DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–42]

Pronto Pharmacy, LLC; Decision and Order

On August 23, 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 Pronto Pharmacy, LLC (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1.[*A] The OSC informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FP2302076 (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. 3. The hearing in this matter was conducted from January 28–29, 2020, in Tampa, Florida. On May 5, 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 May 26, 2020, the Government and Respondent filed exceptions to the Recommended Decision (hereinafter, Gov Exceptions and Resp Exceptions, respectively). Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's Recommended Decision with minor modifications, as noted herein.[*B] 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[*C 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. FP2302076, 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

1. 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 at least January 2018 through at least May 2019, the Respondent repeatedly filled prescriptions for Schedule II narcotics in the face of obvious red flags of drug abuse and diversion. *Id.* Filling these prescriptions violated federal and Florida law, including 21 CFR 1306.04(a) and 1306.06, and Fla. Admin. Code r. 64B16–27.810.

2. In addition, the Respondent engaged in the ''manufacture'' of controlled substances, as the Controlled Substances Act defines that term. ALJ Ex. 1 at ¶ 5. The Respondent is not registered with the DEA as a manufacturer. *Id.* Manufacturing controlled substances without the appropriate registration is a violation of federal law, including 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). *Id.*

Improper Dispensing

Between January 9, 2018, and May 7, 2019, the Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 11. These prescriptions presented numerous red flags of drug abuse and diversion, including drug cocktails, early refills, excessive dispensing of high-strength controlled substances, travelling long distances, and cash payments. *Id.* at ¶¶ 12–15, 18–19. Filling these prescriptions violated federal and state law, including 21 U.S.C. 842(a)(1), 21 CFR 1306.04(a), and Florida Administrative Code r. 64B16–27.810. *Id.* at ¶ 19. The OSC/ISO provided the following specific examples of prescriptions that raised these red flags:

Drug Cocktails

3. Patient A.G.: On at least nine occasions between January 25, 2018, and April 12, 2019, the Respondent filled prescriptions issued by the same prescriber for patient A.G. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(a). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for A.G. on the following four occasions: January 25, 2018; March 1, 2018; April 12, 2018; and May 8, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for A.G. on the following five occasions: December 20, 2018; January 17, 2019; February 14, 2019; March 20, 2019; and April 12, 2019. *Id.*

4. Patient B.S.: On at least five occasions between January 29, 2018, and April 22, 2019, the Respondent filled prescriptions issued by the same prescriber for patient B.S. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(b). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for B.S. on the following two occasions: January 29, 2018, and May 22, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for B.S. on the following three occasions: December 20, 2018; February 28, 2019; and March 26, 2019. *Id.*

5. Patient N.B.: On at least three occasions between September 14, 2018, and January 16, 2019, the Respondent filled prescriptions issued by the same prescriber for patient N.B. for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(c). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for N.B. on September 14, 2018. *Id.* The Respondent filled prescriptions for oxycodone and alprazolam for N.B. on the following two occasions: December 20, 2018, and January 16, 2019. *Id.*

[*A] According to Agency records, DEA removed all controlled substances from Respondent's possession on August 29, 2019, when the OSC was served, pursuant to the Immediate Suspension Order.

[*B] I have made minor, nonsubstantive, grammatical changes to the RD 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 in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

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

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

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

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

6. Patient C.R.: On at least three occasions between March 6, 2018, and July 12, 2018, the Respondent filled prescriptions issued by the same prescriber for patient C.R. for alprazolam and oxycodone on the same date. ALJ. Ex. at ¶ 12(d). Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for C.R. on March 6, 2018; April, 19, 2018; and July 12, 2018. *Id.*

7. Patient J.M.: On at least five occasions between January 25, 2018, and May 16, 2018, the Respondent filled prescriptions issued by the same prescriber for patient J.M. for alprazolam and oxycodone on the same date. *Id.* Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for J.M. on January 25, 2018; March 1, 2018; April 4, 2018; April 19, 2018; and May 16, 2018. *Id.*

Early Refills

8. Patient A.H.: On January 22, 2019, the Respondent filled a prescription for patient A.H. for a 30-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(a). The Respondent filled additional prescriptions for A.H. for 30-day supplies of hydromorphone 8 mg tablets on February 15, 2019 (six days early); February 27, 2019 (18 days early); and March 14, 2019 (15 days early). *Id.*

9. Patient M.M.: On January 3, 2019, the Respondent filled a prescription for patient M.M. for a 28-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(b). The Respondent filled additional prescriptions for M.M. for 30-day supplies of hydromorphone 8 mg tablets on January 24, 2019 (seven days early); February 19, 2019 (four days early); and a 28-day supply on March 15, 2019 (six days early). *Id.*

10. Patient J.D.: On May 10, 2018, the Respondent filled a prescription for patient J.D. for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(c). The Respondent filled additional prescriptions for J.D. for 30-day supplies of hydromorphone HCL powder on May 30, 2018 (10 days early); June 15, 2018 (14 days early); and June 30, 2018 (15 days early). *Id.*

11. Patient R.G.: On January 29, 2018, the Respondent filled prescriptions for patient R.G. for a 30-day supply of oxycodone HCL powder and a 30-day supply of alprazolam 2 mg tablets. ALJ Ex. 1, ¶ 13(d). The Respondent filled additional prescriptions for 30-day supplies of oxycodone HCL powder and alprazolam 2 mg tablets for R.G. on February 21, 2018 (seven days early); March 19, 2018 (four days early); April 17, 2018 (one day early); and May 8, 2018 (nine days early). *Id.*

12. Patient R.L.: On February 1, 2018, the Respondent filled a prescription for patient R.L. for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(e). The Respondent filled additional prescriptions for 30-day supplies of hydromorphone HCL powder for R.L. on February 26, 2018 (five days early); a 29-day supply on March 22, 2018 (six days early); a 30-day supply on April 17, 2018 (three days early); and a 30-day supply on May 11, 2018 (six days early). *Id.*

High-Strength Controlled Substances

13. During the relevant time period, virtually all of the prescriptions for oxycodone and hydrocodone that the Respondent ''compounded'' were for oxycodone 30 mg immediate release and hydromorphone 8 mg immediate release, the highest strengths of these controlled substances. ALJ Ex. 1, ¶ 14. Furthermore, between January 11, 2018, and July 17, 2018, 100 percent of the oxycodone tablet prescriptions and 87 percent of the hydromorphone tablet prescriptions (approximately 44 prescriptions total) issued by a particular prescriber were for the highest strength available for those controlled substances. *Id.*

Long Distances

14. Between September 10, 2018, and May 6, 2019, the Respondent filled:

a. 86 prescriptions for patients with addresses in Cape Coral, Florida, which is approximately 140 miles from the Respondent;

b. 145 prescriptions for patients with addresses in Fort Myers, Florida, which is approximately 130 miles from the Respondent;

c. 41 prescriptions for patients with addresses in Lehigh Acres, Florida, which is approximately 140 miles from the Respondent;

d. 15 prescriptions for patients with addresses in Immokalee, Florida, which is approximately 150 miles from the Respondent;

e. 15 prescriptions for patients with addresses in Naples, Florida, which is approximately 170 miles from the Respondent;

f. 11 prescriptions for patients with addresses in Opa-locka, Florida, which is approximately 270 miles from the Respondent. ALJ Ex. 1, ¶¶ 15(a)–(f).

15. In addition, between September 10, 2018, and May 6, 2019, over 75 percent of the prescriptions for controlled substances filled by the Respondent were issued by prescribers whose medical practices are located more than 150 miles away from the Respondent. ALJ Ex. 1, ¶ 16.

Cash Payments

16. During the relevant time period, over 90 percent of the prescriptions for oxycodone 30 mg and hydromorphone 8 mg filled by the Respondent were paid for with cash. ALJ Ex. 1, ¶ 18. In contrast, in 2018 ''approximately 11 percent of all prescriptions filled by independently owned pharmacies . . . were paid for with cash.'' *Id.*

Illegal Manufacturing

17. Between January 2018 and May 2019, the Respondent was engaged in manufacturing controlled substances, as that term is defined in the CSA, without a separate DEA registration authorizing it to manufacture controlled substances, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). ALJ Ex. 1, ¶ 20–28.

The Hearing

Government's Opening Statement

In its Opening Statement, Tr. 14–17, the Government stated that through its investigation of the Respondent, the DEA obtained the Respondent's dispensing records and patient profiles, a pharmacy expert reviewed those records, and that review revealed suspicious patterns. Tr. 14. Those suspicious patterns included the fact that 99 percent of the Respondent's prescriptions were paid for in cash; over 90 percent of the Respondent's patients travelled more than 100 miles to fill their prescriptions; and that the Respondent dispensed a disproportionately high volume of opioids. *Id.* The DEA's expert reviewed the Respondent's records related to 11 specific patients and found that the prescriptions filled by these patients presented numerous red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice. Tr. 14–15. The expert further opined that based on his review of the Respondent's records, the Respondent made no attempt to resolve the red flags presented by these prescriptions. *Id.*

In addition, the Government previewed that its evidence would show that the Respondent unlawfully manufactured controlled substances, specifically oxycodone and hydromorphone, without a manufacturer's registration. Tr. 15–17. To support this allegation, the Government intended to show that in May 2012 the Respondent's owner, Mr. Norman J. Clement, Sr., told DEA investigators that he compounded oxycodone and hydromorphone because it was cheaper than obtaining them from distributors. Tr. 14–15. In conclusion,

the Government requested that the Respondent's registration be revoked and any pending applications be denied because its continued registration presents a threat to the public. Tr. 17.

