DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–06]

Gulf Med Pharmacy; Decision and Order

On November 18, 2019, 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 Gulf Med Pharmacy (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FG6290061 (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 July 20–23, 2020, from August 12–13, 2020, and on August 20, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference. On November 25, 2020, Administrative Law Judge Mark M. Dowd (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On December 15, 2020, Respondent filed exceptions to the Recommended Decision (hereinafter, Resp Exceptions), and on December 28, 2020, the Government filed a response to Respondent's exceptions (hereinafter, Gov Response). 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.*[A] 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]

The issue ultimately to be adjudicated by the Administrator, with the assistance of this Recommended Decision, is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. FG6290061, issued to the Respondent should be revoked, and any pending applications for modification or renewal of the existing registration be denied, and any applications for additional registrations be denied, because its continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4).

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 Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 4. Specifically, from March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that they were issued for a legitimate medical purpose, in violation of federal and state law, including 21 CFR 1306.04(a) and 1306.06, and Fla. Admin. Code r. 64B16–27.800, .810, and .831. ALJ Ex. 1.

The Order to Show Cause also alleged the following:

1. Gulf Med Pharmacy is registered with the DEA to handle controlled substances in Schedules II–V under DEA COR No. FG6290061. Gulf Med Pharmacy's registered address is 4106 Del Prado Boulevard South, Cape Coral, Florida 33904. Gulf Med Pharmacy's COR expires by its own terms on September 30, 2022.

2. Gulf Med Pharmacy's DEA COR should be revoked and any pending application should be denied because Gulf Med Pharmacy has committed such acts as would render its registration inconsistent with the public interest under 21 U.S.C. 823(f). *See* 21 U.S.C. 824(a)(4). From March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly ignored obvious red flags of abuse or diversion and filled prescriptions without exercising its corresponding responsibility to ensure that they were issued for a legitimate medical purpose, in violation of federal and state law. Given Gulf Med Pharmacy's longstanding and pervasive violations of legal requirements relating to the practice of pharmacy, Gulf Med Pharmacy's continued registration constitutes an ''imminent danger'' as that term is defined by 21 U.S.C. 824(d).

Legal Requirements

3. A ''prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. Pharmacists at Gulf Med Pharmacy were permitted to fill prescriptions ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Although ''[t]he 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.* ''DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Wheatland Pharmacy,* 78 FR 69441, 69445 (2013) (internal quotation marks and citation omitted, alteration in original).

4. In addition to complying with federal statutes and regulations, Gulf Med Pharmacy and its pharmacists also must comply with applicable Florida law. In particular, Florida pharmacists must ''review the patient record and each new and refill prescription presented for dispensing'' to identify, among other things, ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''drug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code Ann. r. 64B16–27.810(1). Upon recognizing any of these red flags of abuse or diversion, a Florida pharmacist ''shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with in brackets, and I have included specific descriptions of the modifications in the brackets or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

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

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

[2] [Footnote omitted, *see supra* n.*B.]

[3] [Footnote omitted, *see supra* n.*B.]

prescriber.'' *Id.* at r. 64B16–27.810(2). Florida pharmacies must also maintain a patient record system that documents resolution of red flags. *See id.* at r. 64B16–27.800. Finally, Florida pharmacists must comply with the standards for filling of controlled substance prescriptions. *See id.* at r. 64B16–27.831 (requiring pharmacists, among other things, to ''exercise[ ] sound professional judgment'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription''). A Florida pharmacy's failure to comply with Florida's prescription review requirements also constitutes a violation of the federal Controlled Substances Act. *See, e.g., Trinity Pharmacy II,* 83 FR 7304, 7329 (2018) (''Thus, [Florida] pharmacists violate Florida law if they fail to identify and resolve the red flags that are part of the prospective drug use review set forth in Rule 64B16–27.810. And if they knowingly fill prescriptions without resolving these red flags during this review, then they violate their corresponding responsibility under 21 CFR 1306.04(a).'').

5. As explained in greater detail below, a Florida pharmacy expert retained by the DEA has reviewed numerous prescriptions filled by Gulf Med Pharmacy and has concluded that from March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for controlled substances in violation of binding minimal standards that govern the practice of pharmacy in the State of Florida.

Cocktail Medications

6. As discussed above, both federal and Florida law require pharmacists to identify and resolve red flags of abuse and diversion. *See* paragraph 4, *supra.* One common red flag of drug abuse or diversion is when a practitioner prescribes (via one or more prescriptions) ''cocktail medications.'' Cocktail medications are combinations of controlled substances that are widely known to be abused or diverted, and when taken together, significantly increase a patient's risk of death or overdose. The DEA's expert reviewed numerous prescriptions filled by Gulf Med Pharmacy, as well as Gulf Med Pharmacy's patient profiles for the relevant patients, and concluded that Gulf Med Pharmacy regularly dispensed cocktail medications without addressing or resolving this red flag. For example, the DEA's expert noted that Gulf Med Pharmacy repeatedly dispensed high doses of opioids (in the form of hydromorphone, oxycodone, and morphine sulfate extended release) along with high doses of other central nervous system depressant medications, such as benzodiazepines (*e.g.,* alprazolam, clonazepam, or diazepam) or muscle relaxants (*e.g.,* carisoprodol). The DEA's expert opined that these controlled substances are dangerous when used in combination.

7. Gulf Med Pharmacy repeatedly dispensed ''cocktail medications'' without any indication that its pharmacists addressed or resolved the fact that such prescriptions present a risk of abuse or diversion. Examples of instances when Gulf Med Pharmacy dispensed cocktail medications in the face of unresolved red flags include the following:

a. On at least three occasions between May 22, 2019, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician R.D. for Patient A.B. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 15 mg, and 30 units of diazepam 10 mg.

b. On at least four occasions between February 9, 2018, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient B.Di. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 30 mg, and 60–90 units of alprazolam 1 mg.

c. On at least five occasions between December 28, 2018, and August 8, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient J.B. for 120 units of oxycodone 30 mg, 60 units of morphine sulfate extended release 30 mg, and 90 units of alprazolam 1 mg.

d. On at least four occasions between May 14, 2019, and August 6, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient R.R. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 60 mg, and 30 units of alprazolam 2 mg.

e. On at least four occasions between May 8, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient B.Da. for 120 units of hydromorphone 8 mg, 30 units of morphine sulfate extended release 30 mg, and 30 units of alprazolam 2 mg. On February 12, 2018, Gulf Med Pharmacy also filled prescriptions written on the same day by another physician in the same practice—Physician D.P.—for Patient B.Da. for 150 units of hydromorphone 8 mg, 90 units of methadone 10 mg, and 30 units of alprazolam 2 mg.

8. According to the DEA's expert, the cocktail of an opioid, a benzodiazepine, and carisoprodol—commonly known as the ''Trinity'' cocktail—is a particularly serious red flag because that combination of controlled substances is highly dangerous and is widely known to be abused and/or diverted. Gulf Med Pharmacy repeatedly dispensed Trinity cocktail medications without any indication that its pharmacists addressed or resolved the fact that such prescriptions present a risk of abuse or diversion. Examples of instances when Gulf Med Pharmacy dispensed Trinity cocktail medications in the face of unresolved red flags include the following: Between May 30, 2019, and July 29, 2019, Gulf Med Pharmacy filled three sets of prescriptions from Physicians D.G. and F.M. for Patient J.R. for the Trinity cocktail. For each set of prescriptions, Physician F.M. prescribed Patient J.R. benzodiazepines and muscle relaxants; specifically, 30 units of temazepam 30 mg, 30–60 units of diazepam 5 mg, and 120 units of carisoprodol 350 mg. Meanwhile, Physician D.G. prescribed Patient J.R. opioids; specifically, 120 units of Norco (hydrocodone-acetaminophen) 5–325 mg, 120 units of Percocet (oxycodone-acetaminophen) 5–325 mg, and 120 units of Percocet 10–325 mg.

Improper Dosing for Pain Management

9. As noted above, both federal and Florida law require a pharmacist to identify and address red flags of drug abuse or diversion including over-utilization and under-utilization. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. According to the DEA's expert, for a patient receiving treatment with both long-acting and short-acting opioids, the proper pharmacologic dosing for pain management is to use larger, scheduled doses of the long-acting opioid to control chronic pain with smaller, as-needed doses of the short-acting opioid for breakthrough pain. According to the DEA's expert, this method of dosing reduces the amount of the short-acting opioid that the patient must use in order to obtain the same level of pain control. In contrast, the DEA's expert opined that prescriptions that provide a larger daily dose of short-acting opioids, rather than long-acting opioids, do not make pharmacologic sense and thus are a red flag of drug abuse or diversion. From at least March 22, 2017, until at least August 8, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for patients receiving a much greater daily morphine milligram equivalent dosage of short-acting opioids than long-acting opioids. The DEA's expert also noted that each of the short-acting or immediate release opioid prescriptions was scheduled four times a day or every

six hours, even though the patient was also prescribed a scheduled, long-acting opioid. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. In the expert's view, because these prescriptions were illogical from a pharmacological perspective, they therefore raised a red flag. The DEA's expert further opined that Gulf Med Pharmacy should have attempted to address or resolve this red flag of drug abuse or diversion prior to filling these prescriptions, but, on numerous occasions, its pharmacists failed to do so. Examples of Gulf Med Pharmacy filling such improper prescriptions include the following:

a. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient A.B. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

b. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Di. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

c. On at least 18 occasions between January 10, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for Patient S.K. for 110 units of immediate release hydromorphone 8 mg (equal to 125–128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

d. On at least 27 occasions between March 22, 2017, and August 8, 2019, Gulf Med Pharmacy filled prescriptions for Patient J.B. for 108–120 units of immediate release oxycodone 30 mg (equal to 162–180 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

e. On at least eight occasions between October 2, 2018, and August 6, 2019, Gulf Med Pharmacy filled prescriptions for Patient R.R. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 28 units of morphine sulfate extended release 60 mg (equal to 60 mg of morphine per day).

f. On at least eight occasions between January 16, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Da. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 30 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).

Long Distances

10. Between October 25, 2017, and August 5, 2019, Gulf Med Pharmacy regularly filled controlled substance prescriptions for individuals who traveled an unusual distance to obtain their prescriptions. The DEA's expert opined that traveling long distances to obtain or fill a controlled substance is indicative of diversion and/or abuse and that such behavior is a red flag that must be addressed prior to dispensing. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. Gulf Med Pharmacy did not do so, as illustrated by the following examples of prescriptions that it filled:

11. On at least 20 occasions between November 8, 2017, and July 17, 2017, Patient A.B. traveled 45 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 15 mg, and diazepam 10 mg, which Gulf Med Pharmacy filled.

12. On at least five occasions between October 25, 2017, and February 12, 2018, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg and methadone 10 mg, which Gulf Med Pharmacy filled. On two of those trips—January 15, 2018, and February 12, 2018—Patient B.Da. also obtained prescriptions for alprazolam 2 mg, which Gulf Med Pharmacy also filled. Subsequently, on at least seven occasions between February 13, 2019, and August 5, 2019, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 30 mg, and alprazolam 2 mg, which Gulf Med Pharmacy also filled.

13. On at least 17 occasions between January 17, 2018, and May 8, 2019, Patient R.D. traveled over 41 miles round trip to obtain prescriptions for hydromorphone 8 mg and lorazepam 2 mg, which Gulf Med Pharmacy filled.

Cash Payments and Price Gouging/ Black Market Pricing

14. Another common red flag of abuse or diversion that pharmacists must monitor is the use of cash payments for controlled substances instead of insurance payments. *See* 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810. According to the DEA's expert, when a prescription for a controlled substance is electronically processed through insurance, the insurance company will frequently reject suspicious controlled substance prescriptions that may be related to drug abuse or diversion, such as controlled substance prescriptions for the same patient filled at multiple pharmacies. Consequently, cash payments for controlled prescriptions are a red flag of abuse or diversion because some suspect patients may choose to pay cash in order to avoid an insurance rejection that might alert the pharmacist to potential drug abuse or diversion. Such cash payments are especially suspicious when the patient bills insurance for other prescriptions, but pays cash for controlled substance prescriptions.

15. Similarly, the DEA's expert indicated that price gouging, or charging more than the market rate for prescriptions for a controlled substance, is a separate indicator of drug abuse or diversion. The DEA's expert explained that price gouging is a red flag because a legitimate patient, who could fill his or her prescription at any pharmacy, will switch pharmacies in order to pay the fair market price for that prescription. In contrast, the highly suspect patient can only fill prescriptions at a suspicious pharmacy and must pay whatever price that suspicious pharmacy sets. Consequently, patients paying inflated prices for controlled substance prescriptions are another red flag of drug abuse or diversion, especially when the price paid is substantially higher than the market price available from other nearby pharmacies. *See Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79188, 79191 (2016). For the same reason, filling controlled substance prescriptions at inflated cash prices shows that a pharmacy has knowledge that it is filling prescriptions that are not legitimate, as its inflated prices reflect a ''risk premium'' that the pharmacy charges to account for the risk it is taking by filling illegitimate prescriptions. *See id.* at 79,199–200 (''[E]ven granting that there are no prohibitions on the prices a pharmacy can charge for controlled substances, when those prices far exceed what other pharmacies would charge, the Agency may properly draw the inference that the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others.''). To determine a baseline of normalcy (*i.e.,* legitimate pricing), the DEA's expert contacted representative pharmacies in Cape Coral, Florida, and found that the price of 120–140 units of oxycodone 30 mg varied from about $1.59 to $1.63 per unit, while the sale price of 120–140 units of hydromorphone 8 mg varied from about $1.25 to $1.27 per unit.

16. From March 22, 2017, until at least August 6, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for oxycodone 30 mg and hydromorphone 8 mg for patients who paid for these prescriptions in cash at substantially inflated prices that far exceeded what other area pharmacies charged. The DEA's expert reviewed Gulf Med Pharmacy's patient profiles for several of these patients. The DEA's expert opined that Gulf Med Pharmacy should have attempted to address or resolve these red flags of drug abuse or diversion prior to filling these prescriptions, but failed to do so. Gulf Med Pharmacy dispensed controlled substances at inflated prices to individuals paying cash in the following instances:

17. On at least 15 separate occasions between March 14, 2018, and April 10, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient R.D. On each occasion, Patient R.D. paid for the prescription in cash, and on all but one occasion Patient R.D. paid $4 per unit ($480 in total)—over three times the market rate.

18. On at least six separate occasions between February 26, 2018, and April 22, 2019, Gulf Med Pharmacy filled prescriptions for 84 to 120 units of oxycodone 30 mg for Patient T.G. On each occasion, Patient T.G. paid for the prescription in cash at a price of $4 per unit ($336 to $480 in total)—over three times the market rate.

19. On at least 16 separate occasions between March 7, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for 108 to 110 units of hydromorphone 8 mg for Patient S.K. On each occasion, Patient S.K. paid for the prescription in cash at a price ranging from $3.56 per unit to $4 per unit ($392 to $432 in total)—in each case at least two-and-a-half times the market rate, and as high as over three times the market rate.

20. On at least 14 separate occasions between March 20, 2018, and April 15, 2019, Gulf Med Pharmacy filled prescriptions for 90 to 120 units of oxycodone 30 mg for Patient L.V. On each occasion, Patient L.V. paid for the prescription in cash at a price ranging from $2.50 per unit to $3.33 per unit ($300 in total)—in each case at least one-and-a-half times the market rate, and as high as twice the market rate. Further, Patient L.V. used insurance to pay for other prescriptions, including prescriptions for controlled substances such as alprazolam and zolpidem.

21. On at least 19 separate occasions between March 22, 2017, and September 7, 2018, Gulf Med Pharmacy filled prescriptions for 108 to 120 units of oxycodone 30 mg for Patient J.B. On each occasion, Patient J.B. paid for the prescription in cash at a price of $3.40 to $4 per unit ($408 to $480 in total)—in each case over twice the market rate.

22. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient A.B. On each occasion, Patient A.B. paid for the prescription in cash at a price of $3.73 to $4 per unit ($448 to $480 in total)—in each case over two-and-a-half times the market rate, and as high as three times the market rate.

23. On at least five occasions between October 25, 2017, and February 12, 2018, Gulf Med Pharmacy filled prescriptions for 150 units of hydromorphone 8 mg for Patient B.Da. Subsequently, on at least six occasions between March 13, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Da. On each of these 11 occasions, Patient B.Da. paid for the prescription in cash at a price of $4 per unit ($480 to $600 in total)—over three times the market rate.

24. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Di. On each occasion, Patient B.Di. paid for the prescription in cash at a price of $4 per unit ($480 in total)—over three times the market rate.

25. On at least 18 occasions between December 5, 2017, and least August 6, 2019, Gulf Med Pharmacy filled prescriptions for 120 to 168 units of hydromorphone 8 mg for Patient R.R. On each occasion, Patient R.R. paid for the prescription in cash at a price ranging from $4 per unit to $4.60 per unit ($480 to $672 in total)—in each case over three times the market rate. ALJ Ex. 1.

The Hearing

Government's Opening Statement

The Government seeks to revoke the Respondent's DEA certificate of registration, and deny any applications for renewal, or modification of that registration because the Respondent has committed acts that render its continued registration inconsistent with the public interest. Tr. 14–15. The testimony and evidence will show that the Respondent repeatedly ignored red flags of abuse and diversion—many established under prior Agency decisions—and sold prescriptions for controlled substances without exercising their corresponding responsibility to ensure that those prescriptions were issued in the usual course of professional practice, and for a legitimate medical purpose.

With respect to the prescriptions that the Respondent filled for the charged patients in this matter, the Government's expert, Dr. Tracy Schossow, will explain that the Respondent filled prescriptions for controlled substances for those patients in the face of multiple red flags of abuse and diversion. Tr. 15–16. The red flags that the Respondent ignored include filling prescriptions for patients (J.B., A.B., B.Da., R.D., B.Di., R.R., and L.B.) that were cocktail combinations of opioids and benzodiazepines that are dangerous when used in combination, and are widely known to be sought after for drug abuse and diversion.

The Respondent also filled prescriptions for two charged patients (J.B. and R.R.) for the Trinity drug cocktail, which is a non-therapeutic combination of an opiate, a benzodiazepine, and muscle relaxer, Carisoprodol, which is a known dangerous combination and used for drug abuse and diversion.

The Respondent filled prescriptions for Patient J.R. for benzodiazepines, which duplicated the therapeutic effects. The Respondent also filled prescriptions for charged patients (J.B., A.B., B.Da., B.Di., S.K., and R.R.) for both long-acting and short-acting opioids in combinations that do not make pharmacological sense. Tr. 16–17. The Respondent filled prescriptions for Patient R.R. for benzodiazepines at dosages that do not make pharmacological sense.

The Respondent filled prescriptions for charged patients (J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.B.) despite each paying cash for controlled substances. The Respondent also sold prescriptions for charged patients (J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.B.) for opioids despite substantial mark-ups in price. The Respondent also filled prescriptions for charged patients (A.D., B.Da., and R.D.) despite these patients travelling long round-trip distances to have the Respondent's pharmacy fill the controlled substance prescriptions.

DI will explain that the DEA executed administrative inspection warrants and served three administrative subpoenas on the Respondent during the investigation. Tr. 17–18. This gave the Respondent several opportunities to provide the DEA with evidence that it identified and resolved red flags of diversion or abuse before dispensing the charged prescriptions. As Dr. Schossow will testify, the Respondent's records

indicate that it failed to address and resolve any of these red flags of diversion or abuse, and that it failed to exercise its corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the normal course of professional practice. Therefore, the Respondent violated federal and state law when it dispensed the charged prescriptions.

Respondent's Opening

Gulf Med Pharmacy is a small, independent pharmacy in southeast Florida. Tr. 19. Respondent contended that it has been unfairly and inappropriately targeted by the DEA for conduct that does not violate any Florida state or federal statues or regulations. Respondent contended that this action is based upon the DEA's created idea about review of prescriptions retrospectively related to some opiate prescriptions, and combinations of those opiates and benzodiazepines. Respondent contested that the DEA's position is not supported by medical literature or by anything other than supposition and conjecture on the part of the DEA's expert witness.

The Respondent will present testimony from Dr. Daniel Buffington. Dr. Buffington is a professor associated with the University of South Florida in the Departments of Medicine and Pharmacy. Tr. 19–20. He has extensive experience in pharmacy practice, and will describe the appropriateness of the Respondent's actions in filling prescriptions defined in the Order to Show Cause, as well as the appropriateness of the documentation related to those prescriptions.

Respondent contended that what is important in this matter is there has been, and continues to be, a tortured and unsupportable interpretation of the Florida Administrative Code, as it related to the obligation of a pharmacist licensed by the state. Tr. 20. The State of Florida has the right and obligation to control the scope and the manner of the practice of pharmacy and medicine within the state, consistent with the Supreme Court of the United States' precedence.

The Respondent's evidence will be direct and will show that the attempt to characterize the distance that was traveled by the charged patients to the Respondent's pharmacy is nothing short of manufactured. Tr. 20. In order to make the distances seem longer, the Government included round-trip travel as opposed to direct travel or the direct distance between the residence of the patient and the pharmacy. Tr. 20–21. Given the distances in south Florida, since patients are coming from some of the barrier islands, the distance between a straight line and coming from the barrier islands and comparing them to facilities on the mainland, is a significant factor that was not considered by the DEA or its expert witness.

Respondent contended that the DEA's expert witness is neither qualified, nor capable of, having any knowledge or information to justify opinions regarding the price paid for medications by the patients, or on the distance, travel, or mechanism of payment. Tr. 21. Even though it does not have any burden of proof, the Respondent will demonstrate the fallacies of the DEA's position. Tr. 21. It also looks forward to receiving a recommendation that Gulf Med Pharmacy's DEA registration be reinstated and continuing to operate in its usual and appropriate manner. Tr. 21.

Government's Case-in-Chief

Diversion Investigator (DI)

DI has been a Diversion Investigator with the DEA for three years and has been assigned to the Miami Field Division, Western office for most of that time. Tr. 25–27. Prior to working for the DEA, DI worked as a transportation screening officer with the Transportation Security Administration. Tr. 26. As a Diversion Investigator, DI is tasked with enforcing the Controlled Substances Act, which regulates the manufacture, distribution, possession, use, and importation of controlled substances. Diversion Investigators also strive to prevent the diversion of controlled substances to the streets. DI conducts civil and criminal investigations, including administrative actions like the current matter. Tr. 26–27. DI has attended the DEA Academy at Quantico and has conducted approximately twelve investigations with the DEA. Tr. 27–28, 279–81.

The investigation of Gulf Med Pharmacy was initiated because Gulf Med Pharmacy was found to be one of the top ten purchasers of Oxycodone, Hydromorphone, and Hydrocodone in the State of Florida. Tr. 28–29, 362.[4] This was the impetus for the DEA inquiry, to investigate why Gulf Med was a top purchaser of these controlled substances. Tr. 30.

DI became the case agent in approximately December 2018, after DI 2, the original case agent[5] retired. Tr. 28, 39, 315. Upon becoming case agent, DI reviewed the case file, which included the administrative inspection warrant. Tr. 40–42. DI had not reviewed the case file before he became the case agent or before the administrative inspection warrant was served. Tr. 368–70. Based solely upon DEA reports he later reviewed, DI confirmed that Gulf Med Pharmacy was one of the top purchasers in Florida of these controlled substances in 2017. Tr. 362, 365–68. At the hearing, he could not confirm whether the sole supplier of these controlled substances to the Respondent was Cardinal. Tr. 364.

Initially, DI's role in this matter was to assist the case agent with the administrative inspection warrant. Tr. 28. The administrative inspection warrant allows the DEA to inspect and copy records, information, reports, files, inventories, invoices, official order forms, prescriptions, and other documents required to be kept under the Controlled Substances Act. Tr. 302; GX 2 at 1; *see,* 21 U.S.C. 880. The warrant describes what records and information are subject to seizure, including all of the electronic data maintained by the Respondent pharmacy. Tr. 302–03; GX 2 at 2. In terms of the Respondent's compliance with the Controlled Substances Act and the laws applicable to the operation of a pharmacy, the DEA has the authority to go into the pharmacy and seize all of the relevant electronic data. Tr. 304–06. An administrative inspection warrant is used if the investigators suspect that the pharmacy may deny entry to investigators presenting with a notice of inspection. Tr. 289. When an administrative inspection warrant is served, DI follows the instructions of his group supervisors. Tr. 286. During an inspection, one or two agents conduct the inspection during normal business hours. Tr. 288.

The purpose of the inspection warrant was to gather all information relevant to the investigation, including both inculpatory and exculpatory evidence. Tr. 281–85. The warrant was based upon an affidavit by DI 2, the original case agent. DI did not create the warrant and he does not know the circumstances under which it was issued. Tr. 36–38. DI was part of the pre-inspection briefing session, which was conducted by DI 2. Tr. 281. He was advised that the Respondent was one of the top ten

[4] This evidence was admitted as relevant to the allegations. The Respondent probed this evidence, but gave notice that he was delving into this issue only on the basis the evidence was ruled to be relevant to the existing charges, and was not consenting to broaden the scope of the charges. The Tribunal explained to the Respondent that it did not permit the Government to expand the scope of the charges at the hearing, without giving timely notice to the Respondent, so that the Respondent had an opportunity to object. Tr. 359–61.

[5] [Footnote omitted.]

purchasers of oxycodone, hydromorphone, and hydrocodone in the State of Florida by DI 2 during the briefing before the execution of the warrant. Tr. 370–71.

DEA investigators served an administrative inspection warrant on Gulf Med Pharmacy on February 14, 2018. Tr. 31. DI was present when the warrant was served on the Respondent. Tr. 33–35.[6] The inspection of February 14, 2018, was performed by both diversion investigators and armed DEA special agents. Tr. 289–90. DI could not recall if any local law enforcement were present. Tr. 290. Prior to and at the point of service of the administrative inspection warrant, DI did not know where the Respondent kept its records. Tr. 387. DI knew that the employees of the pharmacy would know where the requested documents were located within the pharmacy, including the pharmacy technician and the Pharmacist-in-Charge. Tr. 391–92.

On February 14, 2018, the DEA simultaneously served an administrative subpoena on the Respondent through Dr. Ricard Fertil, the pharmacist in charge of Gulf Med Pharmacy. Tr. 44–45, 57, 393–94; GX 3; *see* 21 U.S.C 876. DI is familiar with administrative subpoenas, and regularly uses them. Tr. 46. DI was present on the day it was served and is familiar with the document. Tr. 46–49. The Respondent produced documents in response to the subpoena, and the DEA seized those documents from the Respondent. Tr. 64. The DEA provided a receipt for seized documents to the Respondent through a DEA–12 form. Tr. 50–60; GX 4. The receipt was signed by DI 2 and Mr. Ricard Fertil. DI did not attend the closeout meeting with the Respondent following the February 14, 2018 inspection. Tr. 356–57.

Items seized, and reflected in the receipt, included patient profiles, reports and printouts. Tr. 61, 63–64.[7] The investigators also seized the original prescriptions from the date the pharmacy opened until the date of the administrative inspection warrant. Tr. 291–92. During the service of the administrative inspection warrant, the DEA seized all of the Respondent's prescriptions and records, including electronic prescriptions for controlled substances. Tr. 73–75; GX 4 at 3–4, 6.

DI identified the prescriptions written and filled for Patient J.B. that were seized. Tr. 75–76; GX 7. These were included in the controlled substance prescriptions that had been filled by the Respondent pharmacy up until the date of the inspection. Tr. 77. The back side of the prescriptions have a filled sticker that show that the prescriptions were filled by Gulf Med Pharmacy. Tr. 78–79; GX 7 at 2. DI identified prescriptions for Patient A.B. that were taken from Gulf Med Pharmacy. Tr. 80–82; GX 8. DI also identified prescriptions for several patients filled by Gulf Med Pharmacy: Patient B.Da. (Tr. 83–85, 88–89; GX 9); Patient R.D. (Tr. 89–92; GX 10); Patient B.Di. (Tr. 95–98; GX 11); Patient P.G. (Tr. 99–101; GX 12); Patient S.K. (Tr. 101–03; GX 13); Patient R.R. (Tr. 111–13; GX 14); and Patient L.V. (Tr. 114–16; GX 15).

Once the prescriptions were seized from the Respondent pharmacy, they were placed into evidence and scanned. Tr. 93. The original prescriptions are maintained in the custody of the DEA evidence custodian. Tr. 94.

Once a warrant is served, the DEA investigators ask the pharmacist-in-charge where the prescriptions are located. Tr. 86. The investigators request a date range of prescriptions and seize them. Here, the prescriptions were in separate folders and were categorized by prescription number. Tr. 86–87. The folders were in various locations, including in drawers, cabinets, boxes, and ''just out in the open.'' Tr. 87.

A DEA technology specialist retrieved dispensing reports for the patient profiles from the pharmacy's computer. Tr. 87–88, 292. The technician downloaded information from the Respondent's computer system, including patient profiles and dispensing reports. Tr. 292. The investigators did not retrieve a mirror image of the Respondent's hard drive. Tr. 306–07.

On the prescription for Patient S.K., there is a fill sticker, which was printed out once the prescription was filled by the pharmacy. Tr. 103–04; GX 13 at 2. On the fill sticker, the prescription number was identified as N–000346, the date of the prescription, and ''PPCash'' to identify the method of payment. This shows that the prescription was paid for with a method of payment other than by insurance, which in this instance was cash. Tr. 104–05. This prescription was for hydromorphone, eight milligrams. In DI's experience, a cash method of payment for a prescription of a controlled substance is significant, because it raises the question why a patient would pay by cash as opposed to insurance. Tr. 106–07. This was a ''red flag'' [8] that the prescription may be illegitimate. Red flag methods of payment include cash, credit, credit card, or check. Tr. 107–08. There is no DEA regulation that prohibits a pharmacy from accepting cash as payment for a prescription. Tr. 373–74. There is no guidance document from the DEA that instructs pharmacists to limit the acceptance of cash as payment for prescriptions for controlled substances. Tr. 374. DI does not know whether patients can pay cash for prescriptions and then submit claims to their own insurance company. Tr. 375. He did not determine whether the charged patients had insurance. Tr. 375.

