoa, Virgin Islands, Northern Mariana Islands). The STOP Violence Against Women Formula Grant Program was authorized through the Violence Against Women Act of 1994 and reauthorized and amended in 2000, 2005, and 2013. The purpose of the STOP Formula Grant Program is to promote a coordinated, multi-disciplinary approach to improving the criminal justice system's response to violence against women. It envisions a partnership among law enforcement, prosecution, courts, and victim advocacy organizations to enhance victim safety and hold offenders accountable for their crimes of violence against women. The Department of Justice's Office on Violence Against Women (OVW) administers the STOP Formula Grant Program funds which must be distributed by STOP state administrators according to statutory formula (as amended in 2000, 2005 and 2013).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 56 respondents (state administrators from the STOP Formula Grant Program) less than one hour to complete a Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act, as Amended.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the Certification is less than 56 hours.

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

Dated: January 13, 2022.

Melody Braswell,

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

[FR Doc. 2022–00960 Filed 1–18–22; 8:45 am]

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DEPARTMENT OF JUSTICE

[OMB Number 1105–0080]

Agency Information Collection Activities: Extension of a Currently Approved Collection: Annuity Broker Declaration Form

ACTION: 60-Day notice of information collection under review.

The Department of Justice (DOJ), Civil Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until March 21, 2022.

If you have questions concerning the collection, please contact James G.