Respondent's Opening Statement

In the Respondent's opening statement, Tr. 503–06, the Respondent stated that the DEA initiated this case without objectively evaluating the evidence. Tr. 503. The DEA did not interview any patients identified in the OSC/ISO or the doctors who issued the prescriptions involved in this case. *Id.* The DEA also did not subpoena the medical records of the patients at issue. *Id.*

The Respondent argued that the Government's evidence would fail to show that any patients involved in this case suffered adverse consequences from the prescriptions filled by the Respondent. Tr. 504. Furthermore, the Respondent argued that the Government's evidence would fail to meet its burden to revoke the Respondent's registration. *Id.* In the Respondent's view, the Government's case is based on the faulty assumption that the patients must have been drug abusers because they received treatment for chronic pain. *Id.* The Respondent characterized this assumption as ''inherently unfair and inappropriate.'' *Id.*

The Respondent argued that the Government's assumption ignores the Respondent's combined 90-years of pharmacy experience possessed by the Respondent's pharmacists, as well as their professional education and training. Tr. 505. The Respondent's evidence is expected to prove that its pharmacists exercised appropriate professional judgment and resolved red flags. *Id.* The Respondent highlighted that the Government's evidence on red flags comes from a witness who has never practiced in Florida. *Id.* Furthermore, the Respondent argued that its evidence will show that its pharmacists' professional judgment complied with the Florida standard of care, and that the Florida standard of care is established by state statutes rather than an ''ivory tower aspirational goal.'' *Id.*

Government's Case-in-Chief

The Government presented its case-in-chief through the testimony of three witnesses. First, the Government presented the testimony of Diversion Investigator Richard Albert. Tr. 24–180. Second, the Government presented the testimony of Task Force Officer Jeffrey Shearer. Tr. 181–94. Finally, the Government presented the testimony of its expert, Dr. Donald Sullivan. Tr. 195–502.

Diversion Investigator (DI) Richard J. Albert, Jr.

DI Albert has been a Diversion Investigator for more than seven years. Tr. 24–25. He is currently stationed in Tampa, Florida. Previously, he was stationed in Nashville, Tennessee. Tr. 24. To become a Diversion Investigator, DI Albert received training at the 12-week basic diversion school in Quantico, Virginia. *Tr. 25.*

DI Albert became involved in the investigation of the Respondent in May 2017, when he received a call from the Department of Health regarding a pharmacy that was compounding hydromorphone and oxycodone. Tr. 26. DI Albert and his supervisor then met with the Health Department investigator at Respondent. *Id.* The Respondent's owner, Mr. Norman J. Clement, Sr., was not present at the pharmacy, but his daughter and wife were present. Tr. 26–27. The investigators presented a Notice of Inspection to Mr. Clement, Sr.'s, daughter, who allowed the investigators to inspect the pharmacy. *Id.* Approximately 15-minutes into the inspection, Mrs. Clement asked the investigators to leave. *Id.* The investigators complied. Tr. 27.

In September 2017, the DEA served a subpoena on the Respondent requesting Schedule II controlled substance prescriptions, receiving records, and batch records. Tr. 27. Government Exhibit 2 is a receiving record sent from Auburn Pharmaceutical to the Respondent. Tr. 28; GX 2. The DEA received this document in response to the September 2017 subpoena. *Id.*

Government Exhibit 3 is a receiving record for hydromorphone [4] sent from B&B Pharmaceuticals to the Respondent. Tr. 29; GX 3. The DEA received this document in response to the September 2017 subpoena. *Id.*

Government Exhibit 4 is a receiving record for oxycodone sent from Fagron, Inc., to the Respondent. Tr. 31; GX 4. The DEA received this document in response to the September 2017 subpoena. Tr. 32.

Government Exhibit 5 contains batch records for hydromorphone 8 mg. Tr. 32–33; GX 5. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id.* The batch records indicate how many capsules were used in the production of a particular batch. Tr. 38, 40–41. Government Exhibit 5 documents the production of hydromorphone 8 mg. Tr. 33. The initials ''N.C.,'' who DI Albert presumed to be the Respondent's owner, Norman J. Clement, Sr., appear in the columns labelled ''Manufactured By,'' ''Checked By,'' and ''Final Product Checked By.'' [5] Tr. 35–37; GX 5.

Government Exhibit 6 contains batch records for oxycodone 30 mg. Tr. 38–39; GX 6. The DEA received this document in response to the September 2017 subpoena. Tr. 39.

Upon reviewing the batch records received in response to the September 2017 subpoena, DI Albert noticed that the records listed lactose as the only non-controlled substance ingredient. Tr. 42–43. When he reviewed the prescriptions received in response to the subpoena, he noticed that patients were travelling long distances to the pharmacy. Tr. 43, 129–30.

Government Exhibit 10 is a printout of the prescription drug monitoring program (''PDMP'') for the Respondent's dispensing from September 2016 to June 2018. Tr. 46, 159, 162; GX 10, pp. 1, 20. This document represents the total number of controlled substance prescriptions that the Respondent dispensed during that 21-month time period. Tr. 162–63. The document lists 2,360 prescriptions. Tr. 162–63. DI Albert reviewed the Respondent's PDMP records during his investigation. Tr. 43–44. Government Exhibits 8 and 9 also contain PDMP printouts of the Respondent's dispensing. Tr. 49–52; GX 8–9.

DI Albert returned to Respondent in September 2018 to serve an administrative inspection warrant (''AIW'') and subpoena. Tr. 52. Government Exhibit 67 is the subpoena, dated September 5, 2018, that DI Albert served on the Respondent's counsel at the time of executing the AIW. Tr. 52–53; GX 67. The second page of the subpoena is a list of patient names. Tr. 53; GX 67, p. 2. DI Albert did not speak with any patients who presented at the pharmacy while the AIW was being executed. Tr. 168. He also did not speak with any of the Respondent's staff, including Mr. Norman J. Clement, Sr., who was instructed by counsel to not answer any questions. Tr. 168, 173, 177.

During service of the AIW, digital forensic specialists captured mirror

[4] Hydromorphone is a Schedule II controlled substance. Tr. 29.

[5] During cross-examination, the Respondent's counsel directed DI Albert's attention to page 7 and 11 of Government Exhibit 6, which shows illegible initials in the ''Manufactured By'' column (page 7) and the ''Checked By'' column (page 11). Tr. 150; GX 6, pp. 7, 11. DI Albert was also unable to identify the signature on page 13 of Government Exhibit 6. Tr. 151; GX 6, p. 13.

images of the Respondent's computer system. Tr. 54, 62, 91, 93, 134. The Respondent used Rx30 pharmacy software. Tr. 135. DI Albert received the information that was captured from the Respondent's system in Excel format, but he did not know the process that the digital forensic team used to convert that information into the format he received. Tr. 136. DI Albert was unable to determine whether errors were made in converting the captured images of the Respondent's system into Excel. Tr. 136–37.

During execution of the AIW, DI Albert observed Mr. Clement, Sr., conduct a closing inventory of the controlled substances that the Respondent had on-hand at the time. Tr. 54, 56, 165–66. Mr. Clement, Sr., signed the closing inventory. Tr. 56, 58; GX 7. The closing inventory lists 470 tablets of hydromorphone 8mg, 3,546 capsules of hydromorphone 8 mg, hydromorphone powder, 204 tablets of oxycodone 30 mg, 574 capsules of oxycodone 30 mg, and oxycodone powder. Tr. 59, 61; GX 7. Medications from distributors are in the form of tablets. When medications are compounded from powder in batch at a pharmacy, the dosage units are contained in capsules. Tr. 60.

Government Exhibit 11 is saved on a DVD. Tr. 63–64; GX 11. Government Exhibit 11 contains records electronically downloaded from the Respondent's computer system during execution of the AIW. Tr. 63.

Government Exhibit 12 is a report of the Respondent's dispensing over a three-month period from November 2015 through January 2016. Tr. 68; GX 12. This document was obtained electronically during execution of the AIW in September 2018. Tr. 69. Government Exhibit 13 was also obtained during service of the AIW. Tr. 70; GX 13.

Government Exhibit 14 is a PDMP dispensing record for patient A.G. Tr. 71–72; GX 14. Government Exhibit 15 is a record kept by the Respondent for patient A.G. with information about the patient as well as notes. Tr. 73–74; GX 15. It was electronically downloaded from the Respondent's computer system during the AIW search. Tr. 75. The DEA also obtained Government Exhibits 16 and 17 during the AIW search. Tr. 76–81, 140; GX 16–17. Government Exhibits 16 and 17 are dispensing records for patient A.G. maintained by the Respondent and obtained from the pharmacy. *Id.*

Government Exhibit 19 is a PDMP dispensing record for patient A.H. Tr. 81–82; GX 19. The Government moved for the admission of Exhibits 19 through 43 and 46 through 52 as a group. Tr. 85–87. These exhibits were either obtained from the Respondent during the AIW search in September 2018 or printed from the PDMP. *Id.* They relate to the specific patients identified in the OSC/ISO. *Id.*

After executing the AIW at the pharmacy in September 2018, DI Albert sent the records he obtained to a pharmacy expert, Dr. Donald Sullivan, for review. Tr. 88. DI Albert served another subpoena on the Respondent in May 2019. Tr. 88–89; GX 68. Attached to the subpoena is a list of seven patients. Tr. 89; GX 68, p. 2. This subpoena requested that the Respondent produce five categories of documents, to include (1) patient profiles for the patients identified in the attachment; (2) other records documenting the steps taken to avoid or resolve any issues or red flags with prescriptions; (3) original prescriptions and fill stickers of all prescriptions filled for patients listed in the attachment from September 10, 2018, to May 10, 2019; (4) any pharmacist notes evaluating potential red flags with prescriptions; (5) and any other documentation related to the specific patients identified, such as dispensing records, billing records, PDMP records, and medical records. Tr. 89–90; GX 68.

DI Albert received additional documents from the Respondent in response to the May 2019 subpoena. Tr. 94. The documents that DI Albert received related to patients A.G. and R.B. are contained in Government Exhibits 18 and 44. Tr. 94–98; GX 18, 44. DI Albert sent the documents that he received in response to the May 2019 subpoena to the expert witness for review. Tr. 118. He then began preparing the OSC/ISO. Tr. 118–19.

In his investigation of the Respondent, DI Albert calculated the approximate distances from the cities where patients lived to the Respondent pharmacy. Tr. 99–105, 130. DI Albert made these calculations by using Google Maps to determine the distance from the cities of residence to the Respondent's address. Tr. 99–101. The approximate distances on Google Maps are contained in Government Exhibit 54.[6] Tr. 99; GX 54.