On the prescription for Patient S.K., below the ''PPCash'' language, there is an indicator of the price paid for the prescription. Tr. 108. The price that is paid for a controlled substance is a significant factor because, if the price paid is two or three times higher than a traditional price, it is an indicator that the patient is willing to pay any cost in order to get the prescription filled. Tr. 109–110. This would be an indication that the prescription may be illegitimate. These red flags are not only true for hydromorphone, but for other controlled substances as well.

Apart from the prescriptions, patient profiles, and dispensing reports previously discussed, there were no other documents pertaining to the specific patients that either the Respondent produced pursuant to the administrative subpoena, or that the DEA seized pursuant to the administrative inspection warrant. Tr. 117–18, *but see* 358–59 (purchase orders, invoices from suppliers, were seized during the administrative inspection warrant).

As the Government's investigation continued, the DEA served two additional administrative subpoenas. Tr. 118–19. The second administrative subpoena was served on the Respondent's attorney in May of 2019 by DI. Tr. 119–22, 350, 396; GX 16. DI was the investigator responsible for collecting and maintaining the evidence received from the Respondent. Tr. 350–51.

Dr. Fertil completed, and DI received, a completed copy of a certificate of authenticity of domestic business records, along with the documents responsive to the second administrative subpoena. Tr. 122–25; GX 18. In response to the May 2019 subpoena, the Respondent produced hard-copy prescriptions, patient profiles, and dispensing reports. DI did not know

[6] DI identified the Respondent's DEA COR. Tr. 32–33; GX 1. He also identified the administrative inspection warrant, dated February 14, 2018. GX 2.

[7] DI identified the patient profiles for Patients J.B., T.G, and L.V. Tr. 65–69; GX 5. DI also identified the patient dispensing reports for Patient J.B., T.G., and L.V. Tr. 69–71; GX 6.

[8] A ''red flag'' serves as an indication that a ''prescription may be illegitimate.'' Tr. 107.

who actually gathered the documents that were responsive to the subpoena. Tr. 396–97. The DEA provided a receipt for these documents. Tr. 125–28; GX 17. The second administrative subpoena required documents dated from February 15, 2018 to May 3, 2019, which begins the day after the end of time period of the administrative inspection warrant. Tr. 129, 347; GX 2.

DI identified patient profile printouts for Patient R.D. (Tr. 129–31; GX 19); Patient P.G. (Tr. 132–33; GX 20); Patient S.K. (Tr. 135–37; GX 21); and Patient L.V. (Tr. 137–39; GX 22).

The Respondent also produced hard copy prescriptions in response to the second administrative subpoena. Tr. 142, 348–49. The prescriptions were for Schedule II to V controlled substance prescriptions. DI identified prescriptions and fill stickers for Patient J.V. (Tr. 143–46; GX 23); Patient A.B. (Tr. 146–48; GX 24); Patient B.Da. (Tr. 148–51; GX 25); Patient R.D. (Tr. 151, 156–58; GX 26); Patient B.Di. (Tr. 158–60; GX 27); Patient P.G. (Tr. 160–62; GX 28); Patient S.K. (Tr. 163–65; GX 29); Patient J.R. (Tr. 165–70; GX 30), which includes prescription drug monitoring reports (GX 30, pp. 16–17, 26); Patient R.R. (Tr. 170–75; GX 31), which includes an E–FORCSE PDMP reports, a Florida Department of Health license verification printout for Dr. M.L., and a DEA website printout for Dr. M.L. (GX 31, pp. 19–21, 26, 31, 36, 39); Patient L.V. (Tr. 175–77; GX 32). No other documents were produced by the Respondent pursuant to the second administrative subpoena served in May of 2019, including dispensing reports. Tr. 178, 349–50.

A third administrative subpoena was served in August of 2019 by DI. Tr. 179–82; GX 33. DI served the administrative subpoena on Respondent's counsel on behalf of Gulf Med Pharmacy. Tr. 396. Ricard Fertil produced documents in response to the third administrative subpoena to DI. Tr. 183. DI did not know who actually gathered the documents responsive to the third subpoena. Tr. 396–97. The Respondent completed a certificate of authenticity of domestic business records. Tr. 184–85; GX 34. The documents produced include patient profiles, hard copy prescriptions, dispensing reports, and any notes for the patients. DI identified the produced records for Patient J.B. (Tr. 186–89; GX 35); Patient A.B. (Tr. 189–92; GX 36); Patient B.Da. (Tr. 192–94; GX 37); Patient B.Di. (Tr. 194–96; GX 38); Patient J.R. (Tr. 196–98; GX 39); Patient R.R. (Tr. 198–201; GX 40).

DI is familiar with the E–FORCSE program. Tr. 201–02, 206–08. E–FORCSE is the Florida prescription drug monitoring program, which is a database of controlled substance prescriptions filled, as reported by pharmacists or pharmacies to the State of Florida. Tr. 202–03. During the investigation, DI obtained information from the E–FORCSE database about the prescriptions that were filled by the Respondent. He logged onto the website and set his search query. Tr. 203–04, 206–07. A request then generated an electronic report. The report is produced after the database pulls all of the requested information and it is approved by a PDMP administrator. Tr. 205. An E–FORCSE PDMP report was generated for dates between January 1, 2018 and May 16, 2019 for Gulf Med Pharmacy. Tr. 205–06, 208–10; GX 41. Not including the title bar, there are 2,566 lines of data in the spreadsheet. Tr. 383. A second E–FORCSE PDMP report was generated for dates between February 14, 2018 and August 27, 2019 for Gulf Med Pharmacy. Tr. 211–17; GX 42. Not including the title bar, there are 2,912 lines of data in the spreadsheet. Tr. 384. Each line of data represents a separate prescription. Tr. 385. DI did not compare the E–FORCSE data with the data provided by the Respondent. Tr. 385. He did not do any investigation regarding the E–FORCSE data available prior to February 14, 2018 for the charged patients. Tr. 385–86.

During the service of the administrative inspection warrant in February of 2018, electronic printouts of purchase orders, patient profiles, dispensing reports, and other documents related to the charged patients were seized from the Respondent's computers. Tr. 237. The computers were not seized. Tr. 237–38. Copies of the software and hard drives were not taken. DI was aware that the pharmacy uses the PioneerRx software on their computers. During the investigation, the DEA obtained a declaration from a representative of PioneerRx, concerning the function of the software. Tr. 238–48; GX 48. DI received it from PioneerRx's attorney. Tr. 239, 242.

DI never spoke to Jenny Roe directly. Tr. 343. Because DI had a printout, he did not perform any investigation to determine what information was in the computer system behind the tabs of information on the computer program. Tr. 343–46; GX 5. The administrative subpoena asked for all documents maintained in patient profiles, so if the Respondent only provided one page, then the investigators assumed that is all the Respondent had. Tr. 346. The Respondent is expected to produce what is listed in the subpoena. Tr. 347.

DI is familiar with the term National Average Drug Acquisition Cost (NADAC). Tr. 249, 255.[9] DI first became familiar with it during the investigation of the Respondent. Tr. 255. It is a database monitored by the Center for Medicare and Medicaid Services, where a survey is sent out to pharmacies throughout the country. Tr. 256. The pharmacies will voluntarily submit acquisition costs for the drugs that they purchase from the manufacturers. Tr. 256, 275. The Center for Medicare and Medicaid Services is a government agency, whose role with respect to the NADAC is to determine prices to be compensated for insurance purposes. Tr. 256–57. The results of the survey are updated monthly and posted online. There is data that relates to different controlled substances. Tr. 257–58. DI reviewed the data for Oxycodone 30 mg and Hydrocodone 8 mg. Other data available include the name of the substance, cost per unit, NDC number, and effective date. DI identified the NADAC results for Hydrocodone 8 mg and Oxycodone 30 mg. Tr. 259–62; GX 44–45.[10]

DI found NADAC by doing a Google search. Tr. 272. He had never worked with it before. There is a fact sheet which explains how NADAC gathers their information and its use. Tr. 273. DI did not communicate with anyone at NADAC. For the Center for Medicare and Medicaid Services, the data only applies to patients whose medications are being paid for by Medicare or Medicaid. Tr. 273–74.

DI does not know if any of the NADAC volunteered information is from independent pharmacies in the Fort Meyers or Cape Coral area, or any in southeast Florida. Tr. 275. He is aware that prices are different in terms of acquisition cost for chain pharmacies versus independent pharmacies. Tr. 276. He does not know whether chain pharmacies have a greater buying power than independent pharmacies, or whether there are different reimbursements that are paid by insurance companies compared to private pay price. Tr. 277–78. He does not know whether independent pharmacies are reimbursed at a lower rate than chain pharmacies. Tr. 357–58.

DI became familiar with the term ''federal upper limit'' as part of his duties. Tr. 263. He became familiar of the term through the NADAC database. Federal upper limit is a multiplier that the Center for Medicare and Medicaid

[9] [Footnote omitted, *see infra* n.*P.]

[10] Pursuant to the Tribunal's previous ruling, Government's Exhibits 44 and 45 were not admitted. Tr. 262.

Services uses from the NADAC average. Tr. 264–65.[11] When the Center determines the federal upper limit, it is provided online on their database website. Tr. 267–68. The federal upper limit is available with respect to particular drugs, including controlled substances. DI reviewed the data for Oxycodone 30 mg and Hydrocodone 8 mg. DI identified the NADAC federal upper limit results for Hydrocodone 8 mg and Oxycodone 30 mg. Tr. 268–71; GX 46–47.[12]

The federal upper limit pertains to people who are not using insurance to pay. Tr. 274. It does not matter where a person fills their prescriptions if they are a Medicare patient. The same upper limit of what can be charged applies. Tr. 274–75.

DI's intention through the second and third administrative subpoenas was to obtain the same type of information and documents that the DEA sought at the time of the administrative inspection warrant and administrative subpoena on February 14, 2018. Tr. 293–98; GX 3, 16, 33. DI did not draft the first administrative subpoena, but he did draft the second and third administrative subpoenas. Tr. 308–09. He is familiar with the process for the service of an administrative subpoena, which includes identifying a return date for the person on whom the subpoena is served to produce information. Tr. 310. The first administrative subpoena directs the person to whom that subpoena is served to respond to DI 2 by February 9, 2018. Tr. 310–11; GX 3 at 2. The return date had already passed by five days by the time the subpoena was served. Tr. 311. DI explained that when drafting administrative subpoenas, the system auto-populates the date at the bottom of the subpoena that is within two weeks or ten business days. Tr. 312. Taking into consideration travel and getting appropriate signatures, these subpoenas are drafted ahead of time. The date of issue on this subpoena is the date that the document was printed and submitted. Tr. 312–13.

The return date for the third administrative subpoena was for was February 9, 2018. Tr. 314. The date and time for appearance auto-populates, so it appeared that the drafter forgot to change the date, but DI was not sure. It would be impossible for the Respondent to timely respond to the subpoena as the Respondent did not receive it until February 14, 2018. Tr. 314–15.

DI did not interview any of the physicians that prescribed the charged prescriptions. Tr. 319–20. He also did not interview any of the charged patients. Tr. 320. DI did not do any investigation to determine the distances from the charged patients' home to the pharmacy. Tr. 377–78. DI did not have any evidence that any of the charged patients were abusing or diverting their medications. Tr. 321–24.[13] He did not know the number of patients that had been served by the Respondent prior to February 14, 2018, and did not know what percentage of patients in the Order to Show Cause are of the Respondent's total patients. Tr. 325–26.

DI did not receive training at the DEA Academy regarding the Florida administrative code or Florida law. Tr. 327. In the administrative subpoenas, DI referenced Florida Administrative Rule 64B16–27.800. Tr. 331. DI has previously read Florida Administrative Rule 64B16–27.800. Tr. 351. He understood that investigators were looking for the same types of profile information that the DEA technology specialist had downloaded during the administrative inspection warrant on February 14, 2018. Tr. 331–32.[14]

When he was assigned as the case agent, DI reviewed all of the information that the DEA had then collected. Tr. 339. Following the service of the second and third administrative subpoenas, he compared the patient profiles that were seized on February 14, 2018 to the patient profile information that was obtained in response to the second and third administrative subpoenas. Tr. 339–40, 342–43.

DI transmitted the documents collected in response to the administrative subpoenas to Dr. Schossow. Tr. 378. The subpoenas were not issued at the request of the expert. Tr. 379. DI did not review any of the information with Dr. Schossow. Dr. Schossow provided a written report to DI before the OSC was issued, but he did not recall the exact date. Tr. 379–80.

All of DI's interactions with Ricard Fertil and Gulf Med Pharmacy were both pleasant and cooperative. Tr. 399.

Dr. Tracey Schossow

Dr. Schossow is a contracted expert with the Drug Enforcement Administration. Tr. 863–64. She expects to make $15,000 on the instant case. Tr. 879–80. She has only testified as an expert for government agencies. Tr. 865. Although she was not averse to defending someone charged by the Government, she has never been hired to defend anyone charged by the Government or by the State. Tr. 876–78. Dr. Schossow is a licensed pharmacist in the State of Florida. Tr. 404. She has a Bachelor's of Science Degree in Pharmacy from Florida A&M, and later received her Doctorate in Pharmacy from the University of Florida in 2001. Tr. 881. Although she has written non-peer reviewed articles, she has not published a peer reviewed article. Tr. 939–40. She worked in retail pharmacy for a total of fifteen years, including time as a drug clerk and pharmacy tech for her father, who was a pharmacist. She worked as a pharmacist in retail pharmacy for approximately twelve years. She has also worked as a pharmacy intern, assistant manager, a pharmacy manager, and then as a ''floater'' for other pharmacy chains. Tr. 406–07, 417. She has worked in over 200 different pharmacies during her retail pharmacy experience, but never one in southwest Florida. Tr. 988. However, she has not worked in a retail pharmacy since 2012. Tr. 417, 881. Since 2012, she has only worked for pharmacy benefit managers. Tr. 883. Her last position in retail pharmacy was with Publix Pharmacies from July 2008 to October 2012. Tr. 418, 930. She last served a customer at a pharmacy approximately seven years ago. Tr. 880.

She has worked for ProCare, a hospice-centered company, as a clinical pharmacist. Tr. 404, 418–19. In that capacity, she worked with patients who were dying, and managed cocktail medications for comfort management, while still maintaining cost effectiveness. Tr. 404–05, 419–20. She was also part of the PNT committee, which decided which medications were non-formulary based on cost and efficacy. Tr. 405. She additionally managed a rejection queue, where claims are rejected for being excessively priced. Dr. Schossow offered more cost-effective therapies.

[11] [Footnote omitted, *see infra* n.*P.]

[12] Pursuant to the Tribunal's previous ruling, Government's Exhibits 46 and 47 were not admitted. Tr. 270–71.

[13] The Tribunal sustained the Government's objection as to being outside the scope of the Government's direct examination and that this information is irrelevant. The Tribunal found that the Government does not require evidence of diversion or abuse to initiate or pursue an investigation, and they do not require evidence of diversion or improper behavior by the pharmacist to initiate an investigation. The Tribunal permitted the Respondent to make a proffer, but advised that the Government's theory is set out in the Order to Show Cause and Immediate Suspension of Registration and the Government's prehearing statements, which will serve as the focus of the hearing. Tr. 321–23.

[14] The Tribunal sustained the Government's objection to relevancy of the underlying Government investigation. The Tribunal found that the focus of the hearing is not on whether there were mistakes or missteps in the investigation, but rather on the evidence that was seized and noticed with the allegations set out in the Order to Show Cause. Tr. 333–39.

Dr. Schossow presently works as a pharmacist at Florida Blue Cross/Blue Shield. Tr. 403. As part of her duties, she reviews ''high-dollar reports'' (meaning high cost medications) and makes sure that the medications are being issued for a legitimate medical purpose. Tr. 403. If she determines they are being issued for a legitimate medical purpose, she works with the patient and provider to offer cost-effective alternatives. Tr. 403–04. If, upon speaking to the pharmacy and patient, she determines the medications are not for a legitimate medical purpose, she reports those findings and opens up an investigation through Blue Cross's fraud, waste, and abuse department for further investigation. She also works on a team of ''complex members'' with a nursing team and reviews medications with patients. Blue Cross provides pharmaceutical education and offers cost-effective alternatives to its members.

Blue Cross also submits test claims at different pharmacies, including independent pharmacies, to determine costs at different pharmacies in the area where patients reside. Tr. 405. Dr. Schossow did not actually prescribe medications in these roles, but she made recommendations to physicians based on the patient's symptoms. Tr. 406. She was a member of an interdisciplinary team, which made medication recommendations that the physicians generally followed. In that role, she served as a clinical pharmacist. Tr. 406.

There are differences between a regional pharmacist and a clinical pharmacist. Tr. 407. A regional pharmacist receives the prescriptions from the physician. The pharmacist evaluates it, looks at the computerized patient profile and ensures the medication is safe for the patient before dispensing. A clinical pharmacist makes the recommendations saved on the computer patient profile. In Dr. Schossow's current position, she looks at all of the claims that the patient has, from the insurance perspective. She can review all of the medications the patient has received, and then she can make a recommendation based on the profile, and by talking to the patient and physician. Dr. Schossow has similar responsibilities as a regional pharmacist, except she does not dispense medications. Tr. 407. There is no difference in licensure between a clinical pharmacist and a community pharmacist. Tr. 419.

Dr. Schossow has been a pharmacist for approximately twenty-six years. Tr. 408. All of her experience is in the state of Florida. She has experience filling approximately one million prescriptions. Dr. Schossow also holds a consultant license in the state of Florida. The consultant license allows her to perform additional duties, including nursing home inspections.

Dr. Schossow has taught in the pharmacy field. Tr. 409. She taught at a pharmacy technician school, teaching subjects including diversion, red flags, and issues involving opioids. Tr. 409–10. She also worked at the Veterans Administration (VA) for six years. Tr. 412. In this role, she was a clinical pharmacy specialist and mentored residents and interns. Tr. 412. At the VA, Dr. Schossow prescribed medication. Tr. 419. While with the VA, Dr. Schossow could prescribe medications because she operated under the VA regulations. Tr. 422–23. However, with the hospice and retail positions, she cannot prescribe medications and can only make recommendations. Tr. 423. She has never had the ability or authority to prescribe Schedule II controlled substances. Tr. 423. At ProCare, she was a trainer in regards to high-dollar cost rejections, including training pharmacists on these rejections, how to handle them, and how to offer cost-effective alternatives. Tr. 412, 936–38. She also worked for Caremark, a PBM, where her role was to control costs for contracted healthcare plans. Tr. 972–73. Dr. Schossow conceded that, outside the realm of insurance subsidization, there is no limit on the mark up a pharmacy can charge for medications. Tr. 1035.

Dr. Schossow is familiar with DEA regulations with respect to dispensing of controlled substances. Tr. 408–09, 888–92, 927–28. She has previously testified as an expert witness three times in DEA administrative cases. Tr. 411–12, 423–24. She has been qualified each time she has been offered as an expert. She has only testified in administrative hearings, not in courts. Tr. 928. Her opinions have been accepted by the DEA Administrator. Through her education and professional experience,[15] she is familiar with the responsibilities of a retail pharmacist in the detection and prevention of abuse and diversion of controlled substances. Tr. 414. She is familiar with the standard of care [16] and professional obligations of a pharmacist in the state of Florida. Tr. 888–92.

In the instant case, Dr. Schossow was offered as an expert in Florida pharmacy practice and the standard of care for the practice of pharmacy in Florida. Tr. 414, 416. She reviewed all of the exhibits in this matter, including prescriptions, patient profiles, E–FORCSE reports, and documents provided by Gulf Med Pharmacy. She asked the Government to gather information that a responsible pharmacist would look at before determining whether a prescription could be safely filled for a legitimate medical purpose. So she asked for those items that she would look for if she was standing in the pharmacy filling the prescriptions. Tr. 415–16.

Dr. Schossow was qualified as an expert in Florida pharmacy practice and the standard of care for the practice of pharmacy in Florida.[17] The duties of a Florida pharmacist with respect to filling controlled substance prescriptions include exercising a corresponding responsibility to make sure that medications are being issued for a legitimate medical purpose by the practitioner acting within their usual course of professional practice. Tr. 431. The pharmacist is responsible for evaluating prescriptions based on the manufacturer's guidelines and for the safety for the patient. Tr. 432. Florida Administrative Rule 64B16 lists responsibilities regarding what should be maintained in the patient record systems, including the patient's name address, allergies, pharmacist's comments, and a Drug Use Review (DUR) for each new prescription and refilled prescription. A DUR includes side effects, drug interactions, whether the medication is being clinically abused or misused, and dosages.

Dr. Schossow is familiar with Florida Administrative Rules 64B16–27.800, 27.810, and 27.831. Tr. 434–36, 891–92. These provisions inform the standard of care of a pharmacist working in Florida. Tr. 434–36, 891–94, 912–16.[18] They provide an outline of the minimal requirements for Florida pharmacists in regards to patient safety and continuity of care. Florida Administrative Rule

[15] Dr. Schossow identified her curriculum vitae. Tr. 412–13; GX 43.

[16] The term of art, ''standard of care'' was used by the Tribunal, the parties and sometimes witnesses as a shorthand reference to a pharmacist's professional obligations, or acting within the ''course of professional practice of pharmacy.'' *See* Florida Statute XLVI § 893.04. However, the term ''standard of care'' is defined in § 766.102, and has a different usage and application. This distinction will be discussed in detail below.

[17] The Respondent objected to the Government's offer of Dr. Schossow as a proposed expert witness and to restriction on voir dire as to her opinions relating to specific aspects of the standard of care. The Tribunal overruled the Respondent's objections and Dr. Schossow was qualified as offered. Tr. 424–27. The Tribunal noted that the burden to qualify an expert is by a preponderance of the evidence. Thereafter, apparent limitations to expertise will impact the weight given to the expert's testimony.

[18] Dr. Schossow testified that the pharmacist is required to apply the version of the regulation or statute applicable at the time the subject prescription is filled. Tr. 896–97, 904–05.

64B16–27.831 describes methods a pharmacist should use to validate a prescription. Tr. 897–900. This provision also requires pharmacists to maintain a computerized record of controlled substances dispensed, which the Respondent did in this case as to the charged patients. Tr. 908–12. The Florida statutes define requirements for patient care and for maintaining a patient records system. Tr. 437. These statutes provide that the pharmacist shall ensure a reasonable effort is made to obtain, record, and maintain certain information, including the patient's full name, address, date of birth, gender, and prescription list, as well as the pharmacist's comments relating to allergies, drug interactions or any idiosyncrasies, and any conversations that the pharmacist had with the healthcare provider in regards to the patient's individual drug therapy. Tr. 438, 913–20. The Florida statutes also require prescription drug review, including therapeutic inappropriateness, which the pharmacist must address for drug therapies that do not fall within the guidelines of the standard of care. This ensures continuity of care with the next pharmacist reviewing the medication protocol, as well as to assure that the medication is safe for the patient. Tr. 927–30. These concerns include over or under-utilization of medication, therapeutic duplications, drug interactions, incorrect dosage forms, drug allergy interactions, and clinical abuse. The pharmacist must take appropriate steps to resolve these issues and to record those resolutions. Tr. 438–39, 888, 918–26. Dr. Schossow conceded that the relevant federal regulations that she relied on to inform the standard of care do not specifically require documentation of the resolution of red flags. Tr. 927–28.

A prospective drug use review is a checklist that a pharmacist should go through when reviewing each new and refilled prescription to ensure therapeutic appropriateness and patient safety. Tr. 439–40. Additional concerns include therapeutic duplication, drug interactions, correct dosages, clinical abuse and misuse, and drug allergy interactions. Prospective drug utilization review is discussed in the Florida Administrative Rules under section 27.810. Tr. 440–41. Upon recognizing any therapeutic inappropriateness, the pharmacist is supposed to take appropriate steps to resolve the issue and to record the resolution in the patient records. It is important to document the results of a review for continuity of care, so that when the next pharmacist reviews the medication protocol, he will have the information readily available and the prescription can be filled without delay. Tr. 441–42. It also represents a safety issue. In Dr. Schossow's opinion, the Florida standard of care requires documentation of the resolution of these matters. Tr. 442.

Dr. Schossow is familiar with DEA regulations regarding a pharmacist's corresponding responsibility. Tr. 442. The pharmacist has just as much responsibility as the doctor to ensure that the medication is for a legitimate medical purpose and that the practitioner is acting in the usual course of professional practice. Tr. 442–43. It applies to all pharmacists. This responsibility is in addition to all of the requirements under the Florida rules and regulations. A pharmacist's corresponding responsibility is not satisfied by simply verifying that a doctor wrote the prescription. The pharmacist has an independent responsibility to evaluate each prescription. Tr. 444.

Dr. Schossow is familiar with the phrase ''in the usual course of professional practice.'' Tr. 444. This means that the doctor is issuing prescriptions in an effective and safe manner and ''within his training.'' This is a requirement for a pharmacist. ''Within his training'' means within the scope of his practice. Tr. 444–45. Pharmacists are required to fill prescriptions in the usual course of their profession.

Apart from the requirements for pharmacists set forth by the State of Florida and the DEA, Dr. Schossow testified that she believed that a pharmacist's standard of care is also informed by past DEA administrative cases.*[C] Tr. 445–46. Pharmacists learn about the DEA administrative decisions through mandatory CMEs and during education seminars, including those required by § 27.831. Tr. 457–62.

Dr. Schossow is familiar with the term ''red flag.'' Tr. 446. Red flags are circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm. These concerns are codified under clinical abuse and misuse within the DUR in Florida's Administrative Rule 64B16. The section also talks about abuse under Chapter 893, in which abuse is defined. Tr. 446. Pharmacists in the State of Florida ''must learn three main statutes'' in order to pass the Florida Board: ''64B16, 893, and 465.'' Tr. 449, 1004–05, 1039–40. Pharmacy students learn these statutes for the Florida Board of Pharmacy. Chapter 893 informs the Florida standard of care for pharmacists as it defines potential for abuse, which relates back to 64B16. Tr. 449–50. The prospective DUR requires that one of the things a pharmacist must review is clinical abuse or misuse, so a pharmacist must understand what abuse means.

Florida pharmacists become familiar with red flags through their training in pharmacy school and through their on-the-job training. Tr. 451, 888. This training includes the opioid crisis in the United States, which led to mandatory continuing education in Florida for the validation of prescriptions for controlled substances. Tr. 451–53. This additional training includes, use of the PDMP, appropriate therapeutic values for opioids, legitimate medical purpose and the laws and rules around it, as well as protocol that addresses how to resolve red flags, and the CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016. The CDC guidelines relating to opioid prescribing are reviewed in the Continuing Medical Education (CME) courses. Tr. 454. The CDC guidelines cover appropriate dosing, which is part of the mandatory CME that all Florida pharmacists must attend every other year, as well as risks of certain dosages of Morphine Milligram Equivalent (MME). Tr. 455. The training covers dosing and risks to patients, as well as combining central nervous system depressive medications that may lead to overdose and death. Tr. 456. The training also covers dosage concerns based on clinical studies, for which the pharmacist is responsible to know. The standard of care requires pharmacists to remain current as to the therapeutic appropriateness findings of these studies. The items outlined in Florida Administrative Rule 64B16–27.810 represent red flags. Tr. 457.

The presence of a red flag itself does not mean that a pharmacist cannot fill a prescription. Tr. 462. Consistent with the standard of care, a red flag means that there is a potential concern with the prescription, which the pharmacist must address and resolve, and to make a record of its resolution, assuming it is resolvable. Tr. 462–63, 906–07. If the pharmacist is unable to resolve the red flag, he should not fill the prescription. Tr. 907–08. This is something that a Florida pharmacist acting in the usual course of professional practice would do upon encountering one or more red flags relating to a prescription. The lack of documentation identifying and resolving of a red flag warrants the

*[C] It is noted that DEA administrative cases rely on expert testimony to establish the standard of care.

conclusion under the standard of care that the prescription was treated as falling within the guidelines for a legitimate medical purpose and is safe for the patient to take. Tr. 463–66.

Dr. Schossow was asked by the DEA to review material relating to Gulf Med Pharmacy. Tr. 466, 983–84. She reviewed the front and back of hard-copy prescriptions, the computer printouts of the patients' pharmacy files, which included any pharmacist comments, medical records from the pharmacy, dispensing reports, and patient profiles, including the PDMP reports for patients. Tr. 466–71. Dr. Schossow does not know if she received all of the relevant information from the Respondent's computer system used to fill the subject prescriptions. Tr. 976–78. Specifically, Dr. Schossow confirmed the screen shots of the patient profile only depicted one of five tabs. Tr. 978; GX 19. The tab opened in the relevant Government exhibits was the ''comment'' tab. The tab identified as ''profile'' was not revealed. Tr. 978–79. Similarly, the tab, ''RX history'' is not revealed. Tr. 979.