DI Albert also searched for specific addresses in Google Maps. Tr. 105–12. Each of the specific addresses that DI Albert searched relate to a specific patient. Tr. 106, 108–09, 111–12. The one-way distances from those addresses to the Respondent are in Government Exhibits 55 through 60 and 62 through 65. Tr. 105–12; GX 55–60, 62–65.

Government Exhibit 55 shows a distance of 131 miles.[7] Tr. 106; GX 55, p. 1. Government Exhibit 56 shows a distance of 132 miles. Tr. 109; GX 56, p. 1. Government Exhibit 57 shows a distance of 148 miles. Tr. 110; GX 57, p. 1. Government Exhibit 58 shows a distance of 134 miles. GX 58, p. 1. Government Exhibit 59 shows a distance of 130 miles. GX 59, p. 1. Government Exhibit 60 shows a distance of 144 miles. GX 60, p. 1.

Government Exhibit 62 shows a distance of 137 miles. GX 62, p. 1. Government Exhibit 63 shows a distance of 138 miles. GX 63, p. 1. Government Exhibit 64 shows a distance of 131 miles. GX 64, p. 1. Government Exhibit 65 shows a distance of 138 miles. GX 65, p. 1.

Government Exhibit 61 shows the roundtrip distance from patient M.M.'s home, to the doctor's office, to the Respondent, and then back home. Tr. 112–18, 131, 172; GX 61. The total roundtrip distance from M.M.'s home to the doctor's office and the Respondent, and then back home, is 327 miles. Tr. 117, 131; GX 61, p. 1. Although DI Albert searched for the roundtrip distance between M.M.'s home, doctor's office, and the Respondent, he did not check to see whether M.M. filled any prescriptions at the Respondent in Tampa on the same day that he obtained them from the doctor in Fort Myers. Tr. 133, 171. DI Albert is therefore not sure whether M.M. ever made the roundtrip drive that is depicted in Government Exhibit 61. *Id.* If M.M. had travelled from her home to the doctor's office and the Respondent on separate days, however, the total travel distance would be similar to the roundtrip distance travelled on one day.[8] Tr. 173.

[6] Although Google Maps includes estimated travel times as well as mileage, due to the high variability of travel times, only the mileage is being considered herein.

[7] The Google Maps printouts list three routes with different distances and travel times. When speaking of the distances between patients' homes and the Respondent, I will refer to the route with the shortest mileage.

[8] The distance from M.M.'s home to her doctor's office is 134 miles. GX 61, p. 3. Thus, the total distance travelled if M.M. went to the doctor and returned home on the same day would be 268 miles. The distance from M.M.'s home to the Respondent is 38 miles. Tr. 134; GX 61, p. 6. Thus, the total distance travelled if M.M. went to the Respondent and returned home on the same day would be 76 miles. Added together, these distances total 344 miles. Thus, if M.M. travelled to her doctor's office to obtain a prescription on one day and returned home, and then travelled to the Respondent on another day to fill the prescription and returned home, the total distance travelled to obtain and fill that prescription would be slightly higher (344 miles) than if she had made the roundtrip drive from home, to the doctor's office, to the pharmacy, and back home, all in one day (327 miles). However, during the hearing, counsel

Continued

DI Albert was candid in conceding there were matters and facts of which he was unaware. For example, during his investigation, DI Albert readily conceded he did not talk to any of the 11 patients named in the OSC/ISO. Tr. 123–24, 155. He also conceded that he did not contact the subject prescribing doctors. Tr. 125–26, 128, 173–74, 178–80. DI Albert also conceded that he was unfamiliar with the FDA guidelines on compounding and that he did not receive training on compounding during DI training. Tr. 152. He also admitted that he did not familiarize himself with the Florida laws governing pharmacies, and that he only applied federal law in his investigation. Tr. 152–53. DI Albert also candidly acknowledged that he did not know the significance of the citations to Florida law in the subpoenas that he served. Tr. 153–54. In addition, DI Albert acknowledged that he had not done a comparison of the Respondent's daily, weekly, and monthly dispensing volume to other nearby pharmacies. Tr. 167–68.

DI Albert's willingness to concede these points, excepting in these areas, bolsters his credibility. DI Albert's testimony focused primarily on identifying exhibits and describing his investigation. Based on my close observation of DI Albert at the hearing, my careful review of his testimony in the transcript, and in conjunction with other credible evidence, I find DI Albert to be a credible witness. DI Albert presented as an impartial investigator with no direct stake in the outcome of the case, and his testimony was straightforward, professional, and candid. Furthermore, his testimony was also detailed and internally consistent. For these reasons, I fully credit DI Albert's testimony and find that his testimony merits considerable weight in this Recommended Decision.

Task Force Officer (TFO) Jeffrey Shearer

TFO Shearer has been running a private investigation business for the past five years. Tr. 182. Before that, he was a police officer with the Tampa Police Department for 16 years. *Id.* He spent the last five-and-a-half years of his career with the Tampa Police Department as a task force officer working out of the DEA's Tampa District Office. Tr. 182–83. As a TFO, Mr. Shearer worked with the DEA in the Tactical Diversion Squad on investigations related to the diversion of controlled substances. Tr. 182.

TFO Shearer worked on an investigation of the Respondent. Tr. 183. In May 2012, during execution of an AIW at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. *Id.* Mr. Clement, Sr., was cooperative during execution of the AIW. Tr. 192. Mr. Clement, Sr., was not in custody at the time and was free to leave. Tr. 183. In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183–84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2-$10 per pill. *Id.* Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it was cost effective.[9] Tr. 184–85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id.* Mr. Clement, Sr., was not charged with a crime. Tr. 190.

Based on listening to him testify at the hearing, and reviewing the transcript of his testimony, I find TFO Shearer to be a credible witness who testified in a candid, professional, and straightforward manner. TFO Shearer testified regarding events that had occurred approximately seven years prior to the hearing. He seemed fully capable of recalling the majority of those events with ease, but it is not surprising that some of his answers lacked detail. Any lack of detail, however, did not detract from his credibility or the usefulness of his testimony. He was honest about what he could not recall and he presented as an impartial individual without a direct stake in the outcome of the case. For these reasons, TFO Shearer's testimony is credible and merits significant weight in this Recommended Decision.

Dr. Donald L. Sullivan [10]

Dr. Sullivan is presently employed as a professor of Clinical Pharmacy at Ohio State University College of Pharmacy, and has been for five years. Tr. 196–97. *See* GX 53. Previously, he was employed at Ohio Northern University for 17 years. Tr. 197. He obtained his Bachelor's degree in 1990. Tr. 198. In 1991, he obtained his Master's in pharmacy administration, and his doctorate in pharmacy administration in 1996. Tr. 198. At Ohio State, in addition to performing research, he teaches pharmacy practice law to all four years of students. He teaches two courses on pharmacy operations, financial analysis, marketing, and human resource issues. Tr. 197. His courses cover professional standards for pharmacy personnel, including: Dispensing; record keeping; documentation; drug utilization review; patient education and counseling; compounding from a pharmacy practice perspective, as well as state and federal statutes governing the practice of pharmacy. The study of federal law comprises about 50-percent of the legal curriculum. Tr. 197–98, 203.

He has lectured to independent pharmacies on behalf of wholesalers, including Cardinal Health, AmerisourceBergen, HD Smith, as well as several pharmacy organizations. Tr. 199. For the past four years, he has presented a two-hour Continuing Education program to Florida pharmacists on controlled substance dispensing. Tr. 199. Within the past two-to-three years, Florida has increased the professional requirements for pharmacists, to include validating controlled substance prescriptions, understanding different types of diversion, red flags for diversion, how to resolve red flags, naloxone availability, and state and federal laws governing dispensing controlled substances and related record keeping. Tr. 200. Dr. Sullivan has authored five publications, consumer drug reference books, as well as several peer-reviewed publications. Tr. 200. He has completed a research study into community pharmacists, the resources they use in identifying red flags, and their willingness to identify red flags of diversion. Tr. 202. He presents training for government investigators and attorneys. Tr. 203. He has been qualified as an expert in a California criminal trial and in four DEA show cause hearings similar to the instant hearing. Tr. 201, 354–55, 359.

He is a registered pharmacist in Ohio and in Florida. Tr. 198. He has worked as a pharmacist in Ohio, but not in Florida. Tr. 198. However, he has not worked in retail pharmacy for 20 years. Tr. 414. His background is primarily in community pharmacy, which relates to typical private pharmacies and chain pharmacies. Tr. 199. He has also had experience at a pharmacy located within a mental health clinic, and in a mail order pharmacy. *Id.*

Dr. Sullivan described a recent problematic trend in medication reimbursement in which the pharmacies are sometimes being reimbursed less than their actual costs to purchase the

for the Government conceded, and Dr. Sullivan confirmed, it was the distance from the patient's home to her physician's office which represented the red flag of long distance. Tr. 294.

[9] [Footnote omitted for relevance.]

[10] [I agree with the ALJ's discretionary decision to allow the Government to ask leading questions of its expert witness, over objection by Respondent's counsel. *See* RD, at n.10.]

medications. Tr. 430–31. This trend has caused small independent pharmacies to seek niche markets. Tr. 431.

Through his education, training, and experience, Dr. Sullivan is familiar with compounding in retail pharmacy, as well as issues related to abuse and diversion of controlled substances, and with the responsibilities of a retail pharmacist in the detection and prevention of such abuse and diversion. Tr. 203. Dr. Sullivan is also familiar with a pharmacist's corresponding responsibility under federal law, and the standard of care and professional obligations of a pharmacist in the state of Florida. Tr. 204. Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the state of Florida. Tr. 204–05, 490.*[D]

Dr. Sullivan described the duties of a pharmacist in filling a controlled substance prescription. Tr. 206. First, the pharmacist must ensure the prescription is a ''valid prescription for a legitimate medical purpose.'' *Id.* That is, the pharmacist must determine if it is issued ''in the normal course of professional practice,'' that the pharmacist believes the patient can safely take it, that the medication is for an actual medical purpose, and is not being abused, misused, or diverted. *Id.* These requirements are codified in both federal and Florida law. Fla. Admin. Code r. 64B16–27.800, .810, and .831.

In reviewing a prescription, a pharmacist must first determine if the prescription appears legal on its face; that all the information necessary appears on the face of the prescription. Tr. 208. Then, applying clinical expertise, the pharmacist must consider possible over-utilization and under-utilization, where the patient is taking more or less medication than prescribed; consider possible abuse or misuse; whether it is serving a legitimate medical purpose; and whether it exposes the patient to potential undue risk of side-effects, adverse effects, or overdose. Tr. 208–09. The Florida standard of care requires pharmacists to document their resolution of any potential issues discovered in the pharmacist's review of a prescription. Tr. 210, 437, 489.

Dr. Sullivan was unaware that Florida had codified a definition of ''standard of care'' for healthcare workers. Tr. 438; Fla. Stat 766.102.[11] He was unaware of the Florida Patient Bill of Rights. Tr. 462. Dr. Sullivan initially conceded there was no federal or Florida regulation mandating where or how the resolution of red flags must be documented. Tr. 435–37. In particular, Dr. Sullivan agreed that Florida Administrative Code r. 64B16–27.831, Standards of Practice for the Filling of Controlled Substance Prescriptions, subpart three, is silent as to whether a pharmacist must document the steps a pharmacist takes to validate a prescription. Tr. 449–50, 453–54. [However, Florida Administrative Code r. 64B16–27.831 requires pharmacists to record ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug,'' which Dr. Sullivan agreed would generally include the information that is needed to resolve red flags. Tr. 488–89.]

In conjunction with the precautionary evaluation described, the pharmacist is required to maintain a ''patient profile'' for each patient, which includes: The patient's full name, address and telephone number, age or date of birth, gender, a list of all new and refilled prescriptions obtained by the patient at the pharmacy, and any notes or comments by the pharmacist particular to that patient, such as drug allergies or contraindications. Tr. 209–10.

Dr. Sullivan explained that under federal law, the pharmacist has a corresponding responsibility, an equal responsibility with the prescribing physician, to determine if a prescription has been written for a legitimate medical purpose. Tr. 210–11. That a prescription is written by a physician does not absolve the pharmacist from ensuring that it is for a legitimate medical purpose. Tr. 211. Common potential concerns for a pharmacist are referred to as ''red flags.'' Red flags include potential for diversion or abuse, patients traveling long distances to see their physicians, or to the pharmacy [12] [13] ''drug cocktails commonly abused, large dosage units, payment in cash for all or part of a patient's prescriptions,[14] over-prescribing of immediate release pain killers, and patients traveling in groups. Tr. 213–15, 240–41 [15], 473–76. Traveling long distances to a pharmacy creates the suspicion that pharmacies closer to the patient have declined to fill that particular prescription. Tr. 220. Drug cocktails, or drug combinations known for abuse, such as the combination opioid/benzodiazepine, represent a ''red flag.'' Tr. 220–21; GX 66. Indeed, the FDA issued a ''black box'' warning in August 2016, highlighting the potential danger to the patient of this combination of medications. Tr. 221–23. Cash payment for medications is a red flag as medications are typically expensive and normally patients will defer those costs to their health insurance. Tr. 224–25. Dr. Sullivan testified that ''[t]he theory behind [cash payments] is that patients are selling [the drugs] and that's where they're getting all the cash from.'' *Id.* at 225. Early refills, or early fills of new prescriptions, are suspicious as they may suggest the patient is not taking the medication as prescribed. Tr. 224–25. Florida initiated annual CME four years previously involving ''validation and appropriate use of controlled substances.'' Tr. 235. Florida pharmacists are taught to identify the

*[D] Throughout the case, the Government's expert and all parties appear to have used the phrases ''standard of care,'' ''corresponding responsibility,'' and ''usual course of professional practice'' interchangeably. Dr. Sullivan testified that in the practice of pharmacy the phrases ''standard of care'' and ''usual course of professional practice'' are the same. Tr. 321–22. Dr. Sullivan's testimony regarding the requirement to resolve red flags clearly related to Respondent's corresponding responsibility under 21 CFR 1306.04. The interchangeable use of this terminology does not impact my ultimate finding that Respondent failed to resolve red flags in contravention of Respondent's corresponding responsibility under 21 CFR 1306.04 and outside the usual course of professional practice in violation of 21 CFR 1306.06. For consistency purposes, I will use the language regarding standard of care to encompass corresponding responsibility herein.

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

[12] Dr. Sullivan noted 90% of prescriptions filled at the Respondent involved patients living more than 100 miles from the pharmacy. Tr. 235.

[13] Dr. Sullivan conceded that he was not aware of any federal or Florida regulation limiting the distance traveled to fill a prescription. Tr. 462.

[14] Dr. Sullivan conceded that he was not aware of any federal or Florida laws that prohibit pharmacies from accepting cash as payment for prescriptions. Tr. 444.

[15] 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 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.

above red flags, to resolve them, and to document the resolution. Tr. 235–36.

To resolve red flags, a pharmacist should discuss the matter with the patient, and attempt to get to know each patient. Tr. 239, 445–49; *see* Fla. Admin. Code r. 64B16–27.831. The pharmacist should also discuss the matter with the prescribing physician, which would provide another source of input for the pharmacist. Tr. 229. However, the prescribing physician can never be the only source of information obtained. Tr. 229. Next, the pharmacist would review the patient's drug record, the PDMP, to determine other medications and the strengths of those medications, and conduct a ''prospective drug utilization review,'' to make an independent clinical evaluation whether the subject prescription was written for a legitimate medical purpose. Tr. 211, 227. Once the pharmacist makes his independent clinical evaluation, the standard of care requires the pharmacist to document his evaluation. Tr. at 210, 228, 488–89; *see also* Tr. 236.

If a pharmacist is unable to resolve the red flags he should decline to fill the prescription. Tr. 228, 488. *[Omitted for relevance.]

*[Dr. Sullivan testified that a pharmacist does not look at individual red flags in isolation; rather, he looks at them ''as a collective whole based on what's going on with that prescription at that time.'' Tr. 482, 498. When asked whether you can evaluate a prescription based on isolated red flags alone, Dr. Sullivan testified that ''[i]t's like pieces in a puzzle, you look at everything related to that prescription and patient.'' Tr. 498.

Dr. Sullivan testified that there are some red flags that, ''when taken as a collective whole[,] . . . cannot be resolved.'' Tr. 481. Dr. Sullivan testified that in these circumstances, ''no matter what the patient tells me, what the doctor tells me, any of that, I'm still not filling the prescription.'' Tr. 282. Dr. Sullivan testified that an individual red flag (such as long distances traveled or cash payments) may become unresolvable if it is combined with multiple additional red flags. Tr. 473 (testifying that there is nothing that the patients could have told Respondent to resolve the distance red flag in conjunction with the other red flags); Tr. 475 (testifying that Respondent's lack of contracts for commercial insurance does not resolve the red flag of cash payment ''when taken into account with the other red flags on these prescriptions''); *see also* Tr. 409–11 (testifying that when there are ''so many [red flags],'' a pharmacist can make the decision not to fill a prescription without calling the prescribing physician).]

Dr. Sullivan testified that [it is often difficult to determine whether any individual red flag is unresolvable, because] red flags should be evaluated in combination. Tr. 480–86, 498. However, he testified that a single red flag could be so egregious that it was unresolvable. Tr. 497–99.

Dr. Sullivan explained compounding, in which a pharmacist ''makes a drug . . . from scratch . . . to meet the unique therapeutic needs of a patient.'' Tr. 230. Typical justification for compounding may include a patient's allergies to certain ingredients within commercially manufactured medications, or the unavailability of a particular medication, or strength of medication required for treatment among commercially available medications. Tr. 230–32, 336–38. Both oxycodone 30 mg, and hydromorphone 8 mg, are commercially available. Tr. 232. [Dr. Sullivan testified that compounding would typically be a ''very very small'' percentage of a pharmacy's business because it is ''very time and labor intensive. Tr. 232.]

Dr. Sullivan reviewed materials sent to him by DI Albert related to Respondent's dispensing. Tr. 233, 349, 405–06. These materials included the Respondent's pharmacy prescription log covering approximately three months [GX 11], PDMP data over an eighteen-month period [GX 8–10], and the Respondent's Prehearing Statement, which included witness summaries. Tr. 341–43, 347–48. Dr. Sullivan did not speak with the pharmacy customers at issue. Tr. 407, 416–18. Dr. Sullivan did not review copies of the actual prescriptions. Tr. 348, 416, 500. Dr. Sullivan agreed that the average 4–5 prescriptions filled at the Respondent's pharmacy per day were much fewer than the average community pharmacy of 190 prescriptions. Tr. 420.

Dr. Sullivan reviewed a list of prescriptions issued by Dr. L. Tr. 251; ALJ Ex. 42 [16], p. 8. Dr. L.'s prescriptions for the highest strength available opioid was a potential red flag for diversion or abuse. Tr. 251–52. As to Dr. P., whose prescribing history revealed he prescribed 65,000 doses of hydromorphone 8 mg to only 135 doses of hydromorphone 4mg, Dr. Sullivan opined that a prudent pharmacist would not fill Dr. P.'s prescriptions for the highest dosage of hydromorphone. Tr. 253, 496. Similarly, Dr. Sullivan opined a reasonable pharmacist would not fill Dr. P.'s prescriptions for oxycodone 30 mg, as Dr. P. prescribed over 24,000 dosage units of oxycodone 30 mg, to only 200 of the lower dosage units. Tr. 253–54.

Turning to specific patients, Dr. Sullivan opined the distance traveled by Patient A.G. from his home to the Respondent's pharmacy was a red flag. Tr. 254; GX 55; ALJ Ex. 42, p. 10. In reviewing A.G.'s prescription history, he was always prescribed the highest dose of hydromorphone and of oxycodone, and except for one instance, the highest dose of alprazolam. Tr. 254–55; GX 17; ALJ Ex. 42, p. 11. The combination of opioid and benzodiazepine, coming even after the FDA's black box warning, is a well-known red flag of diversion and abuse. Tr. 255–56. A review of the PDMP report revealed the dangerous combination of the highest dosage unit of opioid along with a benzodiazepine, in addition to early fills on April 12, 2019, representing unresolvable red flags. Tr. 256–57, 267; GX 14; ALJ Ex. 42, p. 12.