Dr. Schossow is familiar with pharmacy management software, which maintains patient records. Tr. 471. She is familiar with how it generally works and has worked with different systems of pharmacy management software. However, she is not familiar with the Respondent's system, PioneerRx. Generally, when a prescription is submitted to a pharmacy, the technician types up the prescription, which then goes through the system. Tr. 472. Most pharmacies perform the DUR. It is the responsibility of the pharmacist to override it or to document that issues revealed by the DUR were addressed. Tr. 475. Not all red flags are flagged in the computer system, but red flags that are flagged include major drug interactions, including central nervous system (CNS) depressant medications that fall under an X interaction according to the DEA and the CDC, and the FDA black box warnings on things such as benzodiazepines combined with opioids. Tr. 476.

After a warning appears in the electronic program, that is considered a DUR [19] and the severity of the DUR should be addressed by the pharmacist with either the patient or the doctor to assure patient safety going forward and how it was resolved. There is generally a click-through function on the program and documentation must be provided. Tr. 476–77. For example, in the system at Walgreens, the pharmacist has to document what they did to resolve the red flag. If the software program does not allow the pharmacist to document in the computer, then the pharmacist must either document in the computer program under the patient notes or somewhere in the patient records system, or on the prescription, as to how the DUR was resolved in terms of patient safety, for the continuity of care for the next pharmacist. A click-through does not count as documentation of a red flag. Tr. 477–78. A click-through allows the pharmacist to override a DUR. For example, at Publix, the pharmacist has a lanyard that the pharmacist clicks to override the DUR. However, a higher level DUR requires more documentation because of patient safety concerns. Tr. 478–79.

A pharmacist practicing in the normal course of pharmacy practice in Florida would record what the resolution of the red flag was for continuity of care and to assure patient safety. Tr. 479–80. In a pharmacy, the pharmacist is responsible for resolving any potential red flag of abuse or diversion. Tr. 480. A pharmacy technician cannot resolve or sign off on the resolution of a red flag.

Dr. Schossow is familiar with a combination of controlled substances known as a ''trinity''. Tr. 480–81. A trinity is usually an opioid like Hydromorphone or Oxycodone, plus a benzodiazepine like Alprazolam, Temazepam, Diazepam, plus Soma or Carisoprodol, which is a controlled muscle relaxant. Tr. 481. It is a dangerous combination. In Dr. Schossow's experience and training, the trinity is commonly sought by drug abusers. Tr. 482–83. A trinity is a red flag.

Patient J.B.

Dr. Schossow identified a patient medication dispensing report printout for Patient J.B. Tr. 483–84; GX 6. The number in the quantity column is the amount of dosage units dispensed by the pharmacy of the controlled substance. Tr. 485. On March 22, 2017, six prescriptions were filled. The bottom-listed controlled substance is Carisoprodol. Tr. 485; GX 6 at 2. The prescription immediately above is Oxycodone 30 mg. Tr. 486. The prescription above that is another controlled substance, listed as Alprazolam. Two lines above Alprazolam, Morphine Sulfate Extended is listed. Morphine Sulfate Extended is an opioid, Alprazolam is a benzodiazepine, Oxycodone is an opioid, and Carisoprodol is a controlled substance muscle relaxant. Together, these controlled substances form a trinity. Dispensing these controlled substances on the same day represents a red flag for the pharmacy. Tr. 486–87.

Dr. Schossow noted prescriptions paid for in cash indicated a red flag.[20] Tr. 851–53; GX 6 at 1–2; GX 23 at 61–63. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 852–53, GX 6 at 2. Dr. Schossow identified prescriptions demonstrating a red flag for combining extended release and immediate release opioids. Tr. 853–57; GX 23 at 57, 61–63, 66–69, 72–74, 77–80; GX 35 at 10, 21, 11–14, 19, 20, 24–27.

On April 19, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, 90 units of Alprazolam, and Carisoprodol. Tr. 487–88; GX 6. This is a trinity combination. In addition, the patient was also on Gabapentin and Butalbital, Aspirin, and Caffeine, which are also additional CNS depressants, which make this combination even more dangerous. These were prescription numbers 734 through 737; GX 6 at 2. On May 19, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 488; GX 6 at 2. This is a trinity combination and a red flag. Tr. 488–89.

On June 16, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 489. This is a trinity combination and a red flag. These included prescription numbers 1306, 1317, 1319, and 1321.

On July 14, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 489–90. This is a trinity combination and a red flag. These included prescription numbers 1627, 1628, 1633, and 1634.

On August 11, 2017, another series of prescriptions were filled, including Morphine Sulfate Extended Release, Oxycodone 30 mg, Alprazolam 10 mg, and Carisoprodol. Tr. 490. This is a trinity combination and a red flag. These included prescription numbers 1946, 1947, 1950, and 1951.

On September 8, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, and Alprazolam 10 mg. Tr. 491. These included prescription numbers 2250, 2251, and 2252. There was no Carisoprodol issued on this date. It is still a dangerous combination because all of those drugs suppress the central

[19] Dr. Schossow appeared to use the term DUR in place of ''red flag'', as per the subject question.

[20] Dr. Schossow conceded that she was not aware whether the charged patients, who paid cash for the subject controlled substances, later sought reimbursement from their insurance companies. Tr. 1036.

nervous system and can lead to respiratory depression, overdose, and death.

The records indicate which pharmacist actually filled the prescription. Tr. 492. At the top of the patient record, the initial RPH, which means registered pharmacist, lists the initials of the pharmacist that filled the prescription. Tr. 492; GX 6 at 1.

On October 6, 2017, another series of prescriptions were filled, including Morphine Sulfate, Oxycodone 30 mg, Alprazolam, and Carisoprodol. Tr. 497–98; GX 6. This is a trinity combination and a red flag. These included prescription numbers 2603 to 2606.

On November 3, 2017, prescriptions were filled, including Oxycodone 30 mg and Alprazolam. On November 6, 2017, prescriptions were issued, including Morphine Sulfate and Carisoprodol. Tr. 498–99. This is a trinity combination and a red flag. These included prescription numbers 3034, 3036, 3062, and 3064. It is a red flag as the medications were dispensed so close in time.

On December 1, 2017, another series of prescriptions were filled, including Oxycodone 30 mg and Alprazolam. Tr. 499. These included prescription numbers 3474 and 3475. These prescriptions represent a red flag. Tr. 500. Both of these drugs depress the central nervous system and the Oxycodone dosage is the highest strength available, which in itself is a red flag. These prescriptions fall under the FDA black box warning and 2016 CDC guidelines that specifically recommend against taking benzodiazepines with opioids. Although familiar with the 2016 CDC Guidelines, and upon which she relied in forming her opinions herein, Dr. Schossow was unfamiliar with the clarification issued, which clarified that the 2016 Guidelines did not apply to patients on long-term opioid treatment. Tr. 992–94. Dr. Schossow conceded that if a patient had been on a long-term drug regimen, that would be a consideration of the pharmacist in conducting the DUR analysis. Tr. 1035. Dr. Schossow clarified that she had previously reviewed the CDC's clarification to the 2016 CDC Guidelines, and noted it did not change her opinion as it did not relate to the combination of benzodiazepines and opioids. Tr. 1060–64.

On December 29, 2017, another series of prescriptions were filled, including Oxycodone 30 mg, Alprazolam, Morphine Sulfate, and Carisoprodol. Tr. 503; GX 6. These included prescription numbers 3973, 3975, 3976, and 3979. These prescriptions represent a trinity and thus a red flag.

On January 26, 2018, another series of prescriptions were filled, including Oxycodone 30 mg and Alprazolam. Tr. 503. These included prescription numbers 4549 and 4550. On January 31, 2018, Morphine Sulfate Extended Release was issued, which includes prescription number 4658. Tr. 504. These prescriptions are a combination of opioid and benzodiazepine and thus represent a red flag.

Dr. Schossow identified the actual prescriptions for Patient J.B. Tr. 504–05; GX 7. She did not see any resolution of red flags documented for any of the subject prescriptions that were filled. Tr. 505–06; GX 7 at 1–69. The notation ''PDMP'' on the back of the prescription would mean that the pharmacist checked the PDMP before filling the prescription. Tr. 506; GX 7 at 18. This does not resolve the red flag as there are several red flags present regarding that prescription. Tr. 507. The red flags include the high strength of the Oxycodone at 30 mg. The second is that the medication is over 50 mg MME, which puts the patient at risk for CNS depression, overdose, and death. The third red flag is the scheduling of an immediate relief opioid. Checking the PDMP did not resolve or address any of those red flags, but only satisfied part of the law that requires the pharmacist to check the PDMP to ensure the patient is not doctor or pharmacy shopping and to check the total milligram of MME. Reference to the PDMP does not contribute to resolving any of the red flags related to the prescription. Tr. 507–08. Dr. Schossow identified a patient computer profile for Patient J.B. Tr. 529–30; GX 35.[21] She did not see any documentation or resolution of the red flags previously discussed on the first page. Tr. 530, 857–58; GX 35, p. 1. She did not see any documentation of red flags, or the resolution thereof, in the patient profile, particularly under the critical comments section where the pharmacist can fill in comments. Tr. 493–96, 504, 857–58. Nor did she see any indication the medical records or dispensing log for J.B. indicated the subject red flags as to J.B. were addressed, resolved or documented. Tr. 858–59; GX 35 at 2–5, 8, 9.

There were additional prescriptions of the same opioid and benzodiazepine (Oxycodone 30mg, and Xanax) that were also red flags, based upon the cocktail created by the controlled substances, which are central nervous system depressants, which can cause sedation, respiratory depression, overdose, coma, and death. Tr. 530–34; GX 35, pp. 6–7, 10, 11–16, 21. There were additional prescriptions for Oxycodone, Xanax, and Morphine that were red flags for the same reasons. Tr. 533–34; GX 35 at 17–20, 22–27. Dr. Schossow did not see any indication of red flags being documented or resolved on the prescriptions. Tr. 534, 857–58, 860; GX 35 at 2–27.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient J.B., would not have filled the subject prescriptions without addressing, resolving, and documenting the red flags discussed. Tr. 859–60; GX 5 at 1.

Patient L.V.

Dr. Schossow identified a patient medication dispensing report printout for Patient L.V. Tr. 510; GX 6 at 6. On March 2, 2017, prescriptions for Morphine Sulfate, Alprazolam, and Oxycodone were filled. Tr. 511. They are included as prescription numbers 308 to 310. Dispensing these medications on the same day causes concern and serves as a red flag as they each suppress the CNS and fall under the FDA black box warning for risk of sedation, respiratory depression, coma, and death.

Oxycodone is an opioid and Xanax is a benzodiazepine. Tr. 513. Looking at fill stickers, these prescriptions were issued on February 23, 2018. Tr. 513–14; GX 23 at 2, 4. These prescriptions are a red flag since they both depress the central nervous system and fall under the prospective DUR for drug interaction and side effects. Tr. 514–15. Viewing additional prescriptions, Oxycodone 30, Xanax 1 mg, and Soma were both filled on March 21, which again, represents a trinity. Tr. 515; GX 23 at 8–10. There are two more prescriptions for Xanax and Oxycodone 30 mg, which indicate a red flag because an opioid and benzodiazepine were filled on the same day. Tr. 516; GX 23, p. 11, 14.

A prescription for an opioid, Oxycodone 30 mg, and a benzodiazepine, Alprazolam 2 mg, prescriptions 5127 and 5129, are a red flag. Tr. 520; GX 7 at 1–4. There were additional prescriptions of the same opioid and a benzodiazepine (Oxycodone 30mg and Xanax) that were also red flags, based upon the cocktail created by the controlled substances, which are a central nervous system depressant, and can cause sedation,

[21] Although both parties used the term, ''patient profile'', Dr. Schossow confirmed the Florida subject regulations did not define the term. Tr. 1035.

respiratory depression, overdose, coma, and death. Tr. 521–28; GX 7 at 8–9, 10–11, 14–17, 22–25, 26, 28–29, 31–36, 37, 40–42, 43, 46–47, 49, 55–59, 60–65, 66–71, 72–76, 77–82. When checking both the front and back of the prescriptions, Dr. Schossow did not see any indications that any of the red flags were documented or resolved as to any of the subject prescriptions. Tr. 529.

Additional red flags for cash payments were present. Tr. 758, 767–68, 772–74, 776, 778; GX 15 at 1–6, 7–12, 13–8, 19–21, 25, 27, 31–36, 38, 40, 43–48, 50, 52, 56, 58, 62, 64, 75–80. Red flags for the unusually high amount of the cash payment were also present. Tr. 758–64, 767–68, 772, 775–78; GX 15 at 8, 16, 22, 34, 50, 58, 64, 76.

An additional matter of suspicion arose in L.V.'s alternate use of insurance to pay for benzodiazepine prescriptions in lieu of the many cash payments for opioids, especially considering the high prices L.V. paid for them. Tr. 768–76, 677–78; GX 15 at 30, 31–36, 42, 48, 54, 60, 71, 72, 75.

Patient A.B.

Dr. Schossow identified patient computer profiles and prescriptions for Patient A.B. Tr. 534–35, 538; GX 8, 24. Viewing the prescriptions in the patient profile, she found that the listed prescriptions, which included combinations of a benzodiazepine and an opioid to create a cocktail, which are a central nervous system depressants, again were red flags. Tr. 535–38; GX 3 at 1–6, 7–12, 13–18, 19–24; GX 24 at 1–6, 7–12, 13–18, 19–24, 26–31, 32, 33, 35, 38, 39, 40, 42–45. These prescriptions included additional controlled substances, including Diazepam (a benzodiazepine), Hydromorphone, OxyContin, and Valium (a benzodiazepine). Tr. 540–41. She did not see any of the subject red flags documented or resolved in the prescriptions that she reviewed. Tr. 539; GX 8.

Patient T.G.

Dr. Schossow identified a patient medication dispensing report printout for Patient T.G. Tr. 509–10; GX 6 at 3. She also identified the patient profile prescriptions for Patient T.G. Tr. 556; GX 12. She identified ''ACQ Cost'' in the record, as referring to acquisition cost. Tr. 556; GX 1 at 2. Viewing the second column, she saw an acquisition price of $43.19. Tr. 557. Further up on the same page in the record, there was a ''price paid'' in the same column. The price paid was $480. This accounting occurred with additional groups of prescriptions for this patient. Tr. 563; GX 12 at 5–8, 10. In Dr. Schossow's opinion, the amount paid by a customer can be a red flag. Tr. 563–65.[22]

Dr. Schossow's experience in the pricing of medications in Florida reflected an approximate twenty percent mark-up from acquisition cost. Tr. 570–72. She also did research on her own of the pricing of the subject medications within the subject locale. She phoned pharmacists at Walgreens and CVS and obtained the actual prices for the subject medications.[23]

Viewing Patient T.G.'s patient profile prescriptions, the type of payment was an ''RX-lock'', which Dr. Schossow understood to mean a cash payment. Tr. 579; GX 12 at 13–16. It applied to both prescriptions. The method of payment and the amount paid by the customer are red flags. This also applied to additional prescriptions for Patient T.G.[24] Tr. 580–83, 589–94; GX 12 at 17–20, 21–24, 25–28, 29–32, 33–34, 35–38, 39–42; GX 28 at 1–4, 5–8, 9–10, 11–12, 13–14, 15–17. There was no documentation that the red flags relating to payments in cash or high prices paid were flagged or addressed by the pharmacy. Tr. 595–96; GX 5 at 2; GX 20. A pharmacist acting in the usual course of professional practice would not have filled the charged prescriptions without addressing those red flags and documenting the resolution. Tr. 596–97.

Patient S.K.

Dr. Schossow identified the patient profile prescriptions for Patient S.K. Tr. 597; GX 13. All of the prescriptions were paid for in cash, which is a red flag. Tr. 597–98; GX 13, pp. 1–6. It is also a red flag for the high amount of cash paid by the customer. Tr. 598; GX 13 at 2. There are additional concerns for these prescriptions. Looking at the first prescription, the first concern is that the doctor is writing for the highest dosage of immediate release Hydromorphone; the second is that the doctor scheduled the medication, which is usually given as a PRN (''take as needed'') dosing or breakthrough medication; and the third is that the prescription was written for an anxiety disorder, while Hydromorphone is not indicated for anxiety. Tr. 598–99; GX 13 at 1.

Another prescription written for this patient included concerns that the doctor wrote a prescription for Morphine ER 15 mg, one tablet, twice daily. Tr. 599. This prescription was concerning because the prescription was for an opioid. It was also concerning because the pharmacist did not address that the prescription was for an anxiety disorder, for which Morphine is not indicated. Another concern was that long-acting opioid prescriptions were developed by the manufacturers to limit the number of PRN medications the patient would have to take. In this case, the lowest dosage of Morphine was 15 mg twice a day, along with the Hydromorphone 8 mg, which is equivalent to around 32 mg of Morphine four times per day. It is not within the standard of care for a low-dose Morphine to be prescribed with the highest dose of another opioid. Tr. 599–600.

In order for a pharmacist to safely dispense medication, she must know the dosing and how long the drug lasts in the body. Tr. 603. Pharmacists know that Hydromorphone lasts in the body from two to four hours, while a long-acting opioid like MS Contin lasts in the body eight to twelve hours. Long-acting opioids were meant to reduce the amount of immediate release opioids given. In this case, there are very high doses of immediate release opioids, which are usually given on an as-needed basis because they only last a short time. When working in pain management, the doctor determines the total daily dose of the MME and schedules that dose on the basis of the long-acting opioid; the doctor does not

[22] Dr. Schossow has experience working in retail for twelve years in different pharmacies all over the State of Florida, but not including southwest Florida. Tr. 564. There are regional variations for the prices of medication, but the typical mark-up of medications is around 20 to 25 percent. Tr. 565. Dr. Schossow is familiar with the price of these medications during the charged period from her time working in hospice. Tr. 566. She worked with the rejection queue with high-cost medications for patients all over the State of Florida. Tr. 566–67. She was the lead of the team, and a trainer for the queue, so everyone who she trained understood normal pricing for Oxycodone and Hydromorphone. The mark-up is about 20 percent over the pharmacy's acquisition cost. There are slight variations regionally in different counties and different areas of Florida, but the typical mark-up is 20 to 25 percent over the acquisition. Tr. 569. When Dr. Schossow sees very high prices, it is a red flag. Hospice also would not pay for it, so she would contact the pharmacy and inquire how much they paid for it. Dr. Schossow could not definitively quantify what the slight variations would be, but it would typically be around 20 percent at most. Tr. 569–70. I overruled the Respondent's objections to Dr. Schossow's testimony and allowed her to testify about the acquisition cost and how she determined that the price paid is much higher than what would normally be charged in Florida, even with slight variations in prices regionally. Tr. 571–72.

[23] The Respondent objected to this hearsay evidence, and it was ruled inadmissible as the individuals who provided the pricing information were not identified in the Government's Supplemental Prehearing Statement, as required by the Order for Prehearing Statements. Tr. 572–78, 1009–10; ALJ Ex. 6.

[24] I sustained the Respondent's objections to Dr. Schossow speculating on the connection between the price paid for the prescription and how the drug-seeking community is taking advantage of using this system, including the pharmacy's reputation within the community as without established foundation. Tr. 583–89.

give more immediate release medication than a long-acting opioid. Tr. 1036–37. In this case, because the way the doctor wrote the prescription did not make pharmacological sense, the pharmacist should have done his due diligence to address the inappropriate dosing of the medications. Tr. 605. Dr. Schossow did not see any documentation on the resolution of these red flags, including the pharmacist contacting the doctor. Improper pharmacological drug dosing is discussed in ''Florida Rule 64B16–27.810.'' Tr. 605. The lower dose of the long-acting opioid with the higher doses of the short-acting opioid is a red flag. Tr. 606. This is something the pharmacy should have addressed.

The first two prescriptions for the patient are opioids and the third prescription is for Clonazepam, which is a benzodiazepine. Tr. 606; GX 13 at 1–6. Taken together, these prescriptions represent a cocktail, which is a red flag. Additional prescriptions given to the patient indicate red flags for cash payments, the high price paid by the patient, the dosages of the medications, improper medications for listed conditions, and cocktail combinations. Tr. 606–11, 612–24, 626–40; GX 13 at 7–12, 13–18, 19–24, 25–30, 31–36, 37–42, 43–48, 49–54, 55–60, 61–66, 67–72, 73–78; GX 29 at 1–6, 7–12, 13–18, 19–24, 25–30, 31–33, 34–39, 40–45, 46–49, 50–53, 54–57, 58–61, 62–65, 66–69, 70–73, 74–79.

A Florida pharmacist operating within the standard of care should have resolved the red flags and documented that resolution that were identified for Patient S.K. for subsequent pharmacists to assure continuity of care and patient safety, assuming the red flags were resolvable. Tr. 640–41. Looking at the patient profile, there was nothing in the patient profile or prescriptions for Patient S.K. to suggest that any sort of investigation was done or that the red flags were addressed, resolved, or documented. Tr. 641; GX 21. A reasonable pharmacist acting in the usual course of professional practice would not have filled these prescriptions without addressing, resolving, and documenting such resolution of the red flags. Tr. 641.

Patient R.R.

Dr. Schossow identified the patient profile prescriptions for Patient R.R. Tr. 641–42; GX 14. The prescriptions present red flags for cash payment. Tr. 642; GX 14 at 1–7. They also indicate a red flag for high prices paid by the patient. Tr. 642; GX 14 at 2. They also indicate a red flag for cocktail medications. An additional prescription is for Alprazolam or Xanax 2 mg, which is the highest strength available. Tr. 643; GX 14 at 5–6. This drug is called ''Xany Bars'' on the street, and is a highly sought-after diverted medication. Although it is not usual to dose this medication to half a tablet, it raises a red flag with this particular drug that the instructions were to dispense 30, which is the entire tablet. The pharmacist should address why the patient is prescribed 2 mg in order to take half a tablet of a highly sought-after medication, when Xanax 1 mg is available. Tr. 643–44. Dr. Schossow has never seen Xanax directions like this. This prescription represents a red flag with respect to the nature of the dispensing order of the controlled substance. Tr. 644–45. The additional prescriptions issued to the patient demonstrated these red flags, including red flags for clinical abuse use under Florida Regulation 810,[25] inappropriate clinical and therapeutic dosing, and extended release opioids combined with immediate release opioids. Tr. 645–47, 648–66, 666–73; GX 14 at 8–13, 14–19; GX 31 at 1–6, 7–12, 13–18, 22–25, 27–28, 29–30, 32–33, 34–35, 37–38, 40–41, 42–47, 48–51, 52–55, 56–59, 60–63, 64–69, 70–75; GX 40 at 8–11, 12–13, 14–15, 16–19, 20–23, 24–29, 30–31.

A Florida pharmacist operating within the standard of care should have acknowledged the therapeutic inappropriateness of the prescriptions, and should have contacted the patient or the provider and recorded the resolution of those red flags, if they were resolvable. Tr. 673. Dr. Schossow believed all red flags herein were resolvable. Tr. 1038, 1068. Dr. Schossow did not see any indication on the prescriptions for Patient R.R. that any specific red flags were identified or documented or resolved on any of the prescriptions. There is nothing in the patient profile to suggest that an investigation was done or that the red flags were identified, resolved or documented in the patient profile. Tr. 673; GX 40 at 1. The critical comments listed did not address or show how the red flags or DURs were resolved. Tr. 673–74. None of the documents in the dispensing log address the red flags for the prescriptions. Tr. 674; GX 40 at 2–7. Based on a review of the prescriptions, the patient profile, or any other documents for Patient R.R., Dr. Schossow opined that a reasonable pharmacist acting in the usual course of profession practice would not have filled the charged prescriptions without addressing, resolving, and documenting the red flags for this patient. Tr. 674.

[25] Florida Administrative Rule 64B16–27.810.

Patient R.D.

Dr. Schossow identified the patient profile prescriptions for Patient R.D. Tr. 675–76; GX 10. She noted that Ativan is a benzodiazepine. Tr. 676. The prescriptions indicate a red flag for cocktail medications. Tr. 676; GX 10 at 1–4. They also indicate a red flag for payment of cash for controlled substance prescriptions. They further indicate a red flag for the high amount of cash paid for controlled substances. Dr. Schossow explained that one of the medications is Hydromorphone 8 mg, which is the highest dosage of medication commercially available for this medication. Tr. 677. Although the prescribing physician said the medication was not only for anxiety, but also to manage hypertension, this medication does not treat anxiety or hypertension. This is very dangerous because there were no records that the pharmacist attempted to contact the physician to discuss the red flag. Tr. 677.

There was an additional red flag present with Patient R.D. Tr. 678. The red flag involved long distances traveled by the patient. Tr. 678–79; GX 10 at. 1–2. Dr. Schossow looked up the address of the doctor, the patient, and the pharmacy, which she characterized as an abnormally long distance. Additionally, there were other pharmacies that were very close. Dr. Schossow had concerns with the patient traveling longer than necessary to get to the Respondent pharmacy and then paying ''double the amount'' for the prescription. Tr. 679. A community pharmacist knows her community and the area around it, so this presents a safety issue. Tr. 682, 1032. Dr. Schossow would defer to a local community pharmacist's knowledge of the subject area. Tr. 1032. For example, central nervous system depressant drugs suppress the central nervous system and cause drowsiness, dizziness, and profound sedation, including a warning on operating heavy machinery. If a patient can drive across the street to obtain her medication versus driving further, it is safer for the patient. Tr. 950–53.

Dr. Schossow did not suggest that distance is a reason not to fill a prescription, but it is a reason to ask more questions and clear up concerns. Tr. 682–83, 954–58. In this case, there was no such documentation. Dr. Schossow mapped all of the relevant cities and determined the route that the patient used. The patient lived very far west, had to cross over three bridges to get to the prescribing physician, and then crossed over another bridge to get

to the pharmacy. These prescriptions issued to Patient R.D. thus presented a red flag for distance. Tr. 684; GX 10 at 1–4.

The additional prescriptions issued to the patient demonstrated the previously discussed red flags. Tr. 685–701; GX 10 at 5–8, 9–12; GX 26 at 1–4, 5–8, 9–12, 13–16, 17–20, 21–23, 24–27, 28–31, 32–35, 36–39, 40–43, 44–47, 48–51, 52–55, 56–59.

A Florida pharmacist operating within the standard of care must make a reasonable effort to address each red flag for therapeutic appropriateness through either the patient and/or the physician, document if the red flag is resolved, and maintain those records. Tr. 701. Looking at the patient profile and prescriptions, there is nothing to suggest that an investigation or assessment was done of any of the red flags identified by Dr. Schossow. Tr. 701–02; GX 10, 19, 26. In the patient profile, the comments in the critical comments popup box do not address the red flags identified by Dr. Schossow. Tr. 702; GX 19. Based on her review of the prescriptions and patient profile, Dr. Schossow opined that a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.D. without addressing, identifying, resolving, and documenting the red flags observed and charged by the Government. Tr. 702.

Patient J.R.

Dr. Schossow identified the patient profile prescriptions for Patient J.R. Tr. 702–03; GX 30. The prescriptions issued to the patient present a red flag for cocktail combinations or a trinity. Tr. 703; GX 30, p. 47–54. The prescriptions contain two benzodiazepines, Carisoprodol or Soma, and an opioid, Hydrocodone. Tr. 703–04. The prescriptions also indicate another red flag that falls under Regulation 810[26] of the DUR for therapeutic duplication. Tr. 704; GX 10 at 49–50, 53–54. Therapeutic duplication means two drugs that are in the same class, and thus act in the same way. With Patient J.R., there are two medications that are benzodiazepines and they are both long-acting benzodiazepines. They are Temazepam and Diazepam. This represents a dangerous combination. The two medications duplicate effects and are therapeutically inappropriate because they can compound the side effects of each other. These side effects include CNS depression, leading to respiratory depression, pronounced sedation, overdose, and death. Tr. 704–05.

[26] Florida Administrative Rule 64B16–27.810.

Additional prescriptions to Patient J.R. also indicated these red flags. Tr. 705–07; GX 30 at 55–60, 61–68.

Patient J.R. was prescribed additional trinity cocktails. Tr. 708–09; GX 39 at 3–4, 13–14, 31–34. The patient received an opioid, the muscle relaxer Carisoprodol, and two long-acting benzodiazepines. Tr. 710. The prescriptions also indicated a red flag of therapeutic duplication of benzodiazepines. Tr. 710; GX 39 at 31–34. Additional prescriptions indicated these red flags. Tr. 710–16; GX 39 at 2, 7–10, 11–12, 15–16, 35–38.

A Florida pharmacist operating within the standard of care should have made a reasonable effort to contact the patient and/or the doctor and inquire about the therapeutic inappropriateness of the medication, the risk involved in taking the medications together, and if the therapeutic inappropriateness was resolvable, to document the resolution and maintain those records. Tr. 716–17. There is nothing in the patient profile or prescriptions that suggests that an investigation was done of any of the red flags or that the red flags were resolved. Tr. 717; GX 39 at 1. A reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.R. without addressing, resolving, and documenting the red flags that have been charged by the Government. Tr. 717.

Patient B.Di.

Dr. Schossow identified the patient profile prescriptions for Patient B.Di. Tr. 718–19; GX 11. Prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 719; GX 11 at 1–6. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 719; GX 11 at 2. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions for Dilaudid 8mg and MS Contin 30 mg, extended release, indicate a red flag for opioid dosing. Tr. 719–20; GX 11 at 1, 3. Additional prescriptions indicated the previously discussed red flags. Tr. 720–43; GX 11 at 7–12, 13–18, 19–24, 25–30, 31–36, 37–42, 43–48, 49–54, 55–60; GX 27 at 1–6, 7–12, 13–18, 19–23, 24, 26–27, 29–30, 32–35, 36–39, 41–42, 43–44, 46–49, 50–55, 56–61, 62–67, 68–73, 74–79, 80–83, 86–93; GX 38, pp. 5–6, 7–10, 11–14, 15–16, 17–18, 19–20, 21–22.