A review of Patient A.G.'s patient profile in RX30, and of the prescriptions and fill stickers, failed to resolve the red flags noted or to justify the compounding done. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. In the patient memo, it simply stated, ''Doctor OK to receive medication in compound capsule form,'' which Dr. Sullivan testified is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 257–59; GX 15; ALJ Ex. 42, p. 13. *See* 21 U.S.C. 802(10), (15). In addition, Dr. Sullivan noted that A.G. was prescribed both capsules and tablets of oxycodone 30 mg between November 8, 2017, and January 25, 2018, demonstrating there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 256.

Dr. Sullivan was suspicious of the patient questionnaire used by Respondent. Tr. 259–60; GX 18. The questionnaire questioned whether the patient lived more than 100 miles from the pharmacy. Dr. Sullivan interpreted the questionnaire as cover for filling prescriptions for distant patients, rather than an effort to disclose or resolve red flags. Tr. 259–61; GX 18. A follow-up question to the distant traveling patients asked, ''why do you travel this distance,'' and in this case, the patient responded, ''quick and good service.'' Tr. 262. Dr. Sullivan opined that this reason was insufficient to resolve the red flags. The questionnaire contained a certification to be made by the patient, certifying that ''I am taking all of my medication prescribed.'' Tr. 262. Dr. Sullivan deemed this certification ineffectual in resolving the red flags of

[16] The Government's demonstrative exhibit will be marked as ALJ Exhibit 42.

early fills and of diversion. A further statement by the patient that, ''I am not selling any of my medication,'' did not alleviate any concerns that the patient may have been diverting his medication. Tr. 262. Indeed, Dr. Sullivan suspected the question exposed a subterfuge by the pharmacy, revealing the pharmacy believed patients were selling their medications, and the question was designed to relieve the pharmacy of any liability. Tr. 263. If a pharmacist believes a patient is selling his medications, the pharmacist should not fill any further prescriptions of that patient. Tr. 264.[17] Dr. Sullivan was directed to the ''Pharmacy Comment'' at the bottom of the prescriptions for A.G. Tr. 265–66; GX 18, p. 6. The notation, ''non acute pain Uninsured Patient'' suggested to Dr. Sullivan that whoever made the notations was trying to signal that this medication therapy was ongoing and to provide some justification for cash payment. Tr. 266.

As to Patient A.H., Dr. Sullivan opined the 132 miles from A.H.'s home to the Respondent pharmacy represented a red flag. Tr. 268; GX 56; ALJ Ex. 42, p. 14. The prescriptions from January to August, 2018 contained several red flags including, highest dosage of short acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 269. Later prescriptions for A.H. revealed significantly early fill dates for four consecutive months. Tr. 269–71; GX 19; ALJ Ex. 42, p. 16. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 271–72. The fact that the prescribing physician wrote the prescriptions early does not relieve the pharmacist's responsibility to resolve the red flag of early fills. Tr. 272. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to Patient A.H. Tr. 272–73. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice to decline filling the prescriptions for A.H. Tr. 272–73; GX 19, 21; ALJ Ex. 42, p. 15–16.

As to Patient B.S., Dr. Sullivan opined the 132 mile distance from B.S.'s home to Respondent represented a red flag. Tr. 273; GX 57; ALJ Ex. 42, p. 18. The prescriptions from August 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 274, 276. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. He opined that a once a day ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan interpreted the ibuprofen as an attempt to demonstrate that the doctor was trying an alternate therapy as opposed to prescribing controlled substances without a legitimate medical purpose, which Dr. Sullivan viewed as a red flag. Tr. 275. Later prescriptions for B.S. revealed significantly early fill dates. Tr. 275–76; GX 22; ALJ Ex. 42, p. 20. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 276–78. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient B.S. Tr. 277. Dr. Sullivan opined that, for the reasons discussed above, he relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice would have declined to fill the prescriptions for B.S. GX 22, 24; ALJ Ex. 42, p. 19–20.

As to Patient C.R., Dr. Sullivan opined the 134 miles from C.R.'s home to Respondent represented a red flag. Tr. 279; GX 58; ALJ Ex. 42, p. 22. The prescriptions from July 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-reliever, oxycodone 30 mg, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and the muscle relaxant tizanidine. A July 12, 2018 prescription for morphine sulphate 60 mg per day further heightened the danger to the patient. Tr. 280. Dr. Sullivan deemed these unresolvable red flags. Tr. 279–82; GX 27; ALJ Ex. 42, p. 23. A review of this patient's profile by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient C.R. Tr. 281. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist operating within the usual course of professional practice to decline filling the prescriptions for C.R. Tr. 281–83; GX 27; ALJ Ex. 42, p. 23.

As to Patient J.D., Dr. Sullivan opined that the 130 miles from J.D.'s home to the Respondent pharmacy represented a red flag. Tr. 283; GX 59; ALJ Ex. 42, p. 23. The prescriptions from January 2018 to September 2019 contained several red flags including, highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; and the combination of two short-acting pain-relievers, hydromorphone and methadone 10 mg, resulting in an ''extreme risk of overdose.'' Tr. 283–84, 468; GX 30; ALJ Ex. 42, p. 26. Dr. Sullivan deemed these red flags unresolvable and testified that a reasonable pharmacist operating within the usual course of professional practice would not have filled these prescriptions. Tr. 284, 288–89. Several prescriptions filled in mid-2018 revealed unjustified early fills. Tr. 284–87; GX 30; ALJ Ex. 42, p. 27. The pharmacist noted in J.D.'s patient profile, ''NEXT FILL DATE 7/5/18!!! WATCH FILL DATES!!!!!!,'' demonstrating the Respondent knew of J.D.'s issues with early fills. Such note is insufficient to justify filling J.D.'s prescriptions early. Tr. 287–88; GX 29; ALJ Ex. 42, p. 28.

As to Patient J.M., Dr. Sullivan opined that the 144 miles from J.M.'s home to Respondent represented a red flag. Tr. 289; GX 60; ALJ Ex. 42, p. 29. The prescriptions from June 2017 to September 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of oxycodone and hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and a muscle relaxer. Dr. Sullivan deemed these unresolvable red flags. Tr. 290–91. Dr. Sullivan noted that J.M. was prescribed both capsules and tablets of oxycodone 30 mg between April 2018 and May 2018 demonstrating

[17] Dr. Sullivan also questioned the prescribing protocol for A.G., in that he was prescribed alternate monthly doses of 30 mg oxycodone and 10 mg of oxycodone. Tr. 264; GX 18, p. 6. However, I believe Dr. Sullivan misread the 30 mg oxycodone prescription of October 30, 2018, as a 10 mg dosage due to a poor copy. So, his conclusions in this regard will not be considered.

there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 290. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient J.M. *Id.* Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist acting within the usual course of professional practice to decline to fill the prescriptions for J.M. Tr. 291; GX 33; ALJ Ex. 42, p. 30.

As to Patient M.M., Dr. Sullivan opined the distance between M.M.'s home and the prescribing physician's office, south of Ft. Myers, Florida, represented a red flag. Tr. 294; ALJ Ex. 42, p. 32. In reviewing M.M.'s dispensing log, Dr. Sullivan identified many of the same red flags as revealed by the other patient's records: high-strength hydromorphone prescribed and dispensed; and capsules of hydromorphone dispensed without individualized therapeutic justification. Tr. 295; GX 36; ALJ Ex. 42, p. 33. Dr. Sullivan was also suspicious of the .4 mg of folic acid, which he suspected was intended to mask the opioid prescriptions. Tr. 295–96. In reviewing the prescriptions filled from January 2019 to April 2019, Dr. Sullivan noted that the Respondent filled both capsules and tablets of hydromorphone, thus negating any prospect that the patient had an individualized therapeutic need for compounded medication. Tr. 297–98; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan was also concerned regarding a significant break in therapy, from July 18, 2018, and January 3, 2019. Tr. 297. Despite an almost six-month lapse in opioid therapy, the Respondent filled a prescription for hydromorphone 8 mg, the highest commercially available dosage. Tr. 298. If the patient had become opioid naïve during this lapse, there is a heightened risk of overdose. Tr. 298. Dr. Sullivan also recognized some red flags in the form of early fills. Tr. 299; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan deemed the above red flags unresolvable, and testified that no reasonable pharmacist acting within the usual course of professional practice would have filled the subject prescriptions. Tr. 299–301.

As to Patient N.B., Dr. Sullivan opined the 137 miles from N.B.'s home to the Respondent pharmacy represented a red flag. Tr. 301; GX 62; ALJ Ex. 42, p. 36. The prescriptions from June 2017 to August 2018 contained several red flags, including highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; two separate prescriptions for alprazolam with two separate dosage units; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. A once a day low ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan found these red flags unresolvable. Tr. 302–03, 305–06; GX 39; ALJ Ex. 42, p. 37. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 303–04; GX 37; ALJ Ex. 42, p. 38. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 306–07; GX 37, 39; ALJ Ex. 42, pp. 38–39. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 14, 2018, and December 20, 2018, potentially producing opioid naïveté in the patient. Tr. 304. In the patient memo, it simply stated, ''Doctor ok patient to receive medication in compound capsule form,'' which, according to Dr. Sullivan, is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 306, 471; GX 38; ALJ Ex. 42, p. 39.

As to Patient R.B., Dr. Sullivan opined the 138 miles from R.B.'s home to Respondent represented a red flag. Tr. 307; GX 63; ALJ Ex. 42, p. 40. Dr. Sullivan further asserted that the number of patients traveling from the Ft. Myers area to Respondent represented a red flag itself. Tr. 308. The coincidence of patients traveling over 100 miles to the Respondent's pharmacy from the same proximate area represents a pattern that the standard of care would require a pharmacist to notice and to investigate. Tr. 309–10.