A Florida pharmacist operating within the standard of care should have addressed each red flag of concern, documented it appropriately in his patient record, and maintained those records. Tr. 743–44. There is nothing in the patient profile or in the prescriptions to suggest that any sort of investigation or resolution was made or attempted or documented with respect to the identified red flags. Nothing in the patient profile indicated that any of the prescriptions were reviewed. A reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Di. without first addressing, resolving, and documenting the specific red flags identified by Dr. Schossow. Tr. 744.

Patient B.Da.

As to Patient B.D.a., prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 745–46; GX 9 at 1–6. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 745; GX 9 at 4. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 745–46; GX 9 at 1–6. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 746; GX 9 at 7–12. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel. Tr. 747; GX 9 at 7–12.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 747; GX 9 at 13–18. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 747; GX 9 at 14. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748; GX 9 at 13–18.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 748; GX 9 at 19–24. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 749; GX 9 at 20. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 749; GX 9 at 19–24.

Additional prescriptions indicated a red flag for cash payment for controlled

substance prescriptions. Tr. 749; GX 9 at 25–30. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 749; GX 9 at 30. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 749; GX 9 at 25–30. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 750; GX 25 at 1–3. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 751; GX 25 at 1–3. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 751; GX 25 at 1–3. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at. 7–12. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 8. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 752; GX 25 at 7–12. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at 13–18. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 13–18. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 752; GX 25 at 13–18. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 752; GX 25 at 19–24. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 752; GX 25 at 22. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 752; GX 25 at 19–24. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 753; GX 25 at 19–24. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 753; GX 37 at 24–25, 28–31. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 753; GX 37 at 29. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 753; GX 37 at 28–31. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 754; GX 37 at 28–31. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 754; GX 37 at 18–19, 22–23, 26–27. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 754; GX 37 at 27. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 754; GX 37 at 28–31. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 754; GX 37 at 28–31. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 755; GX 37 at 8–9, 16–17, 20–21. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 755; GX 37 at 8–9, 16–17, 20–21. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 755; GX 37, pp. 8–9, 16–17, 20–21. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 755; GX 37 at 10–15. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 755; GX 37 at 11. The prescriptions taken together represent a red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 756; GX 37 at 10–15. The prescriptions demonstrate a red flag for combining extended release and immediate release opioids. Tr. 756; GX 37 at 10–15. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient B.D.a., would have investigated the therapeutic appropriateness of the subject prescriptions by contacting the prescribing physician or patient, document if the red flags were resolvable, and to maintain that documentation. Tr. 756. Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 756–57; GX 37 at 1, 4–8.

Patient L.V.

Dr. Schossow identified prescriptions revealing the red flag for cocktail medications with respect to opioids and benzodiazepines. Tr. 791, 794, 796, 797, 798–807; GX 32 at 1–8, 9–16, 25–28, 37–42, 44–51, 53–60, 61–68, 69–74, 75–80, 83–90, 91–98, 101–08, 109–114, 117–124. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 794, 796–807; GX 32 at 9–16, 23, 24, 25–28, 37–42, 44–51, 53–60, 61–68, 69–74, 75–80, 83–90, 91–98, 101–108, 109–114, 117–124. Dr. Schossow noted a further red flag with some prescriptions paid for by cash, while others were paid for by insurance. Tr. 792–93, 794; GX 32 at 6, 8, 9–16. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 793–807; GX 32 at 2, 10, 24, 26, 37, 47, 54, 64, 70, 75, 84, 94, 102, 110, 120.

Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient L.V., would not have filled the subject prescriptions without addressing, resolving and documenting the red flags discussed. Tr. 812–13. Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 808–09, 812–13; GX 5 at 3; GX 6 at 5–6; GX 22.

Patient A.B.

Dr. Schossow identified prescriptions demonstrating a red flag for combining extended release and immediate release opioids. Tr. 813–16, 819–823, 825, 827–28, 830, 831, 832, 833–34, 835–41, 842–43, 845–48; GX 8 at 1–4, 7–10, 13–16, 19–22; GX 24 at 1–4, 7–10, 13–16, 26–

29, 32–33, 37–38, 40–41, 44–47, 50–53, 56–59, 62–63, 68–71, 74–77, 80–83, 86–89, 92–95; GX 36 at 17–20, 21–24, 27–30. Additional prescriptions indicated a red flag for cash payment for controlled substance prescriptions. Tr. 814, 820–21, 823, 827, 828, 830, 831–34, 836–41, 843, 845–47, 848–49; GX 8 at 1–4, 7–10, 13–16; GX 24 at 1–4, 7–10, 26–29, 32–33, 37–38, 40–41, 44–47, 50–53, 56–59, 62–63, 68–71, 74–77, 80–83, 86–89, 92–95; GX 36 at 17–20, 21–24, 27–30. There is also an indication of a red flag for the payment of an unusually large amount of cash for an opioid. Tr. 816–17, 820, 821–23, 825–27, 828–29, 830–32, 833–37, 839, 841, 842–44, 845–47, 848–49; GX 8 at 2, 8, 14, 20; GX 24 at 10, 20, 27, 32–33, 38, 47, 51, 53, 59, 63, 71, 77, 83, 87, 95; GX 36 at 20, 24, 30. Finally, the prescriptions demonstrate a red flag for long distance travel, with the patient traveling from Bokeelia, Florida. Tr. 748, 816–17, 820–21, 822, 824, 826, 827, 829–30, 832–37, 838–40, 841–44, 847, 848–50; GX 8 at 2, 8; GX 24, p. 4, 7–10, 13–16, 26–29, 33, 41, 44–47, 51, 53, 59, 63, 71, 77, 83, 87, 95; GX 36 at 17–20, 21–24, 30.

Nothing in the patient profile, prescriptions nor medical records suggest any investigation to identify, resolve or document the subject red flags. Tr. 844–45; GX 36 at 1–12. Dr. Schossow opined that a pharmacist, acting within the relevant standard of care, when confronted with the red flags revealed within the subject records for Patient A.B., would not have filled the subject prescriptions without addressing, resolving and documenting the red flags discussed. Tr. 850–51.[27]

Respondent's Case-in-Chief

The Respondent presented its defense through the testimony of five witnesses: Dr. Daniel Buffington, L.V., J.R., Dr. N., and Dr. Ricard Fertil.

J.R.[28]

J.R. lives in Cape Coral, Florida and is a disabled Vietnam veteran. Tr. 1310. He has service-connected disabilities as a result of back problems, including four back surgeries, eye cancer, and suffers from post-traumatic stress disorder. Tr. 1310–1313. Dr. D. has been his pain management doctor for three or four years. Tr. 1313. J.R. began seeing Dr. D. at his practice in Fort Myers, but Dr. D.'s practice has since moved to Naples, Florida. Tr. 1314. Despite Dr. D.'s relocation, J.R. drives to Dr. D.'s new office. Tr. 1314–15. Dr. D. has prescribed J.R. Oxycodone, hydrocodone, and extended-release morphine sulfate. Tr. 1315. J.R.'s primary care doctor, Dr. M., also prescribed J.R. diazepam, temazepam, and carisopridol, also known as Soma. Tr. 1316.

J.R. was a customer with Gulf Med Pharmacy for about two or three years. Tr. 1317. J.R. provided the pharmacy a disk with his MRI from the VA. Tr. 1317. Prior to becoming a customer at Gulf Med, J.R. filled his prescriptions with Walgreens. Tr. 1318. Walgreens failed to provide him with a prescription after a surgery so he went to the closest pharmacy that could fill his prescription, Gulf Med. Tr. 1318. Gulf Med is even closer than Dr. D.'s office in Naples, Florida. Tr. 1319. Gulf Med always answered his questions to his satisfaction and provided him with written or printed materials like brochures or informational material for his opioid prescriptions. Tr. 1319. J.R. discussed information regarding his medical history, treatment, and prescriptions with Gulf Med staff that he had previously discussed with his doctors. Tr. 1320. He spoke with Mr. Fertil about medication he was taking and the ways he could wean himself off some medications and Mr. Fertil appeared very knowledgeable about this. Tr. 1321. J.R. did in fact taper off some of his medicines.

L.V.

L.V. lives at 1103 Northeast 32nd Terrace in Cape Coral, Florida and serves as a billing manager for Charlotte Compassionate Care. Tr. 1292. She suffers from anxiety, cervical disc degeneration, cervicalgia, lumbar or lumbrosacral disc degeneration, lumbago, partial tear of a rotator cuff, chronic pain syndrome, breast cancer and was diagnosed with COVID–19 in July 2020. Tr. 1293–94, 1298. She is a patient of Dr. N. in Fort Myers, Florida. Tr. 1194. Dr. N. prescribed certain medications to L.V. including 30 milligrams of oxycodone and extended-release MS Contin 60 milligram and L.V. had previously been prescribed alprazolam or Xanax. Tr. 1294.[29] L.V. was previously a customer of Gulf Med, but could not recall how many years she was a customer there. Tr. 1301. She had gone to a different pharmacy, Myerlee, but changed to Gulf Med because there was a delay in Myerlee filling her prescriptions, which caused her a lot of pain for weeks at a time until the prescriptions were filled. Tr. 1301–02.

L.V. had tried using other pharmacies. Tr. 1302–03. Walgreens told her to never come back to the pharmacy after putting her name in the computer and Publix told her that it could not run the prescriptions through her insurance and it would not fill her prescriptions. Tr. 1303. She then went to Gulf Med, where her prescriptions were filled in a timely fashion at a reasonable price. Tr. 1303. She selected Gulf Med over other pharmacies because it always had her medications at cheaper prices. Tr. 1305. Gulf Med also provided her with informational materials/brochures regarding the prescriptions it was dispensing to her, which included a CDC pamphlet about prescription opioids. Tr. 1306. Based on discussions with her physician, Dr. N., she learned that Dr. N. had been in contact with Gulf Med regarding her prescriptions. Tr. 1307.

[27] The Government offered various statistical evidence regarding average national prices for controlled substances, average miles driven to the pharmacy by patients nationally, a high percentage of the Respondent's patients traveling long distances to the Respondent's pharmacy, the relatively high percentage of the Respondent's patients paying by cash, the high percentage of the Respondent's controlled substance dispensations versus non-controlled, the extremely high percentage of compounded hydromorphone 8 mg dispensed versus the commercially available hydromorphone 8 mg tablet dispensed by the Respondent, the extremely high percentage of oxycodone 30 mg, and Alprazolam 2 mg (the highest dosage units commercially produced) prescriptions issued as compared with lower dosage units dispensed, that the Respondent dispensed almost twice as many oxycodone 30 mg capsules as tablets. Tr. 235–38, 241, 244–46, 250–51. This evidence was admitted as it related to the prompting and evaluation of various red flags. It was not admitted, and will not be considered, as probative evidence that specific prescriptions were filled contrary to the standard of care in Florida, which determination requires individualized proof and individualized analysis.

[28] The testimony of patients of the Respondent was relevant as relates to information they shared with the Respondent prior to the filling of prescriptions, the protocols employed by the Respondent in filling prescriptions, the reasons they traveled some distance to fill their prescriptions, and as relates to the Respondent's experience in filling prescriptions under 21 U.S.C. 823(f)(2). Any patient testimony relating to the efficacy of their physician's treatment and prescribing, whether their physician performed consistent with professional standards, and whether the Respondent's professional performance was consistent to professional standards will not be considered herein. *See* ALJ Exs. 11, 14.

[29] At this point in the testimony the Respondent's counsel asked L.V. if she had ever discussed the risks associated with taking an opioid and a benzodiazepine together. Tr. 1294. The Government's counsel objected based on relevance and that the information was not provided in the Respondent's prehearing statement. Tr. 1295. The Tribunal sustained the objection of relevance, *see* Tr. 1295, and after reviewing the Respondent's first Supplemental Prehearing Statement, overruled the Government's second objection about the testimony being unnoticed. Tr. 1298. The Respondent's counsel next asked if L.V. takes her medications as prescribed, the Government's counsel objected, and the Tribunal sustained the objection based on relevance. Tr. 1298–99.

Dr. N.[30]

Dr. N. has been a licensed physician since 1979 and is licensed in New York, New Jersey, Massachusetts, Connecticut, and Florida. Tr. 1324–25. He completed his residency at Mount Sinai in New York and currently practices in Fort Myers, Florida with a specialty in pain management and anesthesiology. Tr. 1325.

Dr. N. is aware of what an FDA black box warning is.[31] Dr. N. treated a patient by the name of L.V., but could not recall how long he treated her or what medications he prescribed her. Tr. 1327. It has been in Dr. N.'s practice in the past to include an ICD–10 diagnosis code on prescriptions he writes for his patients, which is a diagnosis that Dr. N. gave for the patient. Tr. 1327–28.[32]

Dr. N. could not recall whether pharmacies ever contacted him or his office to verify prescriptions or ask questions about some of the drug therapies he prescribed to his patient. Tr. 1332. Dr. N. is not familiar with Gulf Med Pharmacy and could not recall whether he or his staff communicated with Gulf Med Pharmacy or its staff about verifying prescriptions or drug therapies. Tr. 1333.

Dr. Daniel Buffington

Dr. Daniel Buffington is a pharmacist practicing in Tampa, Florida. Tr. 1081, 1087. Dr. Buffington received his PharmD degree from Mercer University in Atlanta, Georgia and then completed a post-doctorate degree residency and fellowship in clinical pharmacology at Emory University. Tr. 1079. He has practiced as a pharmacist for over thirty years. Tr. 1078, 1087.

Dr. Buffington has training in conducting drug diversion investigations and has worked with attorneys general, states attorneys' offices, the DEA, and local law enforcement. Tr. 1159. He helped these agencies identify how healthcare investigations are different from other investigations involving drug gangs or illicit drug sales. Tr. 1159–60. Dr. Buffington is active with the National Association of Investigators and Drug Diversion Investigators, which is a multidisciplinary organization that aids healthcare professionals in understanding how to conduct and design investigations and look for healthcare fraud, drug divergence, and substance abuse. Tr. 1160.

Dr. Buffington currently practices as a pharmacist in Tampa, Florida at a practice where patients are referred who are typically prescribed high-risk medications. Tr. 1080–85. Dr. Buffington also provides consulting services to pharmacists, medical practitioners, healthcare facilities and organizations, and law enforcement agencies. Tr. 1080, 1085, 1087, 1091. This includes consulting with practices in both Southeast and Southwest Florida. Tr. 1097. Dr. Buffington has served in several capacities as a pharmacist, including direct dispensing roles, administrative roles, and as a medication safety and review officer. Tr. 1088. Although it is unclear how many prescriptions Dr. Buffington has dispensed in the last year or five years, he has experience making determinations about whether or not a particular prescription should be filled for a controlled substance based on the legitimacy or medical reason for its prescription. Tr. 1088–89.

Dr. Buffington also serves on the faculty at the University of South Florida's Colleges of Medicine and Pharmacy where he teaches toxicology, pharmacy law, and other healthcare administration and practice management aspects. Tr. 1076, 1096. He has served as a guest lecturer or taught pharmacy law at the University of Florida, Florida A&M, Nova, Southeastern, Palm Beach, Mercer University, Marshall University, and the University of Pittsburgh. Tr. 1097. Through teaching these courses, Dr. Buffington must review applicable Florida administrative code provisions and is therefore familiar with Florida Administrative Rules 4B16–27.800, 64B16–27.810, and 64B16–27.831. Tr. 1098. Dr. Buffington is also familiar with the standard of care that applies to pharmacists in the State of Florida as the standard of care relates to these administrative code provisions, and corresponding statutes of the federal Controlled Substances Act. Tr. 1099.[33]

Dr. Buffington reported he has testified as an expert witness on over 300 occasions in state, federal, and administrative proceedings. Tr. 1077–78, 1083, 1094. Dr. Buffington reported he has previously testified in DEA administrative hearings before a DEA Administrative Law Judge, but could not recall when or the names of any participants. Tr. 1230. He has appeared as an expert with respect to the Florida standard of care in a DEA administrative proceeding, but is unsure if his testimony was credited by the DEA administrator in a final opinion. Tr. 1230–31.[34]

In approximately February 2020, Dr. Buffington was contacted by a firm representing Gulf Med Pharmacy and reviewed documents in the instant case including copies of prescriptions, dispensing logs, and PDMP data that was produced by the DEA as well as all exhibits offered by both parties in this case. Tr. 1076–77. This included the Order to Show Cause, the Government's Prehearing Statements, and other documents such as CDC guidelines, statutes, administrative rules, and stakeholder challenges. Tr. 1198–99. He also reviewed different statutes and regulations, including Florida statute 766.102, which includes pharmacists in the definition of a ''healthcare practitioner.'' Tr. 1233–34. Dr. Buffington also wrote the summaries of his testimony in concert with counsel. Tr. 1198. He spent approximately ten to fifteen hours preparing for this hearing. Tr. 1201.

Dr. Buffington testified that the standard of care in Florida does not require a pharmacist to document in writing any specific resolution of ''red

[30] Dr. N. is a treating physician of one of the charged patients. His relevant testimony is limited to his interactions with the Respondent prior to the filling of the subject prescriptions and as relates to the Respondent's experience in dispensing controlled substances. 21 U.S.C. 823(f)(2); ALJ Ex. 11.

[31] At this point in the testimony, the Respondent's counsel asked Dr. N. about the black box warning pertaining to the prescribing of a combination of drug therapies and whether Dr. N. prescribed certain medications. Tr. 1325–26. The Government's counsel objected to both questions and the Tribunal sustained both objections noting that the relevance of Dr. N.'s testimony was limited to his interaction with the pharmacy. Tr. 1326.

[32] After reviewing the Government's Exhibit 15, Page 1, Dr. N. noted that the prescription in the exhibit was for 30 milligrams of oxycodone and instructed the patient to take the medication up to four times per day only when necessary to alleviate breakthrough pain. Tr. 1330–31; GX 15 at 1. Government's Exhibit 15 on Page 3 is for MS Contin, 60 milligrams. Tr. 1331; GX 15 at 3. Page 5 of Exhibit 15 depicts a prescription for Xanax. Tr. 1331; GX 15 at 5. MS Contin and oxycodone are opiate medications and Xanax is a benzodiazepine. Tr. 1331.

[33] Dr. Buffington testified that the Federal Controlled Substances Act does not have jurisdiction over the practice of pharmacy in Florida. Tr. 1099.

[34] During cross-examination, the Government questioned Dr. Buffington regarding his CV. Tr. 1201–1209. Dr. Buffington stated that he was not admonished in a district court case in Ohio and his testimony was not stricken for failing to include his legal experience as part of his CV. Tr. 1208. Instead, Dr. Buffington asserts that there was an issue with an Ohio court where the opposing counsel claimed that Dr. Buffington's CV did not follow Federal Rule 26 formatting and opposing counsel petitioned the court for more detail. This updated information for Dr. Buffington's CV was not provided by the deadline and therefore the testimony was withheld and not permitted. Tr. 1209. Unlike the Government counsel's assertion that the district court had found that this was the third time Dr. Buffington failed to disclose legal testimony, *see* Tr. 1210, 13–14, Dr. Buffington asserts that instead there was simply a formatting issue and the court requested for him to include more detail in another case with the same parties, and that the corrected report was done but was missing a case. Tr. 1214.

flags'' [35] and in fact, he testified that the term ''red flags'' is not mentioned in the Florida regulatory documents or the DEA guidance documents, but rather is a DEA slang term.[36] Tr. 1100, 1124, 1145. Dr. Buffington testified that Florida Code 64B16–27.810 merely states what exercise a pharmacist is supposed to perform professionally in the process of evaluating the prescription, not what is required documentation. Tr. 1100. Dr. Buffington stated that the standard of care for a pharmacist in Florida is based on the level of care that a reasonable pharmacist would use in like circumstances and reasonable pharmacists could disagree about what the requirements are for documentation of prescriptions in the state of Florida. Tr. 1101, 1249.

Dr. Buffington testified that Florida's guidelines are clear that a pharmacist must exercise his or her professional judgment in evaluating each prescription and such judgment should have the patient's safety and therapeutic outcomes in mind. Tr. 1101–02, 1135.[37] He testified that, based on a review of all the prescriptions identified in the Government's exhibits that were admitted into evidence, as well as Respondent's exhibits, the pharmacists at Gulf Med Pharmacy complied with the applicable standard of care as it relates to documentation of the resolution of red flags and the DEA provided no substantive evidence to presume otherwise. Tr. 1109, 1112. Furthermore, Dr. Buffington testified that Florida Administrative Rule 64B–27.810 provides categories of elements that pharmacists would consider in their determination of both legally validated and clinically validated prescriptions based on the record they had while performing prescription fulfillment and dispensing, and the code does not state that a written report is required. Tr. 1110.

Dr. Buffington testified that Rule 64B16–27.800 specifically requires that the pharmacist provide the full name, address, phone number, age, date of birth, gender, and the refill details as well as any related information provided by the healthcare professional. Tr. 1111. Furthermore, he testified that it is in the pharmacist's professional judgment as to what is relevant to address and/or record because there is no specific Florida pharmacy law that clearly states what steps are required for each patient. Tr. 1111.

Dr. Buffington reviewed Florida Administrative Rule 64B16–27.831 as it relates to validating a prescription in the retail setting. Tr. 1112. He testified that the administrative code requires that there must be a valid or eligible prescription to move forward and that if the pharmacist has specific concerns (that does not necessarily mean a red flag), then the pharmacist could resolve any issues by speaking to the prescriber or the patient or taking consultation with the prescription drug monitoring program. Tr. 1112–13, 1122. Furthermore, he testified that if a pharmacist learns that a physician is writing a prescription for non-legitimate purpose or ill-intent by the patients, then the pharmacist has a duty to report this to the Florida Department of Public Health. Tr. 1113.

Dr. Buffington testified that there are pharmacy software programs that identify potential issues through an alert system. Tr. 1113–14. He testified that an alert is not inherently a stop and is a pop-up message that prompts the pharmacist to consider something at the time, but the pharmacist may accept or move past the prompt. Tr. 1114. He testified that when a pharmacist ''clicks through'' the pop-up prompt, the software program records this through a ''click tracking'' program. Tr. 1114, 1115. He testified that this click tracking is a key way to track individual activity. Tr. 1114. He testified that when a person has a prescription for both a benzodiazepine and opiate, an alert does not require a stop because these prescriptions are routinely prescribed together. Tr. 1115–16. He testified that it routinely happens that different prescribers prescribe medications that interact and although a pharmacist with concerns should have an assessment with a patient and a provider, there is no requirement set forth in the Florida administrative code that requires such concerns be put in writing. Tr. 1118.

Dr. Buffington testified that as to the specific software program used by Gulf Med, PioneerRx, there are certain boxes that must be clicked, called pathways, in order to fill a prescription. Tr. 1239. He testified that the PioneerRx system allows someone to run a specific report to see how long a pharmacist spent on a particular pathway click. Tr. 1240. Although Dr. Buffington does not recall seeing a report being run, he thinks he saw a ''time change.'' He testified that whether a pharmacist spent ten minutes or five seconds on a particular box looking at a pathway, however, is irrelevant to the instant case given that there is not a single requirement for documentation formatting and the documentation may not have transpired during that pathway.

Dr. Buffington testified that opiates and benzodiazepines, or Class II drugs in general, are routinely prescribed together and although such a combination is not always justified, there is no default presumption that the two drugs cannot be prescribed together. Tr. 1115–16, 1241. Furthermore, he testified that even if two sets of Class II prescriptions are prescribed, this would not be a hard stop. Tr. 1116. [Omitted. *See infra* n.*L.]

Dr. Buffington testified that if a pharmacist receives a prescription for an opiate, benzodiazepine, and a muscle relaxant, there must be an analysis of clinical oversight. Tr. 1118–19. In particular, he testified that the first analysis would be to evaluate for duplicity and whether other muscle relaxants have been prescribed and whether such an addition should be communicated with the prescriber or assessed with the patient based on the pharmacist's professional judgment. Tr. 1119–20.

Furthermore, Dr. Buffington testified that even a black box warning does not serve as a stop if the pharmacist consults with the patient and the E–FORSCE data demonstrates that a patient has been on a certain treatment regimen for a significant period of time. Tr. 1118. He testified that if a muscle relaxant is prescribed with an opiate and benzodiazepine, the analysis as a clinician changes and a pharmacist would then need to make a professional judgment. Tr. 1119–20. Dr. Buffington testified that pursuant to Section 1306.04 of the Controlled Substances Act,[38] the physician has certain responsibilities and makes decisions based on the needs of the patient and selecting a medication by name, product formulation, and dose. Tr. 1120. [Omitted discussion of confusing testimony purporting to interpret federal and state law.] *D

Dr. Buffington testified that although the combination of three controlled substances—colloquially known as the ''holy trinity'' or ''trinity'' [39]—heightens a risk to a patient, there is the same risk when combining many types of

[35] [Omitted for brevity.]

[36] Dr. Buffington noted that these items should be referred to as ''yellow flags'' or ''yellow lights'' as opposed to ''red flags'' because these are things that should be factored and considered. Tr. 1124.

[37] Dr. Buffington's analysis was a direct contradiction to Dr. Schossow's testimony regarding her analysis of the guidelines for a pharmacist in Florida.

[38] 21 CFR 1306.04.

*D Dr. Buffington's testimony addressed the level of intent required for a violation of 21 CFR 1306.06, which is outside of his expertise as a pharmacy expert.

[39] According to Dr. Buffington, the slang term, ''trinity,'' refers to an opiate, a benzodiazepine, and Carisoprodol being prescribed to one patient at the same time. Tr. 1255.

medications including over-the-counter medications. Tr. 1243. He testified that the circumstance of prescribing this combination of prescriptions alone would not automatically raise a reasonable suspicion. Tr. 1265–68. Therefore, he testified that there is need and merit to evaluate and counsel the patient, but it is not necessarily inappropriate to prescribe three controlled substance together as it is commonplace for physicians to prescribe this combination. Tr. 1243–44. Dr. Buffington testified that it is a clinical question as to whether there is inappropriate use as opposed to a law enforcement question. Tr. 1253–54. Furthermore, he testified that although these three combined substances can also produce a high by illicit drug use, alcohol use and other base medications can have the same effect and this is irrelevant to the case. Tr. 1255. Furthermore, he testified that the practice of prescribing these three drugs together is declining based on the research that Carisoprodol is of less utility. Tr. 1255. Dr. Buffington testified that even if ''red flags'' are an inference to things that a pharmacist should look at and evaluate, these are not something that should be counted and a person is in trouble if his count hits a threshold. Tr. 1254. In Dr. Buffington's view, this would be a disingenuous attempt at an investigation.[40]

Dr. Buffington compared the Florida Administrative Codes to the federal regulations and the Controlled Substances Act, noting that the statute is very clear that the responsibility of the prescriber or the dispenser is to knowingly demonstrate that a prescription was written or dispensed for an appropriate purpose whereas the Florida law speaks to the duty of the pharmacist and the requirement to report. Tr. 1120. Furthermore, he testified that ''combination therapy'' or ''multidrug regimen'' [41] are routine and the Respondent in this case had not failed in its responsibility nor was there evidence that the Respondent breached its standard of pharmacy practice with regards to such medications. Tr. 1121–22.

Dr. Buffington testified that the quantity of the dosage of a product formulation should not itself be a ''red flag'' because pharmacists will instruct patients to take multiples of whatever that formulation is at the time of dosing which makes product formulation an irrelevant basis of a ''red flag.'' [42] Tr. 1124–25. He testified that even lower dosages carry the possibility of adverse side effects. Tr. 1125. He testified that it is not a deviation from a Florida pharmacist's standard of care or corresponding responsibility to fill a prescription that includes a long-acting or extended release opiate (some of which are twelve or twenty-four hours) along with an immediate release for breakthrough pain. Tr. 1129–30.[43]

Dr. Buffington testified that there were no breaches of the pharmacist's responsibilities or that the pharmacist had breached a duty. Tr. 1131–32.[44] Specifically, he testified that there was no evidence presented in this case that a pharmacist in the State of Florida at Gulf Med Pharmacy was knowingly aware. Tr. 1134. He testified that Gulf Med also did not ''turn a blind eye'' or ''bur[y] [its] head in the sand'' when Gulf Med pharmacists were presented with issues due to red flags because the Florida pharmacy statutes, and administrative rules require a pharmacist use professional judgment and there is no requirement that this needs to be documented. Tr. 1135.

Dr. Buffington testified that there is no restriction on the distance a patient may travel to a pharmacy and there are in fact now mail order pharmacists. Tr. 1136. Furthermore, he testified that a patient travelling a distance of thirty miles is not a reason to cause a pharmacist pause because many people like to stay engaged with a particular practitioner or the pharmacy is near their work or doctor.[45] Tr. 1138–39. Furthermore, he testified that the Florida Administrative Code does not require a pharmacist to identify or document the distance a patient travelled to their doctor or the pharmacy. Tr. 1141.

As to payment, Dr. Buffington testified that there is nothing that prohibits a patient from paying in cash and even when a patient pays in cash, this is reported through PDMP and E–FORCSE. Tr. 1144–45. He testified that there is no circumventing the system when a patient pays in cash. Tr. 1145. He testified that E–FORCSE data includes the name of the prescriber, the prescriber's address, the name of the patient, the patient's address, the price that was paid, the date the prescription was issued, and the date it was filled, and the manner of payment. Tr. 1145, 1274. He testified that a pharmacist must evaluate many other data elements including a patient's response to medications and medical history. Tr. 1145. Furthermore, he testified that a patient may pay with cash because there is a better pathway for their out-of-pockets costs, including a discount plan. Tr. 1146. He testified that even paying for an opioid prescription with cash would not change this analysis. Tr. 1151–52.

Dr. Buffington testified that there are also many variables pharmacists consider when choosing how much to charge a patient.[46] Tr. 1147. In Dr. Buffington's view, a pharmacy is like any other business and requires sufficient practice revenue and pricing tables evolve. Tr. 1148. He testified that cash price is usually higher because there is counter-contract similar to Medicaid or Medical programs that will contract at a reduced price.

Dr. Buffington testified that pharmacies must also take into consideration their overhead costs including rent, payroll, taxes, and utilities. Tr. 1149. Furthermore, he testified that whether Gulf Med has a debt or rent against the building is a nonissue because nothing regulates what a physician charges for a medical service, a surgery, a hospital admission,

[40] At this point in the testimony the Tribunal directed Dr. Buffington not to give his opinion about whether the investigation was appropriate as he had not been qualified to give that opinion. Tr. 1254. The Tribunal reiterated that this not a criminal matter, but rather an administrative proceeding, and directed Dr. Buffington to focus on his expertise as it relates to pharmacy practice and to pharmacy law. Tr. 1254–55.

[41] Respondent's counsel referred to ''cocktail medications'' when questioning Dr. Buffington, however, Dr. Buffington asserted that this was a ''colloquial'' or ''slang'' term, and the proper terminology was ''combination therapy'' or ''multidrug regimen''. Tr. 1121, 1122.

[42] Dr. Buffington specifically disagreed with Dr. Schossow's opinion that there should be an inference of an alert or caution if a medication is prescribed at a magnitude or dose in relation to product formulation that the manufacturer produces. Tr. 1123. In fact, Dr. Buffington described such an inference as ''preposterous'' and stated that it is a complete misrepresentation to make such an inference. However, when later prompted by the Tribunal regarding his critique of Dr. Schossow, Dr. Buffington declined, stating that he did not come to testify about Dr. Schossow's findings, but rather to testify about his own findings in the case. Tr. 1248.

[43] Dr. Buffington testified that the long-acting release are also supposed to provide baseline relief, not 100%. Tr. 1129. Dr. Buffington also described that aggravated pain could occur, which can be triggered by things such as a patient's lifestyle and can vary from patient to patient and even with one patient. Tr. 1129–30, 1248.

[44] Respondent had posed a question asking whether there was any evidence that the Respondent pharmacist deviated or violated the Florida standard of care for a pharmacist as to over- or underutilization, therapeutic duplication, drug disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions, or clinical abuse or misuse. Tr. 1132

[45] Dr. Buffington testified that it is ''particularly offensive to infer the opposite.'' Tr. 1139.

[46] At one point Dr. Buffington stated that payment options were unique to each pharmacy; however, he later went on to state that he ''amend[ed] the comment,'' and in fact the pricing was ''almost universal.'' Tr. 1147.

or what a pharmacy charges for a particular dispensed medication. Tr. 1151. Dr. Buffington testified that after reviewing the acquisition price and sales price on the pill stickers, there was no apparent evidence of inappropriate practice based on the fee structure for the cash paying patients. Tr. 1152.

Dr. Buffington testified that the analysis would not change if a person paid in cash, had a combination of drugs, and drove 30 to 50 miles. Tr. 1153. He testified that once a pharmacist finds the prescription to be fillable the first time based on certain factors, each time after that, there is no longer a red flag.[47] Dr. Buffington testified that pharmacists use their professional judgment in deciding whether to fill it, while complying with Florida Rule 64B17–831. Tr. 1155.

Based on his education, training, and experience, Dr. Buffington reviewed the information in this case and did not see any evidence that would support the inferences made by the Government. He testified that no formal metrics were used and he felt that DEA ''attempt[ed] to manifest or fabricate information from pharmacy records that are incomplete or descriptive of things that they're trying to infer.'' Tr. 1161. Dr. Buffington did not see any red flags, noted that there was other attainable information, and that all the prescriptions charged by the Government and issued by the Respondent are within the standard of care and the scope of professional practice of Florida law as to Florida pharmacies. Tr. 1162, 1241, 1277–78. In particular, Dr. Buffington noted that there were additional fields in the PioneerRx database referred to as Medication Therapy Management and that there were multiple other tabs and therefore further additional information that the investigator can request and consider as a factor. Tr. 1163–64.[48] [However, as discussed in more detail below, Respondent was served with three subpoenas that required the production of all documents that contained any discussion or resolution of red flags. Thus, Dr. Buffington's testimony that there might have been additional materials resolving red flags is not entitled to any weight. Further, there is no evidence that Dr. Buffington reviewed any additional tabs and thus his testimony as to whether there could be information on such other tabs is entirely speculative.] As to the legality, Dr. Buffington testified that there is a three-step process: (1) Presuming legality of a prescription absent evidence to the contrary, (2) the pharmacist validates that the order is valid based on data points and data elements, and (3) doing a Prospective Drug Review. Tr. 1278.

Dr. Buffington has also worked with the Florida Department of Health and Board of Pharmacy in developing regulations relating to pharmacy practice. Tr. 1164. At one point, Dr. Buffington served on the national association of the American Pharmacists Board of Trustees, where he had a dialogue with the DEA to express that healthcare professionals feel like they are part of the solution and although the term ''red flag'' has merit, flags are not metrics and are only things to consider. Tr. 1164–65. According to Dr. Buffington, despite pleas from healthcare professionals, no guidance material has been published for pharmacists since the 2010 Pharmacists Manual and in fact the term ''red flags'' is not even in the manual. 1165–66.

Dr. Buffington testified that there is no requirement that a pharmacist learn about DEA administrative decisions or be familiar with or read the **Federal Register** as the DEA does not have jurisdiction over pharmacy practice. Tr. 1168–69. Although Dr. Buffington testified that the DEA administrator's findings are binding upon DEA registrants, he believes that this does not include every pharmacist and such findings would relate to criminal issues rather than the scope of practice. Tr. 1237. Furthermore, he testified that the DEA is law enforcement and has jurisdiction over criminality, not medical decision-making and pharmacologic decision-making over the use of medications. Tr. 1245.

Dr. Buffington testified that the second aspect of the mandatory CE or assessment ''b'' is using the Prescription Drug Monitoring Database, which Dr. Buffington incorporates into his class. Tr. 1169. Dr. Buffington is familiar with the types of data that E–FORCSE maintains, serves as a consultant with the team that manages the E–FORCSE system in Florida, and covers the types of data that E–FORCSE includes in his continuing education course. Dr. Buffington testified that the third assessment, ''c'', is the assessment of prescriptions for therapeutic value, which requires the practitioners involved in dispensing the drug to use their professional judgment in assessing risk and reviewing a patient's historical response to a medication in deciding whether a drug should be dispensed. Tr. 1169–71, 1175. Dr. Buffington testified that unless there is a known drug allergy or an actual drug interaction, the pharmacist does not need to document his process in dispensing prescriptions. Tr. 1171. Furthermore, Dr. Buffington testified that a pharmacist does not always have the opportunity to speak directly with a patient because a caregiver or family member may bring the prescription, the prescription is called in and the patient is not present, or the prescription may be mailed to a patient. Tr. 1172. Dr. Buffington testified that in these instances, and especially with the current pandemic, such events do not minimize the opportunity to call and have a direct dialogue with a patient and practitioners should touch point to discuss concerns instead of just refusing a prescription. Tr. 1173.

Dr. Buffington testified that pharmacists must also learn how to detect whether a prescription is not based on a legitimate medical purpose, which can be done through communicating with a prescriber, evaluating and having a discussion with the patient, and putting down the patient's diagnosis[49] in the records. Tr. 1178. Dr. Buffington also noted that even if a prescription is outside of the FDA-approved list, pharmacologically, using such a prescription is fine as long as the pharmacist has supporting clinical rationale. Tr. 1174–75. Dr. Buffington testified that Florida Administrative Rule 64B16–27.831 is the law and rule related to prescribing and dispensing of controlled substances, which does not require that pharmacists be educated on DEA administrative decisions, because this would be based on criminal issues and not on something in terms of delivery of healthcare services, which is dictated on the a state level. Tr. 1176–77.[50]

Dr. Buffington testified that the next section is proper patient storage and disposal of controlled substances which discusses how a patient is supposed to store and dispose of controlled substances and requires healthcare professionals to record the receipts, the transfer, and the destruction of controlled substances. Tr. 1177. Dr. Buffington testified that the next section of Florida Administrative Rule 64B16–27.831 relates to protocols for addressing and resolving problems

[47] Furthermore, Dr. Buffington noted that there is no evidence in the record providing how often a pharmacist at Gulf Med did *not* fill a particular prescription. Tr. 1154.

[48] Dr. Buffington analogized his review of the record to that of a puzzle and the missing tabs equated to missing pieces of the puzzle. Tr. 1163–64.

[49] Dr. Buffington noted that in his review of the universe of prescriptions for this case, although it is not required, some of the prescribers routinely include diagnostic codes on the prescriptions. Tr. 1175–76.

[50] *See Gonzalez* v. *Oregon,* 546 U.S. 243, 270–72 (2006), for context.

recognized during the drug utilization review, including but not limited to, drug-drug interactions, side effects, high-dose and low-dose guidelines, which is new to the CE as of June 2018. Tr. 1177–78. Dr. Buffington testified that the mere presence of a dosage range is not a rate limiter for dispensing a prescription, but rather a pharmacist must use his professional judgment. Tr. 1178. Dr. Buffington does not advise pharmacies to document any resolution of these DUR-related issues because there is no requirement to do so and each pharmacy has a process within their own facility to convey from peer to peer. Tr. 1178–79.

Dr. Buffington testified that the protocol for addressing and resolving issues relating to drug utilization review are limited to drug-drug interactions, side effects, and high-dose and low-dose guidelines. Tr. 1179. He testified that such issues must rise to the level of needing resolution in a pharmacist's professional judgment, not that something just occurred. Dr. Buffington testified that Section H requires pharmacists to be educated on the availability of NARCAN or naloxone for overdose treatment. He testified that Section I relates to pharmacists initiating counseling with patients who have opioid prescriptions, which makes it imperative for there to be an open dialogue between the pharmacist and patient. He testified that Section J relates to available treatment resources for opioid physical dependence, addiction, misuse, or abuse. Tr. 1181. Dr. Buffington testified that Respondent pharmacists at Gulf Med were not providing copies of the CDC pamphlet to patients receiving opioid prescriptions, but there is no legislative mandate that the pharmacists give that particular document to patients. Tr. 1181–82. Dr. Buffington testified that there was a legislative change in 2019 that requires pharmacists to develop and/or produce or distribute a patient education pamphlet so the CDC's pamphlet would be an acceptable tool to satisfy that requirement. Tr. 1182.

Dr. Buffington testified that when a prescription is dispensed, a label is produced and given to the patient as an educational resource. Tr. 1182–83. He testified that this labeling is in response to an OBRA–90 mandate that serves as an additional trigger to see if a patient has any questions and leaves with information that improves their health outcomes and safety. Tr. 1185. He testified that the software also generates educational information about warning signs, side effects, drug interactions, and how to store and protect medication. At this point in the testimony, the Respondent's counsel discussed that there is a Critical Comments box in the lower right-hand corner on page 1 of Government's Exhibit 39 which includes a data field for pop-ups and went through several patients. Tr. 1185–1192; GX 39. Dr. Buffington testified that for patient J.R., among the critical comments listed for various dates, the signature or the directions for the use of the prescriptions were verified by the pharmacist with the prescriber. Tr. 1184. Dr. Buffington testified that on May 15, 2019, patient J.R. was also given the CDC pamphlet. On August 5, 2019, the pharmacist requested clarification or verification of the prescription with the provider. Tr. 1184–85; GX 39 at 5. Dr. Greshler prescribed Oxycodone acetaminophen, a combination tablet, and the pharmacist wrote a note saying ''per M.D. patient prior dose was ineffective. Need to start oxy/acet 10/325'' and ''Spoke to Rochelle. Patient was told to increase his dose to 10 milligrams per M.D.'' with the ten milligrams referring to the first active ingredient, Oxycodone. Tr. 1186; GX 39 at 5. There is also a prescription from Dr. Mikovic for morphine extended release, fifteen milligram tablet with a note saying ''new regimen is added to help, current therapy is not sufficient.'' Tr. 1178–92; GX at 7. Dr. Buffington testified that there is only a minimal requirement for a pharmacist so such a note would be an acceptable note. Tr. 1187; GX at 7. Dr. Buffington testified that continuity of care information is also available to pharmacies even in different pharmacies for particular patients. Tr. 1188.

There was also a prescription from a physician, Gilberto Acosta, for an Oxycodone and acetaminophen combination for five milligrams of Oxycodone and 325 milligrams of acetaminophen with a note that said ''doctor wants to add long-acting MS Contin with short Percocet 5.'' Tr. 1190. Based on the dispensing log, the patient also received diazepam, a benzodiazepine typically used for management of anxiety and muscle spasms as well as temazepam, another benzodiazepine, which is used as a sleep aid. Tr. 1191. Dr. Buffington testified that such a prescription is not uncommon, but would necessitate counseling of the patient to watch for over drowsiness in the morning from the temazepam and to limit the diazepam used during the day. Tr. 1191–92. Based on Dr. Buffington's review of the universe of prescriptions that were provided in this case, there were no prescriptions that caused him any concerns. Tr. 1192.

Dr. Buffington testified that there is nothing unusual or inappropriate in a patient using insurance to pay for one prescription and not another because the patient may have an access issue, scope of benefit and coverage issue, difference in out-of-pocket cost at one pharmacy, and other reasons. Tr. 1193. Furthermore, Dr. Buffington believes that the prices that Gulf Med charged for prescriptions such as Oxycodone or Hydromorphone were not surprising or astonishing numbers and even if there was a high value there would be no regulatory problem because that is the patient's prerogative. Tr. 1194. Furthermore, there was nothing that Dr. Buffington reviewed that caused him any concern about whether or not Gulf Med and its pharmacists were exercising their corresponding responsibility or violating the applicable standard of care based upon any of the dosing instructions included in any of the prescriptions. Tr. 1193–94, 1995–96.

Dr. Buffington disagreed with Dr. Schossow's testimony regarding driving under the influence of a benzodiazepine and an opiate as there was no way to determine whether or not the patient was the person who was driving and that there is no clinical expectation that combining these two drugs would in fact impair someone's ability to drive or impact their cognitive status. Tr. 1194–1195. Dr. Buffington testified that although it is possible, it would be disingenuous to infer that putting the two drugs together would be an incorrect behavior. Tr. 1195, 1241. In fact, he testified that the FDA does not say in the black box warning that both drugs cannot be used together and it is not inappropriate to prescribe them together. Tr. 1195, 1243. Dr. Buffington testified that once a prescription is dispensed, the pharmacist cannot control if a person is going to independently abuse something. Tr. 1277.

Dr. Ricard Fertil

Dr. Fertil is a licensed pharmacist in Florida. Tr. 1337. He attended FIU for undergraduate school. He attended and received his doctorate of pharmacy degree from Florida A&M in 2003. Tr. 1336–37. During his attendance at Florida A&M, he performed internships and externships at area hospitals including Jackson Hospital, Texas Hospital and Hollywood Memorial Hospital. Tr. 1337–38. He also trained at CVS and Publix pharmacies in Florida. Tr. 1338. All of his training and experience as a pharmacist has been in Florida. Tr. 1339.

Following his licensing, he worked at CVS and Publix Pharmacies, retail chain pharmacies. Tr. 1339. Later, he worked at independent pharmacies in Southwest Florida for eight or nine years. Tr. 1339–40. While at independent pharmacies, he was involved in setting the prices for medications dispensed to customers. Tr. 1340. He was also involved in negotiating contracts with pharmacy benefits managers in setting rates of reimbursement. Tr. 1341.

Dr. Fertil is the pharmacist in charge at Gulf Med Pharmacy. Gulf Med operates with a single pharmacist and a pharmacy technician. Tr. 1370–71. He was involved with software venders, and in setting up the PioneerRx software for Gulf Med, including setting the pricing formulas within the software. Tr. 1341–42.

Dr. Fertil described the layout of Gulf Med. Located within a building formerly housing a bank, Gulf Med has a drive-through window to service customers. It also has separate rooms for compounding medications, and a consultation room, where HIPAA-protected matters are discussed with the patient in private, and where the pharmacist exercises his professional judgement in determining whether to fill each separate prescription. Tr. 1334–35, 1367–68, 1397–98. Dr. Fertil is unfamiliar with the term, ''red flag.'' Tr. 1395. The pharmacist reviews the diagnosis and medical history with the customer. Distance traveled by the customer would only concern Dr. Fertil if they traveled from outside the County, although he was unaware of any law restricting the filling of a prescription on the basis of distance traveled. Tr. 1406–07. Dr. Fertil did not view payment by cash as a suspicious circumstance, nor would it cause him to decline filling a prescription. Tr. 1408–10. If the customer is opiate naïve, as determined by a review of the E–FORCSE, the pharmacy has a policy not to fill the prescription. Tr. 1346–47. The pharmacist determines if the prescription contains the statutorily required components. Tr. 1351–52. The PioneerRx software also prompts the pharmacist as to required components and alerts. Tr. 1352–56; RX 13–22. Review of the E–FORCSE database, which the pharmacist does for every controlled substance prescription presented, also reveals whether the customer is doctor-shopping. Tr. 1347–50, 1357–58; RX 1–11. When directed to review three controlled substance prescriptions for B.D.a., Dr. Fertil confirmed none contained any notations that the E–FORCSE had been referenced. Tr. 1418–21. Dr. Fertil explained that no documentation was necessary, and that his signature on the prescription was proof that he checked the E–FORCSE. When asked if he ever noted PDMP on the prescriptions, he confirmed that sometimes he wrote PDMP to confirm that he checked the PDMP, but that sometimes he simply signed the prescriptions, also confirming that he checked the PDMP. Tr. 1419–20. Ultimately, Dr. Fertil explained that there was no set way that he confirmed on the prescription that he checked the PDMP. Sometimes he would note ''verified E–FORCSE'', sometimes he put a check mark or initials. Tr. 1423. The pharmacist will also consult with the prescribing physicians as needed. Tr. 1349–50.

Dr. Fertil confirmed that he discussed with the charged patients, J.R. and L.V. their restrictions presented for their prescriptions for combinations of medications of opioids, benzodiazepine and a muscle relaxant, the risks of this combination, including the sedative effect. Tr. 1360–61. Further, the patients were questioned as to whether they were experiencing any of the noted side effects of the drug combinations, and were provided written warnings, including drug interactions, abuse and side effects, produced by the PioneerRx software system and stapled to their receipts. Tr. 1361–64. Dr. Fertil confirmed that he used his professional judgement in resolving some of the alerts of the PioneerRx software and in filling the subject prescriptions. Tr. 1362–63. Dr. Fertil explained that Gulf Med had a much smaller volume of prescriptions than the large chain pharmacies, permitting the pharmacist to spend more time and attention with patients than at the chain pharmacies. Tr. 1363.

Dr. Fertil was present when the Administrative Inspection Warrant was served on Gulf Med., on February 14, 2018. Tr. 1364–65, 1372. He also received the Administrative Subpoena requiring ''patient profile'' information. Tr. 1365, 1372–73. Dr. Fertil cooperated and worked with the DEA computer technician to retrieve the information DEA required. Tr. 1365, 1369, 1373–74, 1379. The DEA technician also worked with a representative of PioneerRx to obtain the information required. Tr. 1365. The DEA technician operated the PioneerRx software in obtaining the information sought, and printed the documents in question. Tr. 1367, 1377. The documents printed by the DEA Technician included ''screen shots'' of the first tab of the ''patient profiles.'' Tr. 1425–29; GX 5, 19, 20, 21, 22, 35, 36, 37, 38, 39, 40. Whereas, RX 13–22 represents an Excel spreadsheet reflecting information from all five tabs of the same document. Tr. 1428–29.

When the DEA made further requests for patient profile information, Dr. Fertil produced the same type of information as they retrieved during their first request. Tr. 1365–66, 1381–95. Dr. Fertil could not remember whether he read the May, 2019 subpoena, which required the ''patient profiles'' and patient medication records for the charged patients, so he could not confirm that the documents he provided in response to the subpoena were complete. Tr. 1388–89. Dr. Fertil had great difficulty recalling receiving the third subpoena in August, 2019. Tr. 1391. He could not recall reviewing the subpoena to determine what documents were being requested or what documents were provided in response to the subpoena, despite attempts to refresh his memory. Tr. 1390–95. Although Dr. Fertil could not remember what documents he provided in response to the second and third subpoenas, he was adamant the documents provided were the same type of documents the DEA seized during service of the first administrative subpoena. Tr. 1392–94.

The Facts

Stipulations of Fact

The Government and the Respondent did not agree to any stipulations of fact.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me. The findings of fact are based primarily on those proposed by the Government in its post-hearing brief. I have also considered the findings of fact proposed by the Respondent and found that many of those proposed findings related to matters proposed by the Government or related to matters addressed elsewhere in this Recommended Decision. If a proposed finding of fact is not included in this section and is also not addressed elsewhere in this Decision, it is because that proposed finding was not relevant to deciding this case.

I. Background

1. Respondent is registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. FG6290061 at 4106 Del Prado Boulevard, South, Cape Coral, FL 33904. DEA COR No. FG6290061 will expire by

its own terms on September 30, 2022. GX 1

2. DEA lists Ambien (zolpidem tartrate) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(54).

3. DEA lists Ativan (lorazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(30).

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

5. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15). DEA lists MS Contin (morphine sulfate extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(ix).

6. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(11).

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

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

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

10. DEA lists Restoril (temazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(50).

11. DEA lists Soma (carisoprodol) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(6).

12. DEA lists Valium (diazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(16).

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

II. DEA's Investigation Into Respondent

14. On February 14, 2018, DEA investigators executed an administrative inspection warrant (''AIW'') on the Respondent, pursuant to which DEA seized the hardcopies of controlled substance prescriptions that Respondent had dispensed from its opening through the date the AIW was executed. GX 2; Tr. at 34–35. On the same date, the DEA also served an administrative subpoena on Respondent seeking, (a) copies of Respondent's patient profiles for certain listed individuals; (b) copies of ''[a]ny and all other records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals; and (c) copies of ''[a]ny other documentation kept by'' the Respondent ''in connection with the filling of prescriptions or providing medical treatment'' for those named individuals, including dispensing logs or reports, for those listed individuals. GX. 3; Tr. at 45. Government Exhibits 2 and 3 are true and correct copies of the AIW and administrative subpoena, respectively, that DEA served on Respondent on February 14, 2018. Tr. at 35,41–42,64–65.

15. Government Exhibit 5 contains true and correct copies of the patient profiles for Patients J.B., T.G., and L.V. produced by Respondent pursuant to the administrative subpoena served on February 14, 2018. Tr. at 65–69. Government Exhibit 6 contains true and correct copies of the dispensing logs for Patients J.B., T.G., and L.V. produced by Respondent pursuant to the administrative subpoena served on February 14, 2018. Tr. at 69–71. Government Exhibits 7–15 contain true and correct copies of the prescriptions Respondent dispensed to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.V., respectively, that the DEA seized pursuant to the AIW served on February 14, 2018. Tr. at 76–103, 111–16. The DEA did not seize any other documents pertaining to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., R.R., and L.V. pursuant to the AIW served on February 14, 2018, beyond those reflected in Government Exhibits 5–15; nor did Respondent produce any other documents pertaining to those same patients pursuant to the administrative subpoena served on February 14, 2018, beyond those reflected in Government Exhibits 5–15. Tr. at 117–18.

16. The DEA provided Respondent a receipt for the items that were seized by DEA during the execution of the AIW on February 14, 2018, or that were produced by the Respondent pursuant to the administrative subpoena served that same day. Government Exhibit 4 is a true and correct copy of the warrant return filed pursuant to the AIW served on February 14, 2018, and contains as an attachment a true and accurate copy of the receipt provided to the Respondent. Tr. at 52–59.

17. In May 2019, DI served a second administrative subpoena on Respondent seeking, *inter alia,* (a) hardcopies of controlled substance prescriptions that Respondent had dispensed from February 15, 2018, through May 3, 2019; (b) copies of Respondent's patient profiles for certain listed individuals; and (c) copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed individuals. Gov't Ex. 16; Tr. at 119. Government Exhibit 16 is a true and correct copy of the administrative subpoena that DEA served on Respondent in May 2019. Tr. at 120–21.

18. DI has conducted approximately twelve (12) investigations while employed by DEA. Tr. 27–28.

19. With its production of documents in response to the May 2019 administrative subpoena, the Respondent also produced a signed certificate of authenticity of domestic business records. Tr. at 123–24. Government Exhibit 18 is a true and correct copy of the signed certificate of authenticity of domestic business records produced by the Respondent with its production of documents in response to the May 2019 administrative subpoena. Tr. at 124.

20. Government Exhibits 19–22 contain true and correct copies of the patient profiles for Patients R.D., T.G., S.K., and L.V., respectively, produced by Respondent pursuant to the administrative subpoena served in May 2019. Tr. at 129–38. Government Exhibits 23–32 contain true and correct copies of the prescriptions Respondent dispensed to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., J.R., R.R., and L.V., respectively, that the Respondent produced pursuant to the administrative subpoena served in May 2019. Tr. at 143–77. The Respondent did not produce any other documents pertaining to Patients J.B., A.B., B.Da., R.D., B.Di., T.G., S.K., J.R., R.R., or L.V., pursuant to the administrative subpoena served in May 2019 beyond those reflected in Government Exhibits 19–32. Tr. at 178.

21. The DEA provided Respondent a receipt for the items that were produced by the Respondent pursuant to the administrative subpoena served in May 2019. Tr. at 126–27. Government Exhibit 17 is a true and correct copy of the receipt provided to the Respondent. Tr. at 127.

22. In August 2019, DI served a third administrative subpoena on Respondent seeking, with respect to Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., (a) hardcopies of controlled substance prescriptions that Respondent had dispensed to those patients from May 3, 2019, through August 9, 2019; (b) copies of Respondent's patient profiles for those patients; and (c) copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative

Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those patients ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those patients. Gov't Ex. 33; Tr. at 179.

23. Government Exhibit 33 is a true and correct copy of the administrative subpoena that DEA served on Respondent in August 2019. Tr. at 179–82.

24. With its production of documents in response to the August 2019 administrative subpoena, the Respondent also produced a signed certificate of authenticity of domestic business records. Tr. at 184. Government Exhibit 34 is a true and correct copy of the signed certificate of authenticity of domestic business records produced by the Respondent with its production of documents in response to the August 2019 administrative subpoena. Tr. at 184–85.

25. Government Exhibits 35–40 contains true and correct copies of the patient profiles, prescriptions, and other responsive documents for Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., respectively, that Respondent produced pursuant to the administrative subpoena served in August 2019. Tr. at 186–201. The Respondent did not produce any other documents pertaining to Patients J.B., A.B., B.Da., B.Di., J.R., or R.R. pursuant to the administrative subpoena served in August 2019 beyond those reflected in Government Exhibits 35–40. Tr. at 187, 190–91, 193, 195, 197– 98, 200–01.

26. During the course of the investigation, DI queried the Florida Prescription Drug Monitoring Database (''E–FORCSE'') and obtained information regarding Respondent's dispensing of controlled substance as it was reported to the State of Florida. Tr. at 205–216. Government Exhibits 41–42 are true and correct copies of the data obtained from the E–FORSCE database for the dates listed. *Id.* There is no evidence in the record to indicate that the information reported by Respondent to the E–FORSCE database is inaccurate or unreliable.

27. Subsequent to Respondent's Second Supplement Prehearing Statement, which concerned information retrieved from the PioneerRx pharmacy management software used by the Respondent, DEA obtained a declaration from J.R., Vice President of PioneerRx, concerning the functioning of that software. Tr. at 238–40. Government Exhibit 48 is a true and correct copy of the declaration of J.R. Tr. at 242–48.

28. DI testified that use of cash to pay for a prescription for controlled substances and the willingness of a customer to pay a higher-than-market price to purchase said medications are ''red flags'' that a prescription may be illegitimate. Tr. 106–107; 109–110. However, he later testified that there is no DEA regulation prohibiting a pharmacy from accepting cash as payment for prescriptions for controlled substances. Tr. 373–374.

III. The Government's Expert

29. Tracey J. Schossow, a pharmacy expert retained by DEA, is a clinical pharmacist at Florida Blue Cross Blue Shield. In that capacity, she reviews medications prescribed to Blue Cross members to ensure, among other things, that the medications are being issued for a legitimate medical purpose, and to provide cost-effective alternatives for prescribed medications where appropriate. Dr. Schossow holds both a bachelor's degree in pharmacy and a doctorate in pharmacy. She is a licensed pharmacist in Florida and also holds an additional Florida license as a consultant pharmacist. Tr. at 403–04, 408; GX 43.

30. Dr. Schossow has 26 years of experience as a pharmacist, with 12-years' experience as a retail pharmacist and the remainder as a clinical pharmacist. Immediately prior to her current role, Dr. Schossow was a clinical pharmacist for ProcareRx, a hospice-centered pharmacy benefits manager (''PBM''). While at ProcareRx, Dr. Schossow worked with hospice patients and managed medications for those patients, including opioids, benzodiazepines, and muscle relaxants. Additionally, Dr. Schossow served on the committee that managed which medications were on the ProcareRx formulary based on cost and efficacy considerations, and she also managed the queue for high-cost claims submitted by the hospices and ran test claims for the PBM to determine costs at different pharmacies across the State of Florida. Tr. at 404–08; GX 43.

31. Through her education and experience, Dr. Schossow has gained specialized knowledge regarding the practice of pharmacy, including the costs charged by pharmacies for controlled substance medications, the standard of care for dispensing controlled substances in the State of Florida, the obligations of a retail pharmacist in the detection and prevention of abuse and diversion of controlled substances, and a pharmacist's corresponding responsibility under federal law. Tr. at 411–14.