The prescriptions from June 2017 to August 2018 contained several red flags, including highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; prescriptions for alprazolam at the highest dosage strength; and the combination of an opioid and benzodiazepine. Dr. Sullivan found these red flags were not resolvable according to the standard of care in Florida. Tr. 311, 313, 321; GX 43; ALJ Ex. 42, p. 41. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 311–12; GX 40; ALJ Ex. 42, p. 42. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 12, 2018, to January 22, 2019, potentially producing opioid naïveté in the patient. Tr. 312, 471. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 313; GX 41; ALJ Ex. 42, p. 41. In R.B.'s Patient Questionnaire, R.B. gave conflicting information as to the year of her injury. Tr. 313–14. Furthermore, R.B.'s justification for traveling more than 100 miles to the Respondent's pharmacy, ''it's cheaper and they're good people,'' does not resolve the red flag of long-distance travel. Tr. 315; GX 44. Nor does R.B.'s declaration that she is not selling her medications resolve concerns of diversion. Tr. 315. Patient R.B.'s PDMP report reveals she filled prescriptions at five different pharmacies, including the Respondent's pharmacy. Tr. 316–17; GX 44, p. 5. Dr. Sullivan views this as clear evidence of pharmacy shopping. Another suspicious entry in the PDMP record is the payment source for an April 6, 2016 prescription for oxycodone acetaminophen, and two August 22, 2017 prescriptions for hydrocodone, which were paid for using commercial insurance. Tr. 317–18; GX 44, p. 4. A patient alternately paying cash and using commercial insurance is a red flag of diversion or abuse. Tr. 318–19.

Dr. Sullivan noted prescriptions for R.B. in which it appeared the pharmacist, by permission of the prescribing physician, changed the prescribed ''tablet'' form of medication to compounded capsule. Tr. 319–20; GX 44, pp. 6, 8. As the ''tablet'' form was initially prescribed, changing to compounded capsule does not appear to have been done on the basis of an individualized therapeutic purpose. Tr. 321.

As to Patient R.G., Dr. Sullivan opined the 131 miles from R.G.'s home to the Respondent pharmacy represented a red flag. Tr. 322; GX 64; ALJ Ex. 42, p. 44. The prescriptions from June 2017 to September 2018 contained several red flags, including highest dosage of short-acting pain-reliever, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; the highest strength for alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 322–24, 329–30. A further indication that there was no therapeutic justification for the compounded capsules of oxycodone 30 mg was the two fills on August 10, 2018, for oxycodone. Tr. 324; GX 49; ALJ Ex. 42, p. 45. R.G. was dispensed 68 tablets and 70 capsules on that same day. Tr. 324–26. Dr. Sullivan found these red flags unresolvable. Tr. 322–23, 326,

328–29; GX 49; ALJ Ex. 42, p. 45. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 326–28; GX 49; ALJ Ex. 42, p. 46. The pharmacist noted in R.G.'s patient profile, ''WATCH FILL DATES!!!!!!,'' demonstrating the Respondent knew of R.G.'s issues with early fills. Such note is insufficient to justify filling R.G.'s prescriptions early. Tr. 328; GX 47; ALJ Ex. 42, p. 47. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 329; GX 49; ALJ Ex. 42, p. 45.

As to Patient R.L., Dr. Sullivan opined the 138 miles from R.L.'s home to the Respondent pharmacy represented a red flag. Tr. 330; GX 65; ALJ Ex. 42, p. 48. The prescriptions from June 2017 to September 2018 contained several red flags, including highest dosage of short-acting pain-relievers, hydrocodone 8 mg and oxycodone 30 mg; capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; the highest strength of alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan was concerned by the promethazine 25 mg prescription, as it acts as a muscle relaxant with sedative qualities, thus increasing potential side effects in combination with the opioid and benzodiazepine medications. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 331–32, 329–30. Dr. Sullivan found these red flags unresolvable. Tr. 332; GX 52; ALJ Ex. 42, p. 49.

The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 333–35; GX 52; ALJ Ex. 42, p. 51. The pharmacist noted in R.L.'s patient profile, ''NEXT FILL 6/10/18–10 DAYS EARLY MARCH & APRIL–TOLD HIM THIS 5/11/18GD,'' demonstrating the Respondent knew of R.L.'s issues with early fills. Such note is insufficient to justify filling R.L.'s prescriptions early. Tr. 334–35; GX 51; ALJ Ex. 42, p. 52. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 335–36; GX 50, 52; ALJ Ex. 42, pp. 49–52.

Finally, Dr. Sullivan opined that the compounding done in this case was not legitimate, as it was outside the standard of practice. Tr. 336–38. Dr. Sullivan explained that the FDA wants pharmacists to have the ability to compound to address the rare cases of patients with special needs, such as allergies. Tr. 337–38. If a patient had an allergy that required compounding, Dr. Sullivan would expect that to be documented in the patient profile. Tr. 339. However, compounding is also the subject of licensing and regulation. Tr. 339–40. *See* 21 U.S.C. 353a; Fla. Admin. Code r. 64B16–27.700, .797. Manufacturing is not permitted under a standard community retail pharmacy license. Tr. 340. It requires specific licensing. *Id.*

Dr. Sullivan noted that 95 or 96 percent of the subject hydromorphone medication was compounded. Dr. Sullivan concluded the extreme volume alone as proof positive that the Respondent's compounding was not limited to patients with individualized therapeutic needs. Tr. 337. Although the Patient Profiles reviewed contained a category for ''allergy,'' no allergies were documented, either within the Patient Profiles or in any of the other records reviewed. Tr. 339; *see* Fla. Admin. Code r. 64B16–27.800(2). Dr. Sullivan found no evidence that any of the subject patients receiving compounded medications were subject to medication allergies. Tr. 339.

Expert Opinion

[Omitted for brevity.]

Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the State of Florida. He gave his opinion regarding the relevant standards of care in Florida for the practice of pharmacy, including the existence of red flags, or generally suspicious circumstances. He also gave his opinion regarding the parameters of lawful pharmacy compounding in light of federal statutes and regulations governing compounding and manufacturing. The relevant standard of care 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.]

Dr. Sullivan demonstrated a commanding grasp of pharmacy practice and of the distinctions between pharmacy compounding and manufacturing. However, there were several matters for which he had diminished credibility. For one, he was unaware that Florida had codified the standard of care for medical personnel. Although I later determined the statute in question did not apply to pharmacists, it was somewhat surprising he was unaware of it, as he teaches Florida pharmacy law.[18] [Text omitted.] *E [19]

[Text omitted.] *F

[18] However, under Florida Statute 766.102, pharmacists are not considered ''healthcare providers.'' This Florida law 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.

Fla. Stat. 766.202(4). Pharmacists are administered under chapter 465.

*E I have omitted the RD's statement that Dr. Sullivan agreed that this statute (which does not apply to pharmacists) was consistent with his understanding of the Florida standard of care for pharmacists. RD, at 39. I have also deleted the RD's statement that Dr. Sullivan ''arguably conceded an alternate generalized standard of care for pharmacists in Florida, which is not consistent with Florida law or regulation.'' *Id.* at 39–40. When Respondent's counsel asked Dr. Sullivan whether he was aware of the statute, and whether he agreed with the definition of the standard of care outlined in the statute, Dr. Sullivan replied, ''Is that out of the pharmacy statutes? I'm not familiar with that.'' Tr. 438. Respondent's counsel stated that the definition comes from Florida statute 766.102, and it applies to healthcare providers. *Id.* Dr. Sullivan replied, ''I'll take your word for it that that's what it says.'' *Id.* Their exchange continued:

Q: Okay. Do you agree that, that's the definition—the appropriate definition of the standard of care in Florida?

A: In a broad sense, yes.

Q: Okay. And it talks about reasonably prudent healthcare providers, correct?

A: Can you read that statement in there where it says that again, please?

Q: Sure, I would be happy to. I'll read you the whole thing just to make sure you have it all. ''The prevailing professional standard of care for a given healthcare provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar healthcare providers.

A: And what was the question again, please?

Q: Do you agree that that's an accurate statement of the standard of care that applies in Florida?

A: If that's what the statute says, yes.

Tr. 438–39. During this exchange, Dr. Sullivan did not testify that this statute outlines the standard of care for pharmacists. Dr. Sullivan agreed—when asked whether the statute outlined ''the appropriate definition of the standard of care in Florida''—that it captured the standard of care in a ''[i]n a broad sense.'' *Id.* Dr. Sullivan repeated several times that he was not aware of this statute, but he would ''take [counsel's] word for it'' that he was accurately reciting the definition from the statute. *Id.* I do not find that this testimony diminishes Dr. Sullivan's credibility as an expert in the standard of care for Florida pharmacists.

[19] [Text omitted where footnote was included.]

*F I have omitted the RD's assertion that Dr. Sullivan offered inconsistent testimony regarding unresolvable red flags. RD, at 40. I find that Dr. Sullivan's testimony on this issue was consistent, reliable, and supported by prior Agency Decisions. The RD found that Dr. Sullivan's testimony was

Continued

Dr. Sullivan deemed the questionnaire used by the Respondent as essentially a subterfuge, designed not to reveal red flags and enable the Respondent to assess them, but as cover for red flags already known to exist by the Respondent. This conclusion was developed on the basis of Dr. Sullivan's experience in reviewing pharmacies, which were found to be operating in violation of pharmacy standards. It seemed more in the nature of an observation of coincident patterns. This conclusion assumes the questionnaires were never intended to assist the Respondent in assessing red flags versus being a good faith effort to identify red flags, which was never fulfilled. If the questionnaires were designed to provide cover to the Respondent's illegal behavior, they fail to do so. I did not see the questionnaires as providing any cover to the Respondent's improper filling of prescriptions. If anything, the completed questionnaires highlighted and documented red flags of long-distance travel. The completed questionnaires are damning, not exculpatory. Although not dispositive of this issue, the Government has not alleged intentional diversion. I find Dr. Sullivan's subject conclusion more in the nature of speculation. I don't believe the record provides sufficient factual foundation to support this expert opinion.[20] I also find it inconsistent with the facts of the case. Accordingly, on the basis of the instant record, I find Dr. Sullivan's subject conclusion unjustified.

Dr. Sullivan made a similar conclusion regarding the prescribing of non-controlled substances and of controlled substances not subject to abuse or diversion. Again, he deemed such prescriptions as an apparent subterfuge on the part of the prescriber, designed to mask the improper prescribing of controlled substances highly subject to abuse and diversion, and creating a red flag, which went unaddressed by the Respondent. I question the sufficiency of the factual foundation for Dr. Sullivan's expert opinion that the above prescriptions were an apparent attempt to mask scores of improper opioid prescriptions. [Omitted for brevity].*G[21] This finding does not affect the probity of Dr. Sullivan's opinions as to the therapeutic effect of the subject medications, their contraindication with other prescribed medications, or the justification of their prescription.

The Respondent made the point that Dr. Sullivan did not confer with the subject patients or with their prescribing physicians. Dr. Sullivan 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 argues that the fact Dr. Sullivan did not discuss any red flags with the patients or with the prescribers renders Dr. Sullivan's conclusions regarding red flags questionable as Dr. Sullivan did not attempt to resolve the subject red flags.

Although certainly the extent of Dr. Sullivan's review of relevant material is critical to the conclusions he draws, the focus of Dr. Sullivan'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. Sullivan could have resolved his own concerns regarding the subject red flags by speaking to the patients and prescribers years later. Nor is it dispositive that Dr. Sullivan could have determined that the subject red flags were resolvable at the time they were dispensed, if the Respondent failed to satisfy his corresponding responsibility to resolve them. So, with the exception of his opinion regarding the apparent red flag created by the prescribing of non-controlled substances (discussed immediately above), I don't view the fact that Dr. Sullivan did not speak with the subject patients or prescribers as diminishing the probity of his relevant opinions as to the Respondent's acts or omissions at all.

The Respondent makes the similar point regarding the fact that Dr. Sullivan did not review copies of the physical prescriptions, as there is evidence Respondent may have made notations relevant to resolving red flags directly onto the prescriptions. Dr. Sullivan freely conceded he had not been provided with copies of the prescriptions to review. [Omitted for Relevance.] [However, because Dr. Sullivan credibly testified that the red flags for each patient could not have been resolved by a pharmacist acting within the usual course of professional practice, it was unnecessary for Dr. Sullivan to review the prescriptions.] Here, Dr. Sullivan was provided sufficient materials to develop his opinions, which assist the factfinder to understand or to determine facts in issue. [Citation omitted.]

[The RD does not make an explicit credibility finding on Dr. Sullivan's testimony, aside from stating that Dr. Sullivan was provided sufficient materials to develop his opinions and that he demonstrated a commanding grasp of pharmacy practice and the distinctions between pharmacy compounding and manufacturing. Based on these statements, and based on the controlling weight that the ALJ accorded Dr. Sullivan's unrebutted expert testimony in his legal analysis, it is evident that the ALJ found Dr. Sullivan's opinions to be generally consistent, reliable, and credible. I agree with that conclusion.]

Respondent's Case-in-Chief

The Respondent presented its case-in-chief through the testimony of a single witness, Norman L. Clement, Jr. Tr. 506–57.

Norman L. Clement, Jr.

Mr. Clement, Jr., is the son of Mr. Norman Clement, Sr., the Respondent's

inconsistent because he ''described several red flags as unresolvable,'' but later ''conceded that those same red flags could be resolved. *Id.* Additionally, the RD states that Dr. Sullivan ''at one point suggested no single red flag was unresolvable, rather it was the combination of red flags which made them unresolvable.'' *Id.* The RD does not cite to specific portions of the record here, but an earlier section of the RD discusses portions of Dr. Sullivan's testimony that the ALJ found confusing. RD, at 24.

The ALJ primarily seemed to be concerned with Dr. Sullivan's testimony about prescribing two immediate-release opioids concurrently. The ALJ asked Dr. Sullivan for an example of an unresolvable combination of red flags, and Dr. Sullivan testified that it would be unresolvable if a patient ''brought in a prescription for two immediate release narcotic pain killers *in very high doses.*'' Tr. 228 (emphasis added). The following day, the ALJ said to Dr. Sullivan, ''Yesterday you testified that the prescribing of two fast-acting opioids can never be permitted,'' and Dr. Sullivan replied, ''I'm sorry, Your Honor. If I said that, I misspoke.'' Tr. 481. Dr. Sullivan's testimony, however, had been that the prescribing of two immediate-release opioids *in very high doses* was unresolvable. *Id.* at 228. Dr. Sullivan clarified that there were instances were two immediate-release opioids could be used together. Tr. 481. Dr. Sullivan also testified that this red flag ''didn't apply to this case here.'' *Id.* at 482. I do not find that Dr. Sullivan's testimony about immediate-release opioids undermines his testimony about unresolvable red flags. Throughout the hearing, Dr. Sullivan consistently testified that a pharmacist should analyze all of the red flags with a prescription as a ''collective whole,'' rather than analyzing each red flag in isolation, and that certain combinations of red flags may not be resolvable ''when taken as a collective whole.'' Tr. 282, 409–11, 473, 475, 481–82, 498. Dr. Sullivan further testified that the red flags presented by each prescription in this case were unresolvable. As discussed in more detail below, Dr. Sullivan's testimony finds support in prior Agency decisions, which have consistently held—based on the credible testimony of pharmacy experts—that prescriptions may raise red flags that are so strongly indicative of diversion that they cannot be resolved by a pharmacist acting within the usual course of professional practice.

[20] [Omitted for clarity.]

*G I agree with the ALJ's conclusions about Dr. Sullivan's testimony regarding the physicians' motivations for prescribing non-controlled substances, so I am disregarding this testimony.

[21] [Omitted for clarity.]

owner. Tr. 506–07. Mr. Clement, Jr., has held a pharmacy tech license in Florida since 2014. Tr. 507. He has worked for the Respondent since 2014. Tr. 507, 521. Mr. Clement, Jr., reported the Respondent employs approximately four pharmacists-in-charge. *Id.* He described the Respondent as a family operation. *Id.*

The Respondent gets few patient customers per day. Tr. 508. Typically, the pharmacy would only see two to three patients a day, sometimes none. *Id.* Four patients in one day would make for a busy day at the pharmacy. *Id.* The fact that the Respondent only saw a few patients per day meant that the staff could spend more time talking with the patients and getting to know them. *Id.*

Mr. Clement, Jr., testified that the Respondent's staff always recorded the information it collected from the patients. Tr. 509, 543. The types of information the Respondent collected from patients included ''personal life information,'' how treatment was progressing, and dietary information. Tr. 509. The Respondent recorded this information in the patient's profile. Tr. 543. Sometimes it recorded the information on the hard-copy prescriptions. *Id.*

When a new patient presents at the pharmacy, the Respondent gathers information about the patient to assist the pharmacist in making a decision about whether to dispense to that patient. Tr. 509, 537–38, 540. The Respondent charges new patients $25 for an initial consultation. Tr. 542. As part of this information-gathering process, the Respondent asks patients to complete a questionnaire. Tr. 511, 537–38, 542. The questionnaire solicits information regarding the reason the patient is visiting the Respondent, how the patient feels, and what caused the patient's ailment or injury. Tr. 511–12, 538, 540. Sometimes a patient has been rejected by three to six other pharmacies before visiting the Respondent. Tr. 538. The Respondent creates a patient profile for all new patients and places a copy of the questionnaire in the profile. Tr. 546–48. Notes regarding the resolution of red flags would be contained in the patient's profile. Tr. 553. Mr. Clement, Jr., testified that the Respondent ''look[ed] at every aspect'' of a prescription before filling it, and that if ''everything checks out,'' the patient is cleared to fill the prescription. Tr. 540–41. The Respondent places a check mark on a prescription to verify it is cleared for dispensing. Tr. 554–55.

Mr. Clement, Jr., testified that the questionnaire asks the patients to provide details about their injury; simply claiming that ''my back pain hurts'' will not suffice. Tr. 512. The Respondent also makes a copy of the patient's driver's license. Tr. 513, 538. Mr. Clement, Jr., testified that the pharmacy checked the medical legitimacy of prescriptions [22] and called the prescribing doctor for all controlled substance prescriptions. Tr. 538–40, 542–43, 545. Initially, Mr. Clement, Jr., testified that the Respondent would write down what the doctor says in the patient's profile. Tr. 543–44. Government counsel later asked if the lack of notes about calling the doctor meant the doctor was never called. Tr. 550. Mr. Clement, Jr., responded, ''Not necessarily,'' and explained that sometimes the Respondent would write those notes on the hard-copy prescription. Tr. 550–51. The Respondent would write, ''M.D. okay'' on the prescription to verify the doctor had been called. Tr. 550–52.

After reviewing the questionnaire, a staff member searches for the patient in the PDMP to see if the patient is visiting other pharmacies. Tr. 512–13, 538. Typically, the Respondent attaches a copy of the PDMP reports to the patient's file. Tr. 513. The software system that the Respondent used also produced a ''Narx'' score that informed the pharmacy about a patient's risk of addiction. Tr. 518–19. The Respondent and its staff used the ''Narx'' score feature when deciding whether to fill prescriptions. *Id.* Sometimes after conducting this process the Respondent has turned patients away. Tr. 512, 538, 542.

Mr. Clement, Jr.'s, primary duties at the Respondent are working with the computer system and records. Tr. 515, 522. The Respondent uses Rx30 software. Tr. 514. When the DEA served the OSC/ISO on the Respondent in August 2019, it also executed a search warrant and seized two of the Respondent's computers. Tr. 514–15, 530–31. The Respondent also kept files on a back-up system, which was also seized by the DEA. Tr. 534–35. When the computers were eventually returned, they did not work and the scanned copies of prescriptions had been erased.[23] Tr. 514–15, 530–31. Mr. Clement, Jr., worked with an IT consultant and Rx30's technical support to try to recover the prescription image files from the computers seized by DEA. Tr. 517–18. Those recovery efforts were unsuccessful. *Id.*

The DEA also seized a touch-screen computer monitor. Tr. 516. When DEA returned the monitor, the screen had been shattered and it no longer worked.[24] Tr. 516–17, 531. The DEA also seized most of the hard-copy prescriptions that were kept at the pharmacy.[25] Tr. 516.