32. Dr. Schossow has previously been accepted by this Agency as an expert witness on three occasions. Tr. at 412, 423–24.

33. Dr. Schossow was accepted by the Tribunal as an expert in in the field of pharmacy and the standard of care for the practice of pharmacy in the State of Florida. Tr. at 427.

34. Dr. Schossow was unfamiliar with any clarification issued by the Center for Disease Control (''CDC'') regarding its 2016 opiate guidelines.*[E] Tr. 992.

IV. The Standard of Care in the State of Florida

A. Generally

35. Florida law, like federal law, requires that a pharmacist exercise his or her corresponding responsibility to ensure, prior to dispensing controlled substances, that each prescription is valid and has been issued for a legitimate medical purpose by an individual practitioner in the usual course of professional practice. As part of this evaluation, the pharmacist must perform a drug use review (''DUR'') on each new and refill prescription. This DUR includes examination of, among other things, potential side effects of the medication, potential drug interactions, whether the medication is being clinically abused or misused, and whether the medication is being dosed appropriately. Tr. at 431–32, 438–40. Many of these issues are specifically enumerated in Fla. Admin. Code r. 64B16–27.810. Tr. at 437.

36. Florida law also requires that a pharmacy maintain a ''patient profile'' for its customers that includes a variety of information, such as the pharmacist's comments relevant to the patient's drug therapy. Tr. at 437–39; *see also* Fla. Admin. Code r. 64B16–27.800. The standard of care requires a pharmacist to document the steps that he took to resolve any areas of concern or potential problems in the patient records. Tr. at 437–42.

B. Red Flags

37. Dr. Schossow testified that a red flag is something ''about a prescription that causes the pharmacist to take pause'' when filling a prescription. Tr. at 446. Dr. Schossow testified that the red flag ''may be signs of diversion'' or

*[E] There was an attempt to clarify Dr. Schossow's testimony regarding the 2016 opiate guidelines, but it is difficult from the transcript to tell which documents are being referenced by counsel and the witness. Tr. 1060–1068. The RD states *infra* that Dr. Schossow clarified later that she was generally aware of the CDC's clarification regarding its 2016 opiate guidelines.

signs that the prescription ''may harm the patient,'' and that the pharmacist's examination of red flags was part of the prospective drug use review with respect to issues of clinical abuse or misuse of the prescribed substance. *Id.* Dr. Schossow testified that red flags are well known to pharmacists in the State of Florida. *Id.* at 452–60.

38. Dr. Schossow testified that the standard of care in the State of Florida requires a pharmacist who encounters a prescription with a red flag to address that red flag and to resolve it, if the red flag is in fact resolvable, and to record the issue by identifying the red flag and how the pharmacist resolved it. *Id.* at 462–63. Dr. Schossow further testified that a Florida pharmacist acting in the usual course of professional practice would likewise identify red flags and record the resolution of those red flags. *Id.* at 463.

39. Dr. Schossow testified that the combination of an opioid, a benzodiazepine, and the muscle relaxer carisoprodol—commonly known as the ''Trinity'' cocktail—is a red flag because that combination of controlled substances is dangerous to the patient and known by pharmacists to be sought after by drug abusers. *Id.* at 480–83.

40. Dr. Schossow testified that prescriptions for cocktail medications—specifically the combination of an opioid and a benzodiazepine—is a red flag for the pharmacist because both of those categories of drugs depress the patient's central nervous system. *Id.* at 499–500. Dr. Schossow testified that the CDC Guidelines for Prescribing Opioids for Chronic Pain and FDA black box warning for opioid medications both warn against the combination of opioids and benzodiazepines because that combination of medications, which both depress the patient's central nervous system, can lead to sedation, respiratory depression, overdose, and death. *Id.* at 455–56, 476, 500, 526.

41. Dr. Schossow testified that cash payment for controlled substance prescriptions is a red flag. *Id.* at 580–83. Dr. Schossow further testified that high cash payments for controlled substance prescriptions enhance the red flag for cash payments because ''a drug seeker is willing to pay more for a drug if they can get the drug'' and is ''willing to pay . . . whatever they need to pay to obtain the medication.'' *Id.* at 580–86.

42. Dr. Schossow testified that prescriptions for long-acting and short-acting opioids in a combination that does not make pharmacological sense are also a red flag for pharmacists. *Id.* at 599–600. Specifically, Dr. Schossow testified that long-acting opioids, like MS Contin, last in the body 8-to-12 hours, while a short acting opioid like hydromorphone lasts in the body only 2-to-4 hours, and the proper method of treatment for pain management was to give more of the patient's total daily MME dose of opioids in the form of long-acting opioids than short-acting opioids. Dr. Schossow testified that, in contrast, prescriptions that provide a patient with a greater MME of short-acting opioids than long-acting opioids do not make pharmacological sense and are a red flag. *Id.* at 603–06.

43. [Omitted for brevity and relevance.]

44. Dr. Schossow testified that abnormal travel distances on the part of a patient to obtain and fill controlled substance prescriptions are a red flag. *Id.* at 679. While I accept this concept, I did not find that the evidence supported 30–50 mile round trip distances as abnormal under the facts of this case.

45. Dr. Schossow testified that therapeutic duplication—which is the simultaneous prescription of two medications that are in the same drug class and act the same way—is a red flag because prescribing two medications that do the same thing is not necessary and is therapeutically inappropriate. *Id.* at 704–05. Dr. Schossow testified that therapeutic duplication of benzodiazepines can compound the side effects of those drugs, which depress the patient's central nervous system and can cause respiratory depression, sedation, overdose, and death. *Id.* at 705.

V. Patient J.B.

46. Between March 22, 2017, and August 8, 2019, Respondent filled at least 100 prescriptions for controlled substances for Patient J.B., including 26 prescriptions for 60 units of MS Contin 30 mg, 32 prescriptions for 108–120 units of oxycodone 30 mg, 33 prescriptions for 90 units of Xanax 1 mg, and 9 prescriptions for 30 units of Soma 350 mg. Information regarding the controlled substance prescriptions dispensed to Patient J.B. is accurately set forth in Government Exhibits 6–7, 23, 35, and 41–42.

47. All of the prescriptions filled by Patient J.B. at Respondent pharmacy from March 22, 2017, through September 7, 2018, were paid for in cash. GX 6–7, 23, 48 ¶ 7(b).

48. Dr. Schossow examined the prescriptions dispensed to Patient J.B. and identified multiple red flags with respect to those prescriptions, including prescriptions for the Trinity cocktail, prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for oxycodone 30 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 485– 91, 498–500, 503–04, 513–16, 520–28, 530–34, 851–57. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient J.B. are set forth in Appendix A at 1–3.

49. Dr. Schossow reviewed the patient profile maintained by Respondent for Patient J.B., and concluded that the red flags she had found with respect to the prescriptions filled for Patient J.B. were not mentioned, addressed, resolved or documented on the patient profile. GX 5 at 1; Gov't Ex. 35 at 1; Tr. at 857–59.

50. Dr. Schossow reviewed the medical records maintained by Respondent for Patient J.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 35 at 2–5; Tr. at 858.

51. Dr. Schossow reviewed the dispensing logs maintained by Respondent for Patient J.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 35 at 8–9; Tr. at 858.

52. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient J.B., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.B. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 859–60.

VI. Patient A.B.

53. At all times relevant to this matter, Patient A.B. resided at 12175 Harry Street, Bokeelia, Florida 33922. GX. 36 at 1; GX 41–42. Patient A.B.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 44 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 1–3; ALJ Ex. 23 at 3.

54. Between November 8, 2017, and July 17, 2017, Respondent filled at least 69 prescriptions for Patient A.B., including 23 prescriptions for 60 units of MS Contin 15 mg, 23 prescriptions for 120 units of hydromorphone 8 mg, and 23 prescriptions for 30–40 units of Valium 10 mg. Information regarding the controlled substance prescriptions dispensed to Patient A.B. is accurately set forth in Government Exhibits 8, 24, 36, and 41–42.

55. All of the prescriptions filled by Patient A.B. at Respondent were paid for in cash. GX 8, 24, 36, 48 ¶ 7(b).

56. Dr. Schossow examined the prescriptions dispensed to Patient A.B. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and the distance traveled by Patient A.B. to obtain and fill prescriptions for controlled substances. Tr. at 535–42, 813–17, 819–50. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient A.B. are set forth in Appendix A at 4–7.

57. Dr. Schossow reviewed the patient profile maintained by Respondent for Patient A.B., and concluded that the red flags she had found with respect to the prescriptions filled for Patient A.B. were not mentioned, addressed, resolved or documented on the patient profile. GX 36 at 1; Tr. at 844–45.

58. Dr. Schossow reviewed the medical records maintained by Respondent for Patient A.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX 36 at 2–11; Tr. at 845.

59. Dr. Schossow reviewed the dispensing logs maintained by Respondent for Patient A.B. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient J.B. GX. 36 at 12; Tr. at 845.

60. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient A.B., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient A.B. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 850–51.

VII. Patient B.Da.

61. At all times relevant to this matter, Patient B.Da. resided at 5512 Avenue D, Bokeelia, Florida 33922. GX 37 at 1; GX 41–42. Patient B.Da.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 48.8 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 4–6; ALJ Ex. 23 at 3.

62. Between October 25, 2017, and August 5, 2019, Respondent filled at least 39 prescriptions for Patient B.Da., including 5 prescriptions for 90 units of methadone 10 mg, 8 prescriptions for 30 units of MS Contin 30 mg, 13 prescriptions for 120–150 units of hydromorphone 8 mg, and 13 prescriptions for 30 units of Xanax 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient B.Da. is accurately set forth in Government Exhibits 9, 25, 37, and 41–42.

63. All of the prescriptions filled by Patient B.Da. at Respondent were paid for in cash. GX 9, 25, 37, 48 ¶ 7(b).

64. Dr. Schossow examined the prescriptions dispensed to Patient B.Da. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and the distance traveled by Patient B.Da. to obtain and fill prescriptions for controlled substances. Tr. at 745–56. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient B.Da. are set forth in Appendix A at 8–10.

65. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 757.

66. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient B.Da., and concluded that the red flags she had found with respect to the prescriptions filled for Patient B.Da. were not mentioned, addressed, resolved or documented on the patient profile or prescriptions. GX 37 at 1; Tr. at 756–57.

67. Dr. Schossow reviewed the medical records maintained by Respondent for Patient B.Da. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient B.Da. GX 37 at 4–8; Tr. at 757.

68. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient B.Da., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Da. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 757.

VIII. Patient R.D.

69. At all times relevant to this matter, Patient R.D. resided at 5459 Thomas Street, Bokeelia, Florida 33922. Gov't Ex. 19 at 1; Gov't Exs. 41–42. Patient B.Da.'s approximate roundtrip travel distance from his residence, to his physician, to Respondent, and returning to his residence, is 40.6 miles. ALJ Ex. 21 Attachs. A–B, Attach. C at 2, 7–8; ALJ Ex. 23 at 3.

70. Between December 20, 2017, and April 10, 2019, Respondent filled at least 36 prescriptions for Patient R.D., including 18 prescriptions for 120–140 units of hydromorphone 8 mg, and 18 prescriptions for 30 units of Ativan 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient R.D. is accurately set forth in Government Exhibits 10, 26, and 41–42.

71. All of the prescriptions filled by Patient R.D. at Respondent were paid for in cash. GX 10, 26, 48 ¶ 7(b).

72. Dr. Schossow examined the prescriptions dispensed to Patient R.D. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and the distance traveled by Patient R.D. to obtain and fill prescriptions for controlled substances. Tr. at 675–701. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient R.D. are set forth in Appendix A at 11–13.

73. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 701.

74. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient R.D., and concluded that there was no evidence to suggest that the Respondent had investigated or assessed any of the red flags that she had identified with respect to the prescriptions filled by Patient R.D. GX 19 at 1; Tr. at 702.

75. Dr. Schossow testified that the Respondent's comments on the patient profile that Respondent maintained for Patient R.D. did not address any of the red flags that she had identified with respect to the prescriptions filled by Patient R.D. GX 19 at 1; Tr. at 702.

76. Dr. Schossow testified that, based on her review of the prescriptions, patient profiles, and medical records that Respondent maintained for Patient R.D., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.D. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 702.

IX. Patient B.Di.

77. Between April 21, 2017, and July 17, 2019, Respondent filled at least 85 prescriptions for Patient B.Di., including 28 prescriptions for 60 units of MS Contin 30 mg, 28 prescriptions for 120 units of hydromorphone 8 mg, 28 prescriptions for 60–90 units of Xanax 1 mg, and 1 prescription for 60 units of Adderall 20 mg. Information regarding the controlled substance prescriptions dispensed to Patient B.Di. is accurately set forth in Government Exhibits 11, 27, 38, and 41–42.

78. All of the prescriptions filled by Patient B.Di. at Respondent were paid for in cash. GX 11, 27, 38, 48 ¶ 7(b).

79. Dr. Schossow examined the prescriptions dispensed to Patient B.Di. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 718–43. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient B.Di. are set forth in Appendix A at 14–17.

80. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 743–44.

81. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient B.Di., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient B.Di. GX 38 at 1; Tr. at 744.

82. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient B.Di., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient B.Di. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 744.

X. Patient T.G.

83. Between April 5, 2017, and April 22, 2019, Respondent filled at least 32 prescriptions for Patient T.G., including 14 prescriptions for 60 units of MS Contin 60 mg, 1 prescription for 56 units of oxycodone 15 mg, and 17 prescriptions for 84–120 units of oxycodone 30 mg. Information regarding the controlled substance prescriptions dispensed to Patient T.G. is accurately set forth in Government Exhibits 12, 28, and 41–42.

84. All of the prescriptions filled by Patient T.G. at Respondent were paid for in cash. GX 12, 28, 48 ¶ 7(b).

85. Dr. Schossow examined the prescriptions dispensed to Patient T.G. and identified multiple red flags with respect to those prescriptions, including cash payment for controlled substances and high prices paid for prescriptions for oxycodone 30 mg. Tr. at 556–57, 563–64, 579–94. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient T.G. are set forth in Appendix A at 18–19.

86. Dr. Schossow reviewed the patient profiles and prescriptions maintained by Respondent for Patient T.G., and concluded that there was no evidence to suggest that the Respondent had investigated or assessed any of the red flags that she had identified with respect to the prescriptions filled by Patient T.G. GX 5 at 2; GX 20 at 1; Tr. at 595–96.

87. Dr. Schossow testified that, based on her review of the prescriptions and patient profiles that Respondent maintained for Patient T.G., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient T.G. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 596–97.

XI. Patient S.K.

88. Between March 8, 2017, and May 1, 2019, Respondent filled at least 79 prescriptions for Patient S.K., including 29 prescriptions for 60 units of MS Contin 15 mg, 29 prescriptions for 98–110 units of hydromorphone 8 mg, and 21 prescriptions for 28–60 units of Klonopin 1 mg. Information regarding the controlled substance prescriptions dispensed to Patient S.K. is accurately set forth in Government Exhibits 13, 29, and 41–42.

89. All of the prescriptions filled by Patient S.K. at Respondent were paid for in cash. GX 19, 29, 48 ¶ 7(b).

90. Dr. Schossow examined the prescriptions dispensed to Patient S.K. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, and dosing of long- and short-acting opioids in a manner that did not make pharmacological sense. Tr. at 597–624, 626–640. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient S.K. are set forth in Appendix A at 20–22.

91. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 640–41.

92. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient S.K., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient S.K. GX 21 at 1; Tr. at 641.

93. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient S.K., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient S.K. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 641.

XII. Patient J.R.

94. Between February 27, 2019, and August 2, 2019, Respondent filled at least 23 prescriptions for Patient J.R., including 1 prescription for 60 units of MS Contin 15 mg, 1 prescription for 120 units of Norco 5–325 mg, 3 prescriptions for 120 units of Norco 7.5–325 mg, 1 prescription for 120 units of Percocet 5–325 mg, 2 prescriptions for 60 units of Valium 2 mg, 4 prescriptions for 30–60 units of Valium 5 mg, 5 prescriptions for 30 units of Restoril 30 mg, and 6 prescriptions for 120 units of Soma 350 mg. Information regarding the controlled substance prescriptions dispensed to Patient J.R. is accurately set forth in Government Exhibits 30, 39, and 41–42.

95. Dr. Schossow examined the prescriptions dispensed to Patient J.R. and identified multiple red flags with respect to those prescriptions, including

prescriptions for the Trinity cocktail and therapeutic duplication of benzodiazepine prescriptions. Tr. at 703–16. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient J.R. are set forth in Appendix A at 23.

96. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 716–17.

97. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient J.R., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient J.R. GX 39 at 1; Tr. at 717.

98. Dr. Schossow testified that, based on her review of the prescriptions and patient profile that Respondent maintained for Patient J.R., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient J.R. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 717.

XIII. Patient R.R.

99. Between December 5, 2017, and August 6, 2019, Respondent filled at least 55 prescriptions for Patient R.R., including 15 prescriptions for 28–60 units of MS Contin 60 mg, 20 prescriptions for 120–168 units of hydromorphone 8 mg, 1 prescription for 60 units of Xanax 1 mg, and 19 prescriptions for 30 units of Xanax 2 mg. Information regarding the controlled substance prescriptions dispensed to Patient R.R. is accurately set forth in Government Exhibits 14, 31, 40, and 41–42. All of the prescriptions filled by Patient R.R. at Respondent were paid for in cash. GX 14, 31, 40, 48 ¶ 7(b).

100. Dr. Schossow examined the prescriptions dispensed to Patient R.R. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, high prices paid for prescriptions for hydromorphone 8 mg, dosing of long- and short-acting opioids in a manner that did not make pharmacological sense, and dosing of benzodiazepine medications in a manner that did not make pharmacological sense. Tr. at 642–72. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient R.R. are set forth in Appendix A at 24–26.

101. Dr. Schossow testified that a Florida pharmacist acting within the standard of care should have evaluated the red flags she noted and addressed them with the physician, care giver, or patient as appropriate and should have documented the resolution of those red flags if they could be resolved. Tr. at 673.

102. Dr. Schossow reviewed the patient profile and prescriptions maintained by Respondent for Patient R.R., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient R.R. GX 40 at 1; Tr. at 672–73.

103. Dr. Schossow testified that the Respondent's comments on the patient profile that Respondent maintained for Patient R.R. did not address any of the red flags that she had identified with respect to the prescriptions filled by Patient R.R. GX 40 at 1; Tr. at 673–74.

104. Dr. Schossow reviewed the medical records and dispensing log maintained by Respondent for Patient R.R. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient R.R. GX 40 at 2–7; Tr. at 674.

105. Dr. Schossow testified that, based on her review of the prescriptions, patient profile, dispensing log and medical records that Respondent maintained for Patient R.R., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient R.R. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 674.

XIV. Patient L.V.

106. Between March 2, 2017, and May 14, 2019, Respondent filled at least 93 prescriptions for Patient L.V., including 28 prescriptions for 14–60 units of MS Contin 60 mg, 1 prescription for 120 units of oxycodone 20 mg, 27 prescriptions for 90–140 units of oxycodone 30 mg, 16 prescriptions for 60–90 units of Xanax 1 mg, 8 prescriptions for 60 units of Xanax 2 mg, and 13 prescriptions for 30 units of Ambien 10 mg. Information regarding the controlled substance prescriptions dispensed to Patient L.V. is accurately set forth in Government Exhibits 6, 15, 32, and 41–42.

107. All of the prescriptions for oxycodone 20 mg or oxycodone 30 mg filled by Patient L.V. at Respondent were paid for in cash. GX 6, 15, 32, 48 ¶ 7(b). All of the prescriptions for MS Contin filled by Patient L.V. at Respondent, with the exceptions of the prescriptions filled on January 22, 2019; February 19, 2019; and April 15, 2019, were paid for in cash. GX 6, 15, 32, 48 ¶ 7(b). The prescriptions for 60 units of Xanax 1 mg filled by Patient L.V. at Respondent on March 2, 2017; March 30, 2017; and April 27, 2017, were also paid for in cash. GX 6, 15, 48 ¶ 7(b).

108. Dr. Schossow examined the prescriptions dispensed to Patient L.V. and identified multiple red flags with respect to those prescriptions, including prescriptions for cocktail combinations of opioids and benzodiazepines, cash payment for controlled substances, and high prices paid for prescriptions for oxycodone 30 mg. Tr. at 510–11, 758–59, 767–79, 791–808. Dr. Schossow's conclusions with respect to specific prescriptions dispensed to Patient L.V. are set forth in Appendix A at 27–30.

109. Dr. Schossow reviewed the patient profiles maintained by Respondent for Patient L.V., and concluded that there was no evidence to suggest that the Respondent had addressed, investigated, resolved, or documented the resolution of any of the red flags that she had identified with respect to the prescriptions filled by Patient L.V. GX 5 at 3; GX 22 at 1; Tr. at 808–09, 812.

110. Dr. Schossow reviewed the dispensing log maintained by Respondent for Patient L.V. and concluded that those documents did not address, resolve, or document any of the red flags she had found with respect to the prescriptions filled for Patient L.V. GX 6 at 5–6; Tr. at 809.

111. Dr. Schossow testified that, based on her review of the prescriptions, patient profile, and dispensing log that Respondent maintained for Patient L.V., a reasonable pharmacist acting in the usual course of professional practice would not have filled the prescriptions for Patient L.V. without addressing, resolving, or documenting the red flags that she had identified. Tr. at 812–13.

The Respondent's Expert

112. Dr. Buffington received his Doctor of Pharmacy (PharmD) degree and a Master of Business Administration degree from Mercer University in Atlanta, Georgia. RX 12; Tr. 1078–79.

113. Dr. Buffington completed his clinical practice residency and clinical pharmacology research fellowship at

Emory University Hospital in Atlanta, Georgia. RX 12; Tr. 1078–79.

114. Dr. Buffington represents clinical pharmacists on the American Medical Association (''AMA'') Current Procedural Terminology (''CPT'') Panel, and has served as a medication safety expert for the United States Department of Health and Human Services, Center for Medicare and Medicaid Services (''CMS''). Tr. 1078–79.

115. Dr. Buffington is also a Clinical Associate Professor in both the College of Medicine, since 1991, and the College of Pharmacy, since 2011, at the University of South Florida, in which settings he teaches clinical pharmacology, toxicology, pharmacy law, and a variety of aspects of healthcare administration and practice management. Tr. 1079.

116. Dr. Buffington possesses over thirty (30) years of experience in clinical pharmacology, toxicology, pharmacy and medical malpractice, substance use disorders, and long-term care. Tr. 1079.

117. The patients referred to Dr. Buffington's practice typically have high-risk medications for evaluation from a medication profile, but also a therapeutic and outcomes perspective. Tr. 1080.

118. Additionally, Dr. Buffington's practice designs and manages, as a principle investigator, clinical pharmacology trials involving investigations of newly developed medications or comparison of existing prevailing medications, all for the purpose of improving patient safety and outcomes. Tr. 1080–81.

119. Dr. Buffington's practice also provides a drug information service and forensic consulting services to both public and private clients in the healthcare sector. Tr. 1081. Dr. Buffington's consulting service clients include pharmacists, medical practitioners, healthcare facilities and organizations, and law enforcement agencies. Tr. 1081.

120. Dr. Buffington has worked as a retail pharmacist for an independent pharmacy within the past year, including in the roles of practitioner and auditor. Tr. 1090–91.

121. As a teacher of pharmacy law at various colleges and universities in Florida, Dr. Buffington's instruction includes review of Florida statutes and administrative code provisions. Tr. 1098. These provisions include §§ 64B16–27.800, 810, and 831 of the Florida Administrative Code, the discussion of which is part of the pharmacy law curriculum Dr. Buffington teaches, and with which he is familiar. Tr. 1098.

122. Dr. Buffington was engaged by the Respondent to serve as an expert witness in approximately February of 2020. Tr. 1076–77.

123. Dr. Buffington was provided with all of Respondent's documents that were seized by or produced to the DEA in connection with the Government's investigation into the Respondent. Tr. 1077.

124. Dr. Buffington has served as an expert witness and has been accepted as an expert in state and federal courts. Tr. 1078. He has also previously testified as an expert in administrative proceedings. Tr. 1078.

125. Dr. Buffington is familiar with a wide variety of pharmacy business software platforms used by retail pharmacies to track the dispensing process. Tr. 1113–14.

126. Dr. Buffington is familiar with the alert systems included in pharmacy business software platforms and has, in fact, served as an author of many of them. Tr. 1113–14.

127. Dr. Buffington testified that individuals residing in the Fort Myers/Cape Coral area may often be required to travel inland toward the city center from their home on a barrier island to patronize retail or clinical support services because the services available on the quiet, non-commercial barrier islands are often sparce. Tr. 1141–1142.

128. Dr. Buffington believes that there are many logical explanations for why a person may elect to patronize a pharmacy other than the one that is located nearest their home. Tr. 1142–44. For example, Dr. Buffington testified that they may elect to patronize a pharmacy near their place of employment or near their prescribing physician. *Id.*

129. Dr. Buffington testified that there is no prohibition against a patient paying for a controlled substance prescription using cash or a cash equivalent. Tr. 1144.

130. In forming his opinions in this proceeding, Dr. Buffington drew upon his experience, training and conducting drug diversion investigations with state and federal agencies, including law enforcement agencies. Tr. 1159–1160.

131. Based on Dr. Buffington's review of the Government's exhibits, he believed that there were other relevant data fields within the PioneerRx software that DEA did not obtain. Tr. 1163–1164.

132. In 2015 and 2016, Dr. Buffington participated in helping create a national stakeholders' statement or request to DEA seeking guidance on ''red flag'' issues. Tr. 1164–1165.

Expert Opinion

[Omitted for brevity.] Drs. Schossow and Buffington were qualified as experts in the field of pharmacy and the professional standards for the practice of pharmacy in the State of Florida. They gave their opinions regarding the relevant standards in Florida for the practice of pharmacy, including the existence of red flags, or from Dr. Buffington's perspective, ''yellow lights.'' The relevant professional standards may be established by an expert witness through his experience in the field, and through his reliance upon and application of state and federal professional standards.

[Omitted for brevity.] [51]

As far as expert opinion, Dr. Schossow demonstrated a commanding grasp of pharmacy practice and the standard for pharmacists in addressing ''red flags.'' However, there were several matters for which she had diminished credibility. For one, she was apparently unaware of the CDC Press Release clarifying the 2016 Guidelines for Prescribing Controlled Substances. It clarified that the Guidelines were not intended to apply to patients who had been on high MME on a long term basis. She later explained that she was generally aware of it, however, this clearly diminished her credibility regarding issues related to high MME of long-term patients. [Omitted.]*[F] Finally, her assertion that all pharmacies were fungible and dismissing the reality that a patient may have a preference for one pharmacy over another, all other factors being equal, was not credible.

[Omitted.]

The Respondent made the point in his brief that Dr. Schossow did not confer with the subject patients or with their prescribing physicians. Dr. Schossow conceded that a diligent pharmacist would, as circumstances require, attempt to resolve any red flags by discussing them with the patient and with the prescribing physician. The Respondent infers that the fact Dr. Schossow did not discuss any red flags with the patients or with the prescribers renders Dr. Schossow's conclusions regarding red flags questionable as Dr.

[51] [Footnote omitted.]

*[F] I have omitted the RD's assertion that Dr. Schossow offered inconsistent testimony regarding the dosing of alprazolam for Patient R.R. Patient R.R. received a prescription to take half of a two-milligram tablet of alprazolam every twelve hours. Dr. Schossow testified that in general it is not unusual for a physician to advise a patient to take half of a pill, but it is a red flag when the prescription involves two-milligram tablets of alprazolam, which are highly abused and highly sought after on the street. Tr. 642–44. Dr. Schossow testified that she has never seen these directions on an alprazolam prescription. *Id.*

Schossow did not attempt to determine if the subject red flags were resolvable.

Although certainly the extent of Dr. Schossow's review of relevant material is critical to the conclusions she draws, the focus of Dr. Schossow's opinions relate to whether the Respondent complied with his corresponding responsibility to resolve red flags prior to dispensing the subject medications, and to documenting any resolution within the file. It is neither here nor there that Dr. Schossow could have resolved her own concerns regarding the subject red flags by speaking to the patients and prescribers years later. Nor is it dispositive that Dr. Schossow could have determined that the subject red flags were resolvable at the time they were dispensed, if the Respondent failed to satisfy its corresponding responsibility to resolve them. So, I do not view the fact that Dr. Schossow did not speak with the subject patients or prescribers as diminishing the probity of her relevant opinions as to the Respondent's acts or omissions at all.

Dr. Buffington

Dr. Buffington had very impressive credentials and experience. He seemed to know the Florida statutes and regulations, chapter and verse. [However, I find that Dr. Buffington's credibility was greatly diminished by his combative tone, his evasive and confusing descriptions of a pharmacist's professional obligations, his repeated criticism of the Government's investigation, and his attempts to argue the Respondent's case. For example, on cross examination, Dr. Buffington repeatedly stated that Government counsel's questions were irrelevant to the case.*[G] I also find that Dr. Buffington's conclusion that Respondent dispensed prescriptions within the usual course of professional practice was entitled to little weight, because it does not appear to be based on a meaningful review of the evidence in this case. Although there is little-to-no documentation showing that Respondent addressed or resolved the red flags that Dr. Schossow identified, Dr. Buffington appears to believe that the fact that Respondent filled these prescriptions is proof that it exercised its professional responsibility. Dr. Buffington testified that ''the profound value that a pharmacist brings is their clinical oversight and interaction with the patient,'' but given the lack of documentation, it is unclear how Dr. Buffington was able to reach any conclusions about whether Respondent exercised any clinical oversight or had any meaningful interactions with the patients. Dr. Buffington seemed to believe that the fact that nobody showed him evidence that Respondent knew that the prescriptions Respondent filling were unlawful was proof that Respondent had exercised its corresponding responsibility. *See, e.g.,* Tr. 1163 (''[N]othing I saw [ ] demonstrated an inability to evaluate as the professional judgment takes place.''). Dr. Buffington's credibility was diminished for the following additional reasons.]

Dr. Buffington Misunderstands DEA's Jurisdiction

Despite having testified at a number of DEA administrative hearings, being a consultant for federal agencies, and teaching pharmacy law, Dr. Buffington repeatedly demonstrated a surprising misconception that the DEA and the subject administrative hearings involved only criminal matters. Despite testifying at a hearing in which DEA was obviously evaluating, in part, the Respondent's controlled substance dispensing practices, he maintained that although the DEA administrator's findings are binding upon DEA registrants, this does not include every pharmacist, and such findings would relate to criminal issues rather than the scope of practice. Tr. 1237. Furthermore, he maintained that DEA is a law enforcement agency and determines criminality, not medical decision-making or pharmacologic decision-making over the use of medications. Tr. 1245. Accordingly, he argued, there is no requirement that a pharmacist *[H] learn about DEA administrative decisions or be familiar with or read the Federal Register as the DEA does not have jurisdiction over pharmacy practice. Tr. 1168–69, 1176–77. The Respondent is not herein involved with the criminal arm of the DEA, it is involved with its regulatory arm. And in fact, the 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.] [52] [Omitted for clarity.] [53]

The ''Standard of Care'' Applied by Dr. Buffington Was Less Credible Than Dr. Schossow's

Similarly, Dr. Buffington suffered diminished credibility in that he relied on the reasonable, prudent pharmacist [54] ''standard of care'' applicable to medical malpractice negligence suits (Fla. Stat. § 766.102) rather than on the pharmacist's professional standards, *i.e.,* ''in the course of his professional practice.'' [55] As the Government noted in its post-hearing brief, the medical malpractice standard of care under § 766.102 is not wholly consistent with [the usual course of professional practice].[56] *See* Fl. Admin. Code Ann. r. 64B16–27.800, .810, and .831; Fl. St. §§ 465.103(6)(14), 465.016, 465.023, 893.04(1). [Furthermore, § 766.102 does not even apply to pharmacists. It applies to ''healthcare providers,'' which is defined to exclude pharmacists.*[I]]

[Omitted.] [57] [58] [Dr. Schossow's testimony on the standard of care and

*[G] *See, e.g.,* Tr. 1240 (claiming that the length of time that Respondent's pharmacists spent responding to alerts within PioneerRX that notify the pharmacist of potential problems was ''irrelevant to the case given there is not a single requirement for documentation formatting and the documentation may not have transpired during that pathway''); *id.* at 1253 (''The question was did I think there is not an increased risk when you combine the three medications. My answer was no, there is, and this is what we're faced with every day when you combine a wide variety of medications. That's not relevant to this discussion.''); *id.* at 1255 (testifying, in response to a question about whether consuming the ''trinity'' cocktail could produce a high in illicit drug users: ''Yes. And made worse with alcohol but so can their base medications on their individual basis. That's irrelevant to the case'').

*[H] DEA regulates pharmacies, not pharmacists. Because the pharmacy is the registrant, it is incumbent on the pharmacy to be familiar with DEA decisions and create pharmacy policies that ensure that pharmacists are fulfilling their corresponding responsibility. *See Suntree Pharmacy and Suntree Medical Equipment, LLC,* 85 FR 73,753, 73,770 (2020); *see also S&S Pharmacy, Inc.,* 46 FR 13,051, 13,052 (1981).

[52] [Omitted for clarity.]

[53] [Omitted for clarity.]

[54] [Omitted for clarity.]

[55] [Omitted for clarity.]

[56] The ''prevailing professional standard of care,'' which under Florida law is defined as ''that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate for reasonably prudent similar heath care providers.'' § 766.102, Fla. Stat. (emphasis added).

*[I] Florida Statute § 766.102 defines ''healthcare providers'' as:

. . . any hospital or ambulatory surgical center as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Pharmacists are administered under chapter 465.

[57] [Omitted.]

the usual course of professional practice was informed by numerous materials, such as federal regulations, expert testimony from past DEA administrative decisions, relevant Florida statutes and regulations, Florida mandatory continuing education, on-the-job training, materials promulgated by the CDC and FDA, and accepted practices within the profession. Tr. 408–09, 434–36, 451–55, 476, 888–94, 912–16, 927–28. On the other hand, Dr. Buffington's testimony about the standard of care and the usual course of professional practice did not appear to be informed by all of these materials and appeared to rely in part on an inapplicable Florida Statute.] Thus, Dr. Buffington's conclusory opinions that the various red flags identified by Dr. Schossow were unfounded are accordingly diminished in credibility. Similarly, Dr. Buffington's refutation of Dr. Schossow's opinions regarding the standard of care, based upon a disjointed source, such as a single Florida regulation, have diminished credibility.

Dr. Buffington's Testimony Regarding Documentation Was Not Credible

Dr. Buffington was not always clear in his testimony. He typically dismissed the requirement to document the resolution of red flags as not required by Florida regulation. However, he also testified that the standard of care for a pharmacist in Florida is based on the level of care that a reasonable pharmacist would use in like circumstances and reasonable pharmacists could disagree about what the requirements are for documentation of the resolution of red flags in the State of Florida. Tr. 1101, 1249. This nebulous standard leaves the requirement for documentation of the resolution of red flags apparently debatable among reasonable pharmacists—hardly a workable standard.

Dr. Buffington's Testimony About ''Red Flags'' Was Inconsistent and Not Credible

Dr. Buffington expressed disdain for the use of the term ''red flags,'' [59] but his understanding of the term was not always clear. He sometimes noted that a red flag was something which a pharmacist needed to consider, consistent with Dr. Schossow's testimony. However, he more frequently referred to it as a hard stop, precluding the filling of the prescription, which is inconsistent with Dr. Schossow's testimony.[60] Tr. 1173. This was surprising, as his CV reveals he had officially conferred with the DEA over the use of the term red flags, but to no avail. He suggested ''yellow light'' as a more appropriate term for matters which required investigation. He also observed that any confusion was partly due to DEA's failure to provide meaningful guidance to the regulated community as to red flags.[61] Later, as noted above, Dr. Buffington advised that the Florida professional standards did not require documentation of findings by the pharmacist. Tr. 1135, 1171. He counseled that reasonable pharmacists could disagree whether documentation was required by the pharmacist, a nebulous and unworkable standard. Yet Dr. Buffington testified that the Respondent complied with his obligation to document red flags, even though no documentation resolving the subject red flags appear in the records. Tr. 1109, 1112.

I credit Dr. Schossow's testimony over Dr. Buffington's regarding the requirement of documentation of red flags (yellow lights in Dr. Buffington's vernacular) within the applicable standard of care and Florida course of professional practice in pharmacy. Dr. Schossow's testimony in that regard was logical and internally consistent. [Dr. Schossow emphasized that documentation is important for patient safety and continuity of care. Tr. 441–42, 479–80, 640–41.]

Although Dr. Buffington often noted that the Respondent complied with the regulatory requirements set out in the Florida statutes and regulations in defending his opinion that the Respondent acted appropriately as to the allegations (Tr. 1110–13, 1118, 1135, 1141, 1144, 1171), it is important to note that compliance with the letter of the Florida statutes and regulations is no defense to a finding that the Respondent violated the standard of professional practice. *Cohn* v. *Department of Professional Regulation,* 477 So.2d 1039, 1042–43, District Court of Appeal of Florida, Third District (1985).

[Omitted for brevity.]

Dr. Buffington's Testimony About a Pharmacist's Corresponding Responsibility Was Not Credible

Dr. Buffington also applied a series of presumptions, which [are inconsistent with a pharmacist's] corresponding responsibility. He indicated that the presumption was to fill a prescription, unless evidence revealed that it should not be filled. However, the pharmacist has an affirmative, not passive, corresponding obligation to investigate each prescription. *See* 21 CFR 1306.04(a); *see also* Fla. Stat. § 893.04(2)(a) (''[a] pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription is valid'') (emphasis added).*[J] The onus is on the pharmacist to confirm the validity of each controlled prescription. Under federal law, a [pharmacy has a corresponding responsibility to ensure that a prescription for a controlled substance ''be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).] [62]

Dr. Buffington's Testimony on the ''Trinity'' Cocktail and Other Drug Combinations Was Inconsistent and Confusing

Dr. Buffington's [testimony about a pharmacist's obligations when customers present prescriptions for potentially dangerous drug combinations, such as the ''trinity'' cocktail or the opioid/benzodiazepine combination, was inconsistent and confusing. Although Dr. Buffington acknowledged that pharmacists need to consider the potential adverse effects of certain drug combinations,*[K] at other

[58] [Omitted.]

[59] [Omitted for clarity.]

[60] [Dr. Schossow defined ''red flags'' as circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm. Tr. 446. Omitted remainder of footnote.]

[61] Whether suspicious circumstances are referred to as ''red flags'' or ''yellow lights'', or whether the Agency updated its Pharmacist's Manual, the Agency has consistently [credited the testimony of pharmacy experts] in published decisions out of Florida that suspicious circumstances must be investigated and resolved, with such resolution documented.

*[J] I am not finding a violation of this statute because it was not referenced in the OSC.

[62] *See JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either that the pharmacist filled a prescription (1) notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose, or (2) being willfully blind to (or deliberately ignorant of) the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28,671–72. [Omitted for clarity.]).

*[K] *See, e.g.,* Tr. 1116 (Dr. Buffington's testimony that a pharmacist would be expected to ''look at the impact'' of a patient taking an opioid and a benzodiazepine concurrently, but that there is no default presumption that they cannot be prescribed together), *id.* at 1118 (testifying that the FDA's black box warning informs practitioners of ''potential complications,'' but that it does not mean a pharmacist cannot dispense these two drugs together), *id.* at 1119 (testifying that a pharmacist should conduct an evaluation when a patient

Continued

times he insisted that prescriptions for the ''trinity'' cocktail were always appropriate. For example, Dr. Buffington testified:

> The three together is always okay. The decision to not fill based on another variable may absolutely be the final decision of the pharmacist. It doesn't make the fact that you can't do three together so the only thing would be is if you determined that it was for an inappropriate use. It's not that the three were used together. If you became knowing that it was for an inappropriate use, not that the three were prescribed together. If even the colloquial term and the slang of red flags is an inference to things that you should look at and evaluate, not these are something we count and you are in trouble if your count hits a threshold. That's a disingenuous attempt at an investigation.

Tr. 1254. When asked whether he would document his decision to fill the ''trinity'' cocktail, Dr. Buffington testified that the act of filling the prescription was all the documentation that was needed:

> No, sir. I would document by the assessment and filling of the prescription. If it didn't get filled then it didn't get filled and that is documentation in and of itself. If it is filled then that's documentation that was filled. If you would only record additional notations—if you felt there was an issue to reconcile. The three together are not an issue to not be filled.

Tr. 1261. Dr. Buffington's testimony on drug cocktails was sometimes confusing and his attempts to advocate for Respondent colored his responses. However, I find that Dr. Buffington's testimony was generally consistent with Dr. Schossow's testimony that drug cocktails are a red flag (or yellow flag) that must be considered by the pharmacist prior to dispensing. Dr. Schossow testified that it is a red flag if opioids and benzodiazepines are prescribed together because they are both central nervous system depressants, which can cause sedation, respiratory depression, overdose, coma, and death. *See, e.g.* Tr. 530–34. Dr. Buffington also acknowledged that this drug combination can cause adverse effects (*see, e.g.,* Tr. 1116, 1118–19), although he attempted to minimize the apparent danger posed by the combination of opioid, benzodiazepine and muscle relaxant, by highlighting that other even non-controlled medications, and alcohol, can produce dangerous reactions. Tr. 1243, 1255. Thus, while I find that Dr. Buffington's testimony on this issue is entitled to minimal weight because of its inconsistency, I find that it is generally supportive of my conclusion that prescriptions for the ''trinity'' cocktail or the opioid/benzodiazepine combination are a red flag that a pharmacist must address and resolve before dispensing.] [Omitted.] *[L] [63] [64] [65]

presents a prescription for an opioid, a benzodiazepine, and a muscle relaxant, and should have discussions with the patient).

Dr. Buffington's Testimony on Tallying Red Flags Was Argumentative and Not Credible

Dr. Buffington's position that it was improper to ''count'' red flags to increase the suspicion of improper behavior is contrary to [Dr. Schossow's credible testimony that a pharmacist must consider the combination of red flags presented by each prescription. *See, e.g.,* Tr. 956–57 (testifying that each prescription ''is its own individual entity'' and the distance red flag should be assessed along with the other red flags with the prescriptions). Dr. Buffington's testimony seemed to be aimed at criticizing DEA rather than offering a measured opinion about a pharmacist's obligations in the usual course of professional practice in Florida.].[66]

Partiality

Finally, Dr. Buffington displayed signs of partiality. The credibility of expert witnesses, and thus their value to the factfinder, is based first upon their evident impartiality. An expert witness's hiring by a party contestant presents the obvious profit consideration and potential motivation to appease his employer. Beyond the ubiquitous profit motivation, evidence of overt partiality can be telling. Indications of partiality may arise when an expert appears to argue its employer's case in his responses. Another may be where the expert is more amenable or solicitous to his employer's questions than of those posed by the party opponent, or is even contentious with properly posed inquiries by the opposing party. Dr. Buffington exhibited all of those features.

Dr. Buffington exceeded the scope of his qualified expertise by commenting on the efficacy of the investigation, and, in his view, the ill motives of the investigators, despite being cautioned not to do so.[67] Dr. Buffington exhibited other indications of partiality. He invaded the province of the factfinder. He concluded there was no intent on the part of the Respondent to violate his subject professional responsibilities.[68] *See, e.g.,* 1131–32, 1134–35. He volunteered that the Government presented insufficient evidence to prove their case. He was openly advocating the Respondent's case. His subjectivity and partiality were well exposed.

[The ALJ does not make an explicit credibility finding on Dr. Buffington's testimony, although he identifies multiple inconsistencies and highlights Dr. Buffington's partiality. Based on the RD's criticisms of Dr. Buffington's testimony, and based on the fact that the RD generally gave greater weight to Dr. Schossow's expert testimony than to Dr.

*[L] Dr. Buffington offered confusing testimony about how a pharmacist might react differently to prescriptions for opioids and benzodiazepines based on whether the patient was receiving multiple benzodiazepines and multiple opioids and based on whether these drugs were prescribed by different practitioners. Tr. 1117. In its Exceptions, Respondent argued that the RD mischaracterized this testimony. Resp Exceptions, at 16. I find that this testimony is irrelevant to my Decision and I have omitted the RD's references to it. Based on Dr. Schossow's credible expert testimony (supported by portions of Dr. Buffington's testimony), I find that concurrent prescriptions for an opioid and a benzodiazepine are a red flag that must be addressed, resolved, and documented, prior to dispensing. Dr. Buffington's contested testimony addresses what factors a pharmacist might consider in determining whether the drug cocktail red flag can be resolved in a particular situation. Dr. Buffington did not testify that any of these factors were relevant to any of Respondent's customers in this case, nor did he point to any documentation in Respondent's files indicating that these factors impacted Respondent's decision to fill any prescriptions. Therefore, this testimony does not impact my determination of whether Respondent's dispensing of controlled substances was within the usual course of professional practice in Florida.

[63] [Omitted for clarity.]

[64] [Omitted for clarity.]

[65] [Omitted for clarity.]

[66] [Prior Agency decisions have noted, based on credible expert testimony, that a] pharmacy's filling of multiple prescriptions containing a variety of red flags can support the conclusion that the pharmacy violated its corresponding responsibility under 21 CFR 1306.04 due to the pharmacy's actual knowledge or its willful blindness of the prescriptions' illegitimate nature. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR at 10,896–97 (citing *Hills Pharmacy, L.L.C.,* 81 FR at 49836–39; *The Medicine Shoppe,* 79 FR 59,504, 59,512–13 (2014); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR at 62,317–22; and *E. Main St. Pharmacy,* 75 FR 66,149, 66,163–65 (2010).

[67] The Tribunal advised Dr. Buffington not to give his opinion about whether the investigation was appropriate. Tr. 1254. The Tribunal reiterated that this not a criminal matter, but rather an administrative proceeding and directed Dr. Buffington to focus on his expertise as it relates to pharmacy law, etc. Tr. 1254–55.

[68] Specifically, Dr. Buffington testified that there was no evidence presented in this case that a pharmacist in the State of Florida at Gulf Med Pharmacy was knowingly aware. Tr. 1134. He believed that Gulf Med also did not ''turn a blind eye'' or ''bur[y] their head in the sand'' when Gulf Med pharmacists were presented with issues due to red flags because the Florida pharmacy statutes, and administrative rules require a pharmacist use professional judgment and there is no requirement that this needs to be documented. Tr. 1135. He testified that there were no breaches of the pharmacist's responsibilities or that the pharmacist had breached a duty. Tr. 1131–32.

Buffington's in his legal analysis, it is evident that the ALJ found Dr. Buffington's opinions to be generally inconsistent, unreliable, and lacking in credibility. I agree with that conclusion. Regarding Dr. Schossow's credibility, I agree with the ALJ that she demonstrated a commanding grasp of pharmacy practice and the standard for pharmacists in addressing ''red flags.'' I also find that Dr. Schossow's opinions were consistent and credible and entitled to significant weight in my Decision.]

Credibility of Non-Expert Witnesses

I found DI to be credible, despite several peripheral matters in which his memory failed him. I found both patient witnesses to be fully credible. However, L.V.'s anecdotal opinion that the Respondent's medication pricing she found reasonable does not diminish the credibility of Dr. Schossow's studied conclusion that the subject prices were exorbitant. I also found Dr. N. to be fully credible. Dr. Fertil's credibility will be discussed in the Analysis section.

Analysis

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious red flags of diversion without documenting the resolution of those red flags, in violation of state law under the Florida Administrative Code, and state requirements for the minimum standard of care, and that its continued registration would be inconsistent with the public interest, as provided in 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). ALJ Ex. 1.

In the adjudication of a revocation or suspension of a DEA COR, the DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38363, 38364 (2013). Where the Government has sustained its burden, the registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

The Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). *See also Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (noting, on remand, that despite the respondent having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med. Shoppe-Jonesborough,* 73 FR at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. The Supreme Court has defined ''substantial evidence'' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison Co. of New York* v. *NLRB,* 305 U.S. 197, 229 (1938). 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); *Trawick,* 861 F.2d at 77, 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 Village Pharm.* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys* v. *DEA,* 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall* v. *DEA,* 412 F.3d 165, 183 (D.C. Cir. 2005), but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that since 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.* 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 Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of his discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8 (1947).

Analysis of Dispensing Allegations

Failure To Resolve and To Document Red Flags

The Government alleges that the Respondent filled numerous prescriptions for ten patients that raised red flags of drug abuse and/or diversion, to include drug cocktails; dangerous combinations; traveling long distances; prescriptions for the highest commercially available strength; paying in cash; paying unusually high prices in cash; and therapeutic duplication. ALJ Ex. 1. The Government further alleges that the Respondent failed to resolve these red flags, or failed to document

their resolution. *Id.* The Government claims that by filling these ten patients' controlled substance prescriptions and failing to resolve the red flags they presented, the Respondent violated its corresponding responsibility under 21 CFR 1306.04(a) and dispensed controlled substances outside the usual course of pharmacy practice in violation of 21 CFR 1306.06, in addition to Florida Administrative Code r. 64B16–27.831. *Id.* Furthermore, the Government claims that by failing to resolve red flags and to document that resolution in the patients' profiles, the Respondent violated Florida Administrative Rule 64B16–27.800 and 27.810. *Id.*

With respect to each patient, the Government presented documentary evidence and testimony from its pharmacy expert, Dr. Schossow, that the Respondent filled numerous controlled substance prescriptions that raised red flags, including drug cocktails, dangerous combinations, patients traveling long distances, prescriptions for the highest commercially available strength, patients paying in cash, and patients paying unusually high prices in cash. The Government further presented evidence that the Respondent failed to document any resolution of these red flags in the patients' profiles.

The Government's expert conceded that each of the red flags that she identified were resolvable. Therefore, the question becomes, whether the Respondent resolved them prior to dispensing the controlled substance. The Government's expert testified that documentation of the resolution of red flags is required by the pharmacists' standard of professional responsibilities. The Respondent and his expert testified that no such documentation is required under Florida law or in the course of professional practice. Alternately, Dr. Buffington mused that reasonable pharmacists could differ whether documentation was required. However, despite believing that he had no professional responsibility to do so, the Respondent testified that he fully resolved all red flags and filled the subject prescriptions consistent with his professional judgment and with Florida law. Tr. 1360–64. The Respondent's expert testified that he observed no red flags within the record. Tr. 1162, 1241, 1277–78. Furthermore, he testified that even if there were red flags, there was no requirement to document red flags, but the Respondent resolved all red flags and documented their resolution. However, there is little-to-no documentary resolution of the red flags credibly identified by Dr. Schossow (or yellow lights in Dr. Buffington's vernacular) in evidence, as far as I could discern.[69] The evidentiary record consists of the relevant PDMP records; subject physical prescriptions; the subject patient profiles, including comments by the pharmacist in the comments section; dispensing logs; and any medical records which were part of the pharmacy records, all obtained through a series of administrative subpoenas. Tr. 466–67.

The Government suggests that the factfinder should infer the absence of the subject documentation resolving red flags demonstrates a failure to resolve the red flags. *Superior Pharmacy,* 81 FR 31,309, 31,314 (2016). However, the Respondent's expert, who reported experience with the PioneerRx computer program testified that there were additional fields in the PioneerRx database referred to as Medication Therapy Management and that there were multiple other tabs and therefore [there might have been] additional information that the investigators failed to obtain from the Respondent. Tr. 1163–64. [However, as discussed in more detail below, Respondent was served with three subpoenas that required the production of all documents that contained any discussion or resolution of red flags. Thus, Dr. Buffington's testimony that there might have been additional materials resolving red flags appeared to be speculative and is not entitled to any weight.] Furthermore, Dr. Schossow testified that the few examples of the pharmacist's comments highlighted at the hearing did not resolve the subject red flags.

Administrative Subpoenas

The Government's attempts to obtain documents from the Respondent began with the service of the AIW and administrative subpoena requesting various records from the Respondent on February 14, 2018. It should be noted that subpoenas are not requests, which can summarily be ignored by the recipient. They are duly authorized commands by the Attorney General and enforceable by the U.S. District Court. *See* 21 U.S.C. 875, 876, 880.

The first administrative subpoena was highly detailed and specific in its commands. It required, in part, copies of Respondent's patient profiles for certain listed patients, copies of ''[a]ny and all other records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals; and copies of ''[a]ny other documentation kept by'' the Respondent ''in connection with the filling of prescriptions or providing medical treatment'' for those named individuals, including dispensing logs or reports, for those listed individuals. GX 3; Tr. 35, 41–42, 45, 64–65. Although, as Dr. Buffington noted, the term red flags does not appear in Florida regulations, the documents required by the subpoena would plainly include the type of documentation generated to resolve red flags.[70]

At the February 14, 2018 visit and search of the Respondent pharmacy, the Government's team of investigators included a computer technician. By all accounts, Dr. Fertil was cooperative and assisted the investigators in locating pharmacy and patient records. He helped connect the Government personnel with a technician from PioneerRx in order for the investigators to retrieve information from the PioneerRx record system. Other than that, the evidence discloses that Dr. Fertil did not actively collect any documents in response to the warrant and first administrative subpoena. Rather, he left it to the investigators to collect the required documents, assisting them with access to records and to the PioneerRx system, as they required. He placed them in touch with personnel from PioneerRx, who apparently walked them through the process of downloading the required material from the PioneerRx system. I cannot fault Dr. Fertil's actions on February 14, 2018. I think he did everything the law required and that the Agency would expect. The Government left after apparently retrieving all the documents they required. On February 14, 2018, the investigators did not retrieve all of the information stored on the PioneerRx system. In relevant part, they apparently only obtained screen shots of the first of multiple tabs of the PioneerRx system, by printing those.

In May of 2019, the Government served a second subpoena on the Respondent pharmacy. It required production of hardcopies of controlled substance prescriptions that Respondent had dispensed from February 15, 2018, through May 3, 2019, copies of the Respondent's patient profiles for certain listed individuals, and, like the first subpoena, copies of ''[a]ny and all records . . . maintained pursuant to the

[69] The Respondent submitted an excel spreadsheet encompassing the information contained in the subject patient profiles within the PioneerRx program. I could [not discern any relevance to the spreadsheet in terms of documenting Respondent's attempts to address and resolve the red flags that Dr. Schossow identified].

[70] [Footnote omitted.]

requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those same listed individuals ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed individuals. Tr. at 119–21; GX 16.

In August 2019, DI served a third administrative subpoena on Respondent seeking, with respect to Patients J.B., A.B., B.Da., B.Di., J.R., and R.R., hardcopies of controlled substance prescriptions that Respondent had dispensed to those patients from May 3, 2019, through August 9, 2019, copies of the Respondent's patient profiles for those patients, and copies of ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Code 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' those patients ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those patients. Tr. at 179–82; GX 33.

Adverse Inference

The Respondent, through Dr. Fertil, responded to the second and third subpoenas by providing records specific to the patients identified and dates included. However, the Respondent did not recall if he read the subpoenas, or if he supplied everything requested in the subpoenas. He only remembered that he supplied the same type of information that the Government seized during the service of the search warrant and first administrative subpoena on February 14, 2018.

I can safely conclude that he read the second and third subpoenas, as he supplied highly specific information and documents required. Regarding the aspect of the May and August subpoenas relating to documents required by Florida Administrative Rule 64B16–27.800 for Patient Records, he testified he only supplied the same type of records the government seized on February 14, 2018, believing that those same type of records were what the Government wanted. It was unusual that Dr. Fertil could describe his deliberative process in gathering or screening records in response to the second and third subpoenas, when he could not remember whether he read the subpoenas, nor if he supplied everything requested in the subpoenas. The record is also unclear how, in May and in August, 2019, he knew exactly what records were retrieved by the Government on February 14, 2018, as he testified he left the investigators to retrieve the documents they required with the assistance of a PioneerRx technician, and the receipt provided him for those documents does not disclose that only the first tab of the PioneerRx system was copied and seized.[71] His selective memory loss is not credible. If he did not remember even reading the subpoenas, his rationale for including and withholding records is not credible.

Either there were no [records documenting the resolution of red flags] in the Respondent's records, or Dr. Fertil ignored the subpoena requirements surrounding this [type of] documentation. In either case, we can infer that his failure to provide such highly exculpatory documentation suggests it does not exist. He testified that he was not obligated to resolve red flags and to document their resolution by the Florida regulations, but that he did resolve them and document them. However, he has not identified or presented any such documentation in evidence.[72] Based on his failure to provide the required documentation to the Government in May and August 2019, we can fairly infer that no such documentation exists. [Omitted for clarity.]

Failure To Resolve Red Flags

The Government argues that I should apply the adverse inference that the absence of the subject documentation as to the resolution of red flags suggests no resolution occurred. [I find that such an inference is appropriate in this case.] *M [Omitted.] [73]

Dr. Schossow testified that in evaluating a pharmacist's performance in the course of professional practice, the failure to document the resolution of red flags demonstrated the red flags were not resolved. Tr. 465–66. [Based on this testimony, the adverse inference, and the inconsistent and not credible testimony of the Pharmacist's PIC,] I will conclude [ ] that the failure to document the resolution of red flags establishes that the red flags were not resolved.

Specific Red Flags

Unusual Distance Traveled

[Omitted.] *N [74]

Payment in Cash

The Government argues that, in the context of this case, payment in cash for

[71] In relevant part, the receipt for documents seized on February 14, 2018, only references ''profiles printouts'' for GI 18–351298. GX 4.

[72] Where respondent testified that he had exculpatory inventories in his office, but failed to produce them at his hearing, the Administrator gave no credit to the testimony ''[i]n view of the level of professional exposure attendant upon the potential loss of his DEA registration. . . .'' *Lesly Pompy, M.D.,* 84 FR 57,749, 57,758 (2019). A physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained patient records. *Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019). Pharmacist's testimony that she resolved various red flags merited no weight because she failed to produce documentary evidence to corroborate her claim. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR at 10,887.

*M The ALJ declined to draw an adverse inference that Respondent failed to resolve red flags based on Respondent's failure to document the resolution of the red flags, citing to the Agency's decision in *Hills Pharmacy* as support. *See* RD, at 127–28 (citing *Hills Pharmacy, L.L.C.,* 81 FR 49,816, 49,835–36 (2016). However, in *Hills Pharmacy,* a former Acting Administrator declined to draw an adverse inference based solely on the respondent's failure to document red flags on the prescriptions themselves, when other materials (such as patient profiles) were not in evidence. The Acting Administrator noted that because there was no state or federal law that required red flags to be documented on the prescriptions themselves, the respondent may have documented the resolution elsewhere. *Id.* In this case, however, the Government admitted patient profiles, prescriptions, and other pharmacy records into evidence. Additionally, the Government admitted into evidence all documents that DEA obtained from Respondent in response to a subpoena requesting: (1) All documentation showing the steps taken to resolve red flags, and (2) all documentation reflecting efforts by Respondent's pharmacists to exercise their corresponding responsibility. Thus, I find that it is appropriate in this case to infer that Respondent failed to address and resolve red flags based on the absence of documentation evidencing attempts to address and resolve red flags. Therefore, I apply here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent Pharmacy's decision not to provide evidence within its control gives rise to an inference that any such evidence is unfavorable to Respondent Pharmacy.

[73] [Omitted for clarity.]

*N The ALJ determined that the Government failed to prove that the distances that Respondent's customers traveled to fill their prescriptions, which ranged from approximately thirty to fifty miles, represented a red flag in this case. I find that it is unnecessary for me to determine whether the distances traveled were a red flag in this case because the Government has proven that these prescriptions presented several additional red flags that Respondent did not resolve. I thus conclude

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controlled substances is a red flag, as it may represent an attempt by the patient to avoid scrutiny of an insurance carrier, who may investigate the propriety of the controlled prescription.[75] [Dr. Schossow testified that cash payments are a red flag because ''drug seeker[s] [are] willing to pay more for a drug if they can get the drug. They're willing to pay whatever they want, you know, whatever they need to pay to obtain the medication.'' Tr. 585–86.] [Omitted.] *O

Unusually High Cash Payments

The Government argues that the payment of inflated prices for controlled substances creates a red flag of diversion or abuse. [Omitted.] *P The Government offered the expert opinion of Dr. Schossow, who, although she has not served a customer in seven years, has had extensive and recent experience in the average pricing of the subject medications in Florida. Tr. 405, 564–65. She managed a rejection que, and more recently reviews ''High Dollar Reports'' for Blue Cross/Blue Shield of Florida. Tr. 403–04. She testified that pharmacies throughout Florida charge twenty to twenty five percent over acquisitions costs, while the Respondent's prices were in excess of that, sometimes more than triple the market rate. Tr. 565–66. Dr. Schossow testified that the excessive prices charged by the Respondent represented a red flag, which were not resolved by the Respondent. Her subject opinion is credible and consistent with Agency [decisions that have credited expert testimony that cash payments at high prices for a large quantity of controlled substances are suspicious.[76] I find based on Dr. Schossow's credible expert testimony that it was a red flag that Respondent's customers were willing to pay very high prices in cash for controlled substances.]

Dangerous Combinations

The Government highlighted two medication combinations the Respondent dispensed. They argued these combinations represented red flags, which were not resolved by the Respondent. They were the combination of an opioid and a benzodiazepine, which has a ''black box'' warning from the FDA. This combination has the risk of respiratory suppression and overdose. Although it may ultimately be justified as therapeutic depending on the circumstances, it requires investigation, resolution and documentation by the pharmacist.

The Respondent also filled numerous prescriptions of an opioid, a benzodiazepine, and a muscle relaxant, that raised multiple red flags of drug abuse and/or diversion. Not only did Dr. Schossow opine that these red flags are recognized by Florida's standard of pharmacy practice, but all of these red flags [have been recognized by DEA as indicators] of drug abuse and/or diversion.[77]

Furthermore, the Government's evidence shows that the Respondent failed to document sufficient resolution of these red flags. Although the Respondent testified that he resolved all red flags or suspicious circumstances, there's no documentary evidence to corroborate his claim. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10887 (2018).

Dispensing Immediate Release Opioids in Combination With Long-Acting Opioids

Dr. Schossow testified that dispensing immediate release opioids in combination with long-acting opioids, in which the MME of the immediate release is greater than the MME of the long-term opioids does not make pharmacologic sense and creates a dangerous risk of overdose. Tr. 599–600. She explained that the long-acting opioids had a long half-life and remained in the patient's system for a long period, relieving pain. This would reduce the need for large amounts of immediate release opioids. Although Dr. Buffington defended the use of long-acting opioids in combination with immediate release opioids, he did not directly address Dr. Schossow's point relating to the comparative MME levels of the two. Tr. 1121–22, 1129–30. I credit Dr. Schossow's testimony that this combination of opioids represented a red flag and that the red flag went unresolved by the Respondent.

[Omitted for clarity and brevity.*Q As discussed in more detail below, I find

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that Respondent dispensed prescriptions outside the usual course of professional practice in Florida based on its failure to resolve these red flags, and I find it unnecessary to determine whether the distances traveled represented yet another red flag that Respondent failed to resolve.

[74] [Omitted.]

[75] Payment in cash actually refers to payment in currency, credit card, or even by check. It does not include payment through an insurance carrier or government program payer.

*O I agree with the ALJ's ultimate conclusion that cash payments were a red flag in this case, but I disagree with his statement that cash payments were not ''a huge red flag.'' RD, at 130. I give minimal weight to Dr. Buffington's testimony about the red flag of cash payments because it was not grounded in a discussion of the Florida usual course of professional practice. Dr. Buffington testified that the prices he saw ''were not surprising or astonishing,'' but even if they were high, it is ''the patient's prerogative'' to pay those prices. Tr. 1193. Dr. Buffington also testified that there are many reasons that a patient may pay in cash, which is something that the pharmacist can discuss with the patient. *Id.* However, Dr. Buffington did not adequately address the concern that cash payments are a red flag because drug seekers are willing to pay high prices for a drug. Tr. 585–86. Although I agree with Dr. Buffington that there are legitimate reasons that a patient may pay in cash, I find based on Dr. Schossow's credible expert testimony that cash payments were a red flag in this case, and it was outside the usual course of professional practice for Respondent to fail to address, resolve, and document this red flag, particularly in combination with the other red flags.

*P I have omitted, for brevity, the RD's discussion of his decision to exclude the Government's evidence of national average costs of drugs, which was intended to show that Respondent charged high prices for controlled substances. There is other evidence on the record that shows that Respondent charged high prices for controlled substances—specifically, Dr. Schossow's testimony (which is also discussed in this section) that Respondent's prices greatly exceeded its acquisition costs. Therefore, the Government adequately supported its contention that Respondent charged high prices even without evidence of national average drug costs. Thus, I need not resolve whether the ALJ properly excluded the evidence of national average costs of drugs.

[76] ''[A]ny reasonable pharmacist knows that a patient that . . . wants to pay cash for a large quantity of controlled substances is immediately suspect.' '' *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,194 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018) (quoting *East Main Street Pharmacy,* 75 FR 66149, 66158 (2010)). Where a pharmacy's prices for controlled substances far exceed prices charged by other pharmacies, it may be inferred that the pharmacy knows that those purchasing those high-priced controlled substances are either abusing or diverting them. *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,199–200 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018) (citing *United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996)).

[77] Oxycodone, carisoprodol, and alprazolam are a combination of drugs that the DEA has encountered in investigations of registrants ''engaged in blatant drug dealing.'' *Sigrid Sanchez, M.D.,* 78 FR at 39,332 n.2 (2013) (citing *Paul H. Volkman, M.D.,* 73 FR 30,630 (2008)). ''The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.' '' *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR 79,188, 79,194 (2016), *aff'd,* 881 F.3d 823 (11th Cir. 2018) (quoting *E. Main St. Pharmacy,* 75 FR 66149, 66163 (2010)). Several DEA decisions have discussed the abuse of the ''trinity'' cocktail, which typically consists of carisoprodol, oxycodone, and alprazolam. *Holiday CVS,* 77 FR at 62,321 n.22 (citing *East Main Street Pharmacy,* 75 FR 66,149, 66,158 (2010) (noting expert's testimony that ''[i]t is well known in the pharmacy profession [that] the combination of a benzodiazepine, narcotic pain killer, and Soma [the branded version of carisoprodol] [is] being used by patients abusing prescriptions drugs'') and *Paul J. Volkman, M.D.,* 73 FR at 30,637–38, *aff'd, Volkman* v. *DEA,* 567 F.3d 215 (6th Cir. 2009) (discussing expert's testimony regarding abuse of drug cocktails of oxycodone, alprazolam, and carisoprodol)).

*Q The ALJ concluded that Florida law requires pharmacists to document in the patient profile the steps that they take to resolve red flags. *See, e.g.,* RD, at 134–35 (citing Fla. Admin. Code r. 64B16–27.800). The Respondent takes Exception to this conclusion, arguing that there is no Florida law or regulation that mandates pharmacists to document the resolution of red flags. Resp Posthearing, at 5–12. I need not address whether Florida law requires pharmacists to document red flag resolution, however, because Dr. Schossow offered credible expert testimony that failing to document red flag

that Respondent acted outside the usual course of professional practice by repeatedly filling prescriptions without addressing and resolving red flags, and without documenting the resolution. *See* 21 CFR 1306.06. I further find that Respondent violated its corresponding responsibility by filling prescriptions that Respondent knew were not prescribed for a legitimate medical purpose, or was willfully blind to such. *See* 21 CFR 1306.04.] [78]

Government's Burden of Proof and Establishment of a Prima Facie Case

[In order to make a *prima facie* case that a ground for revocation of Respondent's registration exists, the Government must demonstrate that Respondent's continued registration is inconsistent with the public interest]. [Text omitted for clarity].

Public Interest Determination: The Standard

Pursuant to 21 U.S.C. 823(a)(4) (2006 & Supp. III 2010), the Administrator [79] may revoke a DEA Certificate of Registration if the registrant has committed such acts as would render its registration inconsistent with the public interest. Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with ''the public interest'':

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 . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (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 registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see also Morall,* 412 F.3d at 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie,* 419 F.3d at 482; *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.'' *Krishna-Iyer,* 74 FR at 462.

Factors Two and Four: Experience in Dispensing, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government seeks the revocation of the Respondent's COR based primarily on conduct most appropriately considered under Public Interest Factors Two and Four.[80]

The DEA often analyzes Factor Two and Factor Four together. See, *e.g.,* Fred Samimi, M.D., 79 FR 18,698, 18,709 (2014); John V. Scalera, M.D., 78 FR 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing controlled substances.'' 21 U.S.C. 823(f)(2); *Id.* This analysis focuses on the registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. Kansky J. Delisma, M.D., 85 FR 23,845, 23,852 (2020) (citing Randall L. Wolff, M.D., 77 FR 5106, 5121 n.25 (2012). The Agency has acknowledged that even a considerable level of benign or even commendable experience could be easily outweighed by evidence demonstrating that continued registration was inconsistent with the public interest.[81]

Likewise, under Factor Four, the DEA analyzes an applicant's compliance with Federal and state controlled substance laws with the analysis focusing on violations of state and Federal laws and regulations concerning controlled substances. Delisma, 85 FR at 852 (citing *Volkman* v. *DEA*, 567 F.3d 215, 223–24 (6th Cir. 2009)) (citations omitted). As DEA has held in the past, a registrant's ''ignorance of the law is no excuse'' for actions that are inconsistent with responsibilities attendant upon a registration. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,809 (2015) (quoting *Sigrid Sanchez, M.D.,* 78 FR 39,331, 39,336 (2013) (citing *Patrick W. Stodola,* 74 FR 20,727, 20,735 (2009) and *Hageseth* v. *Superior Ct.,* 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007) (a ''licensed health care provider cannot 'reasonably claim ignorance' of state provisions regulating medical practice'')). Under Agency precedent, ''[a]ll registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules.'' *Id.* at 74809 (internal citations omitted).

[Omitted.] *[R]

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 ALJ that Dr. Schossow's testimony regarding documentation requirements was more credible.

[78] [Footnote omitted.]

[79] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104 (2008).

[80] 21 U.S.C. 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent's DEA COR (Factor One). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor Three).

[81] *See, e.g., Paul J. Caragine, Jr.,* 63 FR 51,592, 51,560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent Pharmacy's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''); *Med. Shoppe-Jonesborough,* 73 FR at 386 (finding that the misconduct outweighed the fact that only a relatively small portion of the respondent's patient population was involved).

*[R] I disagree with the ALJ's assertion that the testimony of J.R. and L.V. constitutes positive dispensing experience under Factor Two, and I disagree with the ALJ's conclusion that Factor Two weighs in Respondent's favor based on this testimony. Dr. Schossow identified several red flags with J.R.'s and L.V.'s prescriptions. Dr. Schossow testified that L.V. presented prescriptions for the potentially dangerous combination of opioids and benzodiazepines, she paid for some prescriptions in cash and others with insurance, and she made unusually high cash payments. Tr. 510–28, 758, 767–68, 772–74, 776, 778. Dr. Schossow reviewed Respondent's records for L.V. and did not find any indication that Respondent addressed or resolved these red flags. Tr. 529. Respondent did not successfully rebut these conclusions. Dr. Fertil testified briefly about his interactions with L.V. Respondent's counsel asked him whether he ''ha[d] any occasion to discuss with patients like J.R. and L.V. their restrictions presented for combinations that included a benzodiazepine, an opioid, and, in some cases, Soma or carisoprodol.'' Tr. 1360. Dr. Fertil confirmed that he had, and he also confirmed that he had provided those customers with information regarding potential side effects of the combination and discussed with them the potential sedative effects. *Id.* at 1361. Dr. Fertil, however, did not testify that he addressed or resolved the red flag that the patient was receiving this potentially dangerous drug combination, or that he resolved the red flags of unusually high cash payments and

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*[S] *Standard of Care as to Charged Violations*

[According to the CSA's implementing regulations, ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. Further, a controlled substance prescription must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). 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 his or 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 at 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 at 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 at 62,341 (citing *Med. Shoppe—Jonesborough,* 73 FR at 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 at 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 at 62,341.]

[Text omitted.] *[T]

In the case before me, the Government presented no evidence that the Respondent's pharmacists filled a prescription with actual knowledge that the prescriptions were not legitimate. Absent actual knowledge, the Government can establish scienter by showing that a pharmacist was ''willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose.'' *Id.* To establish willful blindness, it is necessary to show that a pharmacist subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that the pharmacist deliberately avoided learning the truth. *Id.* Here, the Government argues that the Respondent's failure to document the resolution of numerous red flags when it filled many prescriptions establishes that the Respondent was willfully blind as to the medical legitimacy of those prescriptions. Gov Posthearing, at 34–35.

alternating cash and insurance payments. L.V.'s testimony also did not shed light on whether Respondent made any attempts to address or resolve these red flags. L.V. testified that she was rejected by other pharmacies, and she chose Gulf Med because they filled her prescriptions in a timely manner and at a reasonable price. Tr. 1303. L.V.'s belief that the prices were reasonable is not sufficient to rebut Dr. Schossow's credible expert testimony that the prices were high, and that it was a red flag for L.V. to pay those prices in cash.

Likewise, Respondent did not offer testimony or evidence that suggested that Respondent made adequate attempts to address or resolve the red flags that Dr. Schossow identified with J.R.'s prescriptions. Dr. Schossow testified that J.R. presented prescriptions for the potentially dangerous ''trinity'' cocktail and for multiple benzodiazepines. Although J.R. testified that he discussed his many medical problems with Respondent's pharmacists, and they answered his questions and provided him with instructional material, there is not sufficient evidence on the record that Respondent addressed and resolved the red flags with J.R.'s prescriptions. Dr. Buffington testified that Respondent made some notations in J.R.'s records about conversations with J.R.'s physicians and J.R.'s treatment, but he did not point to any notations that indicated that Respondent adequately addressed the red flags that Dr. Schossow identified. Therefore, I credit Dr. Schossow's testimony that Respondent failed to address and resolve red flags with J.R.'s and L.V.'s prescriptions prior to dispensing, and that Respondent dispensed controlled substances to these customers outside the usual course of professional practice in Florida and in violation of its corresponding responsibility.

*[S] I am replacing portions of the Standard of Care section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

*[T] I have omitted, for brevity, text regarding the legal standard requiring a nexus between the state laws that have been violated and the CSA's purpose of preventing drug abuse and diversion. I find that the Florida laws in this case are sufficiently related to controlled substances to be considered in my public interest analysis, and that my consideration of these state law violations bears a rational relationship to the core purpose of the CSA. *See Salman Akbar, M.D.,* 86 FR 52,181, 52,194–95 (2021) (citing 21 U.S.C. 823(a)(4); *Judulang* v. *Holder,* 556 U.S. 42, 63 (2011)).

The Government has introduced a preponderance of evidence to prove that the Respondent dispensed numerous controlled substance prescriptions for at least ten patients. Those prescriptions raised classic red flags of drug abuse and/or diversion, to include paying in cash, paying high prices in cash, dangerous drug cocktails, and combining extended release and immediate release opioids, highest strength of the medication, among others.*U The Government also introduced the supplied patient profiles for each of these ten patients, as well as hardcopy prescriptions, dispensing reports and PDMP information. The profiles contain insufficient information, and in some cases no information, that [indicates that Respondent took adequate steps to address or resolve the red flags raised by each prescription]. The evidence reveals a concerning pattern of a pharmacy that repeatedly [acted outside the usual course of professional practice by failing] to document information needed to resolve red flags. This concerning pattern demonstrates that regardless of the obvious signs of drug abuse and diversion that are well-known to the pharmacy community, the Respondent repeatedly dispensed controlled substances and rarely, if ever, documented any information in response to those red flags in the patient records. And when the Respondent documented information, it was always insufficient to resolve all the concerns raised by the prescription.

With respect to the prescriptions in evidence, the Government has further demonstrated a violation of the Respondent's corresponding responsibility under 21 CFR 1306.04(a). The Government has proven this violation through documentary evidence and testimony from its expert witness.*V

Furthermore, the Respondent failed to rebut or meaningfully discredit the Government's case. For the reasons discussed, the Respondent and Respondent's expert had diminished credibility. In light of the record as to this factor, I find that the Government has proven that the Respondent failed to comply with federal law [and the usual course of professional practice in Florida] with respect to resolving and documenting resolution of red flags of drug abuse and/or diversion, and with respect to its corresponding responsibility for the prescriptions in evidence.

The totality of this evidence demonstrates a concerning lack of compliance with applicable federal law [and state professional practice standards] that poses a significant risk of diversion and threatens public health and safety. This evidence further demonstrates a lack of commitment on the Respondent's part with respect to its federal and state controlled substance obligations. Therefore, I find that Factors Two and Four significantly favor revoking the Respondent's registration. [The record evidence establishes that Respondent filled controlled substance prescriptions in violation of its corresponding responsibility and outside the usual course of professional practice. Thus, I conclude that Respondent has engaged in misconduct which supports the revocation of its registration. I therefore find that the Government has established a *prima facie* case that Respondents' continued registrations ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).]

Acceptance of Responsibility

With the Government's *prima facie* burden having been met, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR at 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007). As past performance is the best predictor of future performance, DEA has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.,* 54 F.3d at 452; *Medicine Shoppe,* 73 FR at 387; *see also Hoxie,* 419 F.3d at 483 (reasoning that ''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination). Likewise, in making the public interest determination, ''this Agency places great weight on a registrant's candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49,995, 50,004 (2010); *Hoxie,* 419 F.3d at 483.

Although correcting improper behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.,* 77 FR at 62,346; *Daniel A. Glick, D.D.S.,* 80 FR at 74,801.

The Respondent has not unequivocally accepted responsibility for the proven violations. In fact, the Respondent has not tendered any acceptance of responsibility at all, whether equivocal or unequivocal. The Respondent's pharmacist-in-charge testified at the hearing, but denied all wrongdoing. The Respondent's post-hearing brief is silent on this issue.

*U Agency decisions have consistently found that prescriptions with similar red flags were so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility because they had actual knowledge of, or were willfully blind to, the prescriptions' illegitimacy. *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 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).

*V Further, the Government introduced evidence that is consistent with violations of Florida law. Florida law and the Florida standard of care require a pharmacist to conduct a prospective drug use review before dispensing a controlled substance. Tr. 211, 227–28; Fla. Admin. Code r. 64B16–27.810. This includes ''review[ing] the patient record and each new and refill prescription presented for dispensing'' to identify, among other things, ''[o]ver-utilization or under-utilization,'' ''[t]herapeutic duplication,'' ''drug-drug interactions,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code r. 64B16–27.810. After conducting this review, the pharmacist must ''take appropriate steps to avoid or resolve the potential problems.'' *Id.* The purpose of the prospective drug use review is to identify red flags that require resolution before dispensing a controlled substance. Tr. 207–08, 211. Additionally, Florida law requires pharmacists to ''exercise[] sound professional judgment,'' review each prescription ''with each patient's unique situation in mind,'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' Fla. Admin. Code r. 64B16–27.831.

I find that the evidence on the record is consistent with violations of Florida law, based on Respondent's repeated filling of prescriptions without documenting any attempts to address or resolve red flags. However, I find that it is unnecessary for me to determine whether Respondent violated Florida law, because Respondent's repeated violations of federal law are sufficient for me to conclude that Respondent's registration is inconsistent with the public interest. I do find, however, that the Florida laws in this case bolster Dr. Schossow's credible expert testimony that pharmacists must conduct a drug utilization review on every prescription.

Resp't Posthearing Br. 29, ¶ (i); 32, ¶ (ii); 36, ¶ (iii).

The Respondent took the similar approach in its opening statement, arguing that the Government has failed to satisfy its burden; accusing the DEA of never intending to clearly or objectively evaluate the evidence; attacking the credentials of the Government's expert; claiming that the Respondent exercised appropriate judgment when dispensing the relevant controlled substance prescriptions in compliance with Florida law; and complaining about the standard the DEA is imposing on its conduct. Tr. 503–05. In other words, the message from the Respondent's post-hearing brief and its opening statement is that it has done nothing wrong. These sentiments are inconsistent with a registrant that is remorseful for misconduct and determined to regain the Agency's trust. By failing to accept responsibility, the Respondent has failed to overcome the Government's *prima facie* case. In addition to failing to accept responsibility, the Respondent has also failed to offer any evidence of remediation.

Egregiousness and Deterrence

[Omitted for brevity.] The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *see also Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009). [Likewise, DEA considers its interest in deterring future misconduct by both the registrant as well as other registrants. *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013).]

I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. The proven misconduct involves repeated instances of dispensing high-strength schedule II controlled substances despite the presence of well-known signs of drug abuse and diversion. The proven misconduct also involves repeat instances of failing to follow state standards of practice with respect to documenting red flag resolution. Continuously dispensing high-strength schedule II opioids, sometimes dangerously combined with high-strength benzodiazepines, and failing to document any investigation into those red flags, constitutes egregious misconduct because it allowed for the potential of unchecked diversion of controlled substances into illegitimate channels.

[Omitted for brevity.] *[W]

I further find that general deterrence considerations weigh in favor of revocation. Allowing the Respondent to retain its COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite repeatedly failing to resolve and document the resolution of red flags in accordance with [the usual course of professional practice]. Revoking the Respondent's COR communicates to registrants that the DEA takes all failings under the CSA seriously and that severe violations will result in severe sanctions.

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

There is no evidence that suggests the Respondent has learned any lessons from its misconduct and in fact, as discussed *supra,* the Respondent does not appear to believe it has done anything wrong. [Omitted for clarity.] The Respondent's failure to accept responsibly and present remediation evidence has convinced this Tribunal that the DEA cannot trust Respondent with the obligations of a DEA registration.

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it with a COR.

Therefore, I recommend that the Respondent's DEA COR No. FG6290061 should be REVOKED, and that any pending applications for modification or renewal of the existing registration, and any applications for additional registrations, be DENIED.

Signed: November 25, 2020
MARK M. DOWD
U.S. Administrative Law Judge

The Respondent's Exceptions

On December 15, 2020, Respondent filed its Exceptions to the RD. I find that Respondent's seven Exceptions are either without merit or irrelevant to my Decision. Therefore, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's continued registration is inconsistent with the public interest, and that revocation is the appropriate sanction.

Exception 1

In the first Exception, Respondent argues that the RD's conclusion that Florida law and the Florida standard of care require pharmacists to document the resolution of red flags ''was based upon a clear error of law, and thus arbitrary and capricious.'' Resp Exceptions, at 5–11. Respondent argues that the provisions of the Florida Administrative Code that the RD cites to do not support this conclusion. *Id.*

I do not need to address Respondent's arguments about the Florida Administrative Code, because I have concluded, based on Dr. Schossow's credible expert testimony, that a pharmacist operating in the usual course of professional practice in Florida must address, resolve, and document red flags prior to dispensing a controlled substance. Dr. Schossow testified that such documentation is necessary to ensure patient safety and continuity of care. I have thus concluded that, by repeatedly filling prescriptions without adequately addressing, resolving, or documenting red flags, Respondent violated its corresponding responsibility because the pharmacists knew these controlled substances were not prescribed for legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a), and Respondent dispensed controlled substances outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 1306.06. Because documentation of red flags is required in the usual course of professional practice in Florida, I find that it is irrelevant whether Respondent took

*[W] I have omitted, for brevity, the RD's statements that revocation is the appropriate remedy notwithstanding the lack of evidence related to Factors One, Three, and Five. As discussed in more detail above, 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); *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988).

adequate steps under Florida law to document any attempts to resolve the red flags.

Exceptions 2 and 6

Respondent next argues that the ALJ's conclusion that Respondent failed to document the resolution of red flags was ''unsupported by substantial evidence and otherwise arbitrary and capricious,'' because the government failed to offer complete copies of the relevant patient profiles. Resp Exceptions, at 12. Respondent similarly argues that the ALJ arbitrarily and capriciously concluded that the absence of documentation resolving red flags supports the inference that no such documentation exists. *Id.* at 16–17 (Exception 6). These Exceptions are disingenuous and lend further support for my conclusion that Respondent cannot be entrusted with a DEA registration.

The Government served three administrative subpoenas on Respondent throughout the course of the investigation, each of which required Respondent to produce ''[a]ny and all records . . . maintained pursuant to the requirements of Florida Statutes and Florida Administrative Rule 64B16–27.800 for Patient Records, documenting the steps taken to avoid or resolve any issues with the prescriptions presented by'' the listed patients. Gov't Exs. 3, 16, 33; RD, at 125. The second and third subpoenas further specified that Respondent was required to produce all documentation ''reflecting efforts by the pharmacist to exercise their corresponding responsibility to assess the validity'' of controlled substance prescriptions dispensed to those listed patients. Gov't Exs. 16, 33. At the hearing, the Government admitted into evidence all records that it obtained from Respondent pursuant to these subpoenas. *See* RD, at 84–87. Thus, if the record is devoid of relevant records documenting the resolution of red flags, then Respondent is at fault for failing to comply with the subpoenas.*[X] If Respondent realized during the course of the administrative litigation that there were additional materials that it had omitted from its subpoena response, then Respondent should have produced those materials immediately. As discussed in more detail above, I find that it is appropriate in this case to infer that no additional documentation of red flags exists based on Respondent's failure to produce this potentially exculpatory evidence.

Exception 3

I declined to rule on whether the distances that Respondent's customers traveled in this case were a red flag, because there was sufficient evidence on the record that the prescriptions presented several additional red flags that should have been addressed, resolved, and documented. Therefore, I need not address Respondent's third Exception, which addresses the adequacy of Respondent's evidence regarding the distance red flag.

Exception 4

Respondent argues that the ALJ erred in discrediting Dr. Buffington's testimony that there is no presumption in pharmacy practice that concurrent prescriptions for opioids and benzodiazepines cannot be issued or filled. Resp Exceptions, at 15. Respondent believes that the ALJ gave too much weight to the FDA's ''black box'' warning over Dr. Buffington's expert testimony. However, my conclusion regarding the opioid/benzodiazepine combination is not that this drug combination should never be prescribed or dispensed, but rather that it is a red flag that a pharmacist must address, resolve, and document. As stated above, this conclusion was supported by Dr. Schossow's credible testimony and by portions of Dr. Buffington's testimony. This conclusion is further supported by Respondent's Exceptions, which acknowledge that the opioid/benzodiazepine combination poses potential complications. *Id.* (''Dr. Buffington . . . credibly testified that the ['black box''] warning exists to alert healthcare professionals as to potential complications with a particular drug combination.'').

Exception 7[Y]

Finally, Respondent argues that the ALJ arbitrarily and capriciously concluded that Dr. Buffington suffered diminished credibility based on the ALJ's erroneous conclusion that Dr. Buffington ''conflated the reasonable, prudent pharmacist 'standard of care' applicable to medical malpractice negligence suits with a pharmacist's professional standards, *i.e.,* 'in the usual course of professional practice.' '' Resp Exceptions, at 17. Respondent cites to a 2001 case from the Florida District Court of Appeals to support its argument that Dr. Buffington's articulation of the standard care—which relied in part on a medical malpractice statute, Fla. Stat. § 766.102, that applies to ''health care providers,''—was in fact correct. However, as discussed in more detail above, the definition of ''health care providers'' specifically excludes pharmacists. *See supra* n.*I. Thus, I agree with the ALJ's conclusion that Dr. Buffington suffered diminished credibility based on his inaccurate reliance on an inapplicable statute, and based on a number of additional factors, such as his overt partiality and his inconsistent testimony. Overall, I agree with the ALJ's assessment of Dr. Buffington's credibility.

Accordingly, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's registration should be revoked.

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. FG6290061 issued to Gulf Med Pharmacy. 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 Gulf Med Pharmacy for 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 January 21, 2022.

Anne Milgram,

Administrator.

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*[X] One of the three subpoenas was served in conjunction with an administrative inspection warrant, during which DEA obtained certain materials, such as patient profiles, directly from Respondent's computer system. Respondent faults DEA for failing to obtain complete patient profiles from the computer. Resp Exceptions, at 12. However, as the Government points out in its response to Respondent's Exceptions, only three of the named patients in the OSC were included in the initial warrant and subpoena. *See* Gov't Response, at 5. The remaining seven patients were listed in the subsequent two subpoenas, meaning that all of the documents that DEA obtained for those patients were produced by Respondent.

*[Y] I addressed Respondent's fifth Exception above. *See supra* n.*L.