In general, I found Mr. Clement, Jr.'s, testimony to be somewhat subjective. As essentially a party to the litigation, he had a clear personal and family interest in the outcome. The Respondent's position that the Agency has treated the Respondent unfairly was reflected in Mr. Clement, Jr.'s, testimony. His emotional description of the manner of the seizure of Respondent's equipment and records, and their destruction and loss in the hands of the Agency, manifests his partiality in this matter. However, having a personal interest in the litigation, or manifesting an emotional commitment to your cause, are not bars to credibility. They are simply factors to be considered. I had some concerns with aspects of his testimony, however, which detracted from his credibility on certain topics. For the most part, these concerns were situations where Mr. Clement, Jr., provided conclusory testimony, and then followed-up with more detail when pressed by counsel.

There were also instances of inconsistency. For example, Mr. Clement, Jr., initially testified that the Respondent's computer system worked normally after the DEA made mirror images of the Respondent's computer hard-drive. Tr. 522, 525. He then clarified that the Respondent's computers did not work normally. Tr. 525–26. The computer system started working normally again about 3–4 months after the DEA made mirror images of it. Tr. 527.

[22] [Omitted for clarity.]

[23] Although Mr. Clement, Jr.'s, testimony about how files were backed-up was sometimes difficult to follow, Tr. 531–36, he seemed to indicate that the Respondent had the capability of retrieving lost files from Rx30's system. Tr. 535–36.

[24] [I have omitted, for brevity and relevance, the RD's discussion of unfair, unequal, or uneven treatment. Respondent did not raise any claims of unfair treatment in its Posthearing brief, and I do not find sufficient evidence on the record to suggest that Respondent was treated unfairly. Respondent raised concerns prehearing that it had not received access to all of the evidence that DEA had seized when it executed the OSC on August 29, 2019. However, those concerns appear to have been addressed before the hearing. Respondent also raised concerns that certain equipment that was seized by DEA had been damaged. However, the evidence on the record provides no indication of any sort of unequal treatment, or any improper motive in commencing the investigation. In fact, the evidence demonstrates that such an investigation was routine. DEA began investigating Respondent after receiving a tip from the Florida Department of Health in May 2017.]

[25] Mr. Clement, Jr., testified that the Respondent has not received back the hard-copy prescriptions seized by the DEA. Tr. 520. After testifying to this, the Respondent's counsel informed the Tribunal, on the record, that the DEA had provided copies of the prescriptions to counsel's office. *Id.*

Another example concerns the Respondent's efforts to call patients' past pharmacies. At the beginning of direct examination, Mr. Clement, Jr., testified that as part of its intake process for new patients, the Respondent would call a new patient's past pharmacy only if the Respondent had questions of that pharmacy. Tr. 512. Government counsel later asked, ''Sometimes you call their past pharmacist?'' Tr. 546. He answered, ''Yes.'' *Id.* Just moments later, Mr. Clement, Jr., testified that the Respondent always called pharmacies for every new patient. Tr. 547, 549. This testimony paints an unclear picture of whether the Respondent always called a patient's previous pharmacy or whether it only called in certain situations.

Another example concerned the extent to which the Respondent verified prescriptions' medical legitimacy. Mr. Clement, Jr., explained that neither he nor the Respondent's pharmacists were qualified to read an MRI report (or any other laboratory test). Tr. 539–40.[26] He said that some patients would provide a copy of their MRI report, but ''no pharmacist needs to look at an MRI.'' *Id.* This testimony seems to conflict with his testimony that the Respondent got to know its new patients by looking into their history, background, ''pain ailments, what they're going through, [and] sometimes treatment plans.'' Tr. 508. If the Respondent checked a patient's background, and confirmed medical legitimacy of the prescription, then it seems that the Respondent merely took the patient (and his or her doctor) at their word, since checking commonly-procured objective medical findings, such as an MRI report, was outside the Respondent's scope of review. The fact that the Respondent may have merely taken doctors, patients, and pharmacies at their word is supported by Mr. Clement, Jr.'s, later testimony that a patient is cleared to receive controlled substances if the doctor says ''yes'' and the patient's previous pharmacy says the patient is ''okay.'' Tr. 542.

There was another instance where Mr. Clement, Jr., came across as more of an advocate for the Respondent rather than an objective witness. In this instance, the Respondent's counsel asked Mr. Clement, Jr., whether the Respondent had developed a niche business in the types of patients it sees. Tr. 509–10. This seemed to be a straightforward, unambiguous question. Mr. Clement, Jr., responded, however, by describing, at length, the process of checking the patient's identification, and checking the PDMP and NarcFacts. Tr. 510–11. The Respondent's counsel then followed-up with a leading question, asking Mr. Clement, Jr., whether the Respondent ''dispense[d] primarily to patients who are suffering from chronic non-malignant pain?'' Tr. 511. Mr. Clement, Jr., answered in the affirmative. *Id.* Mr. Clement, Jr.'s, non-responsive answer demonstrated an eagerness to advocate the Respondent's safety measures for screening patients and preventing diversion, rather than answering the question about what types of clients the Respondent serviced.

Having listened to Mr. Clement, Jr.'s, testimony at the hearing, and having closely reviewed the transcript of his testimony, I find him to be generally credible, with the few exceptions noted above. He generally presented as a professional, knowledgeable, and honest witness. I will give his testimony weight to the extent it is internally consistent, and to the extent it is consistent with other evidence and testimony of record.

The Government's Rebuttal Case

After each party presented its case-in-chief, the Government presented the rebuttal testimony of DI Albert. Tr. 557–68.

DI Albert

The Government introduced DI Albert's rebuttal testimony to rebut Mr. Clement, Jr.'s, testimony about the resolution of red flags. Tr. 559–60, 563–64. DI Albert testified about a blog post authored by Mr. Clement, Sr.[27] Tr. 559, 561. DI Albert downloaded this blog post from the internet. Tr. 562. The blog post identifies its author as ''Norman J. Clement, R.Ph, DDS.'' Tr. 563. DI Albert also downloaded an attachment from the blog post. Tr. 564–65. The attachment is a copy of the Government's prehearing statement in this case. Tr. 565. There are notes written on the prehearing statement, to include the following note on page 23:

> The question of the red flag issue is not an issue to [me] because I don't challenge the physician for diagnosing and writing prescriptions for the patients because I'm not authorized or qualified to challenge a physician's diagnosis and treatment of his or her patients. Therefore, on the red flag issues, the question is, are they challenging me for filling the prescription or are they challenging the physician who wrote the prescription?

Tr. 566. Neither the hard-copied blog post nor attachment were admitted into evidence; only the oral testimony of DI Albert reading the above-quoted paragraph. Tr. 567.

During this brief rebuttal testimony, DI Albert presented, as he did in the Government's case-in-chief, as an honest, professional, and impartial investigator who had no stake in the case's outcome. DI Albert presented his rebuttal testimony in a credible and reliable manner. Although I fully credit DI Albert's rebuttal testimony, I will only consider his rebuttal testimony to the extent that the paragraph he read into the record rebuts Mr. Clement, Jr.'s, testimony that the Respondent resolved red flags.

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.

1. Respondent is registered with the DEA to handle controlled substances in Schedules II through V under Certificate of Registration No. FP2302076. Respondent's registered address is 1461 West Busch Boulevard, Tampa, Florida 33612. Respondent's DEA Certificate of Registration expires by its own terms on March 31, 2022. GX 1.

2. Oxycodone is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

3. Hydromorphone is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

4. Alprazolam is a Schedule IV controlled substance. 21 CFR 1308.14(c).

5. Morphine Sulfate is a Schedule II controlled substance. 21 CFR 1308.12(b)(1).

[26] Mr. Clement, Jr's., testimony would make sense if he was referring to the actual x-ray or MRI, which require special training to interpret, such as that of a radiologist, who reduces his findings to a written report, which might then be appropriate for a pharmacist to review.

[27] Although the Government offered the title of the blog post, ''DEA's Kourt of the Kangaroo,'' the title was only admitted for authentication purposes.

6. Methadone is a Schedule II controlled substance. 21 CFR 1308.12(c).

7. Hydromorphone 8 mg is a commercially available drug. Tr. 232. Hydromorphone 8 mg is the highest strength of hydromorphone that is commercially available. Tr. 248.

8. Oxycodone 30 mg is a commercially available drug. Tr. 232.

DEA's Investigation

9. After receiving a tip from the Florida Department of Health in May 2017, DEA investigators traveled to Respondent's registered address and presented a Notice of Inspection to the pharmacist present, who consented to the inspection. Approximately ten to fifteen minutes later, Respondent's owner, Norman Clement, Sr., indirectly asked the DEA investigators to leave, which they did. Tr. 26–27.

10. In September 2017, DEA investigators served an administrative subpoena on Respondent seeking, among other things, original Schedule II controlled substances prescriptions, receiving records, and ''batch records.'' Tr. 27. Government Exhibits 2 through 6 were produced by Respondent to DEA in response to the September 2017 subpoena and were admitted into evidence in this matter. Tr. at 27–34.

11. On September 10, 2018, DEA investigators executed an Administrative Inspection Warrant (''AIW'') at Respondent's registered address. Tr. 52.

12. DI Albert and Respondent's owner conducted an inventory of the Schedule II controlled substances contained in the safe located at Respondent's address. Tr. 56. On September 10, 2018, there were 3,546 compounded capsules of hydromorphone 8 mg; 470 commercially-produced tablets of hydromorphone 8 mg; 574 compounded capsules of oxycodone 30 mg; and 204 commercially-produced oxycodone 30 mg tablets in the safe. GX 7. There were also 155.2 grams of hydromorphone powder and 26 grams of oxycodone powder. *Id.* There were no other Schedule II controlled substances contained in the safe. Tr. 59.

13. During the AIW, DEA investigators attempted to inspect and copy certain records. Tr. 56. At the time, Respondent's owner was not able to tell the investigators where these records were located. Tr. 56–57. As a result, one of Respondent's owner's sons (Norman Clement, Jr.) was reached by video-teleconference on a series of mobile devices and was able to direct the investigators to the location of various records. Tr. 61–62; *see also* Tr. 521–23.

14. During the execution of the AIW, DEA investigators also served an administrative subpoena, seeking complete copies of the ''patient record system'' for certain specific patients. Tr. 53; GX 67.

15. During the execution of the AIW, a technician from DEA's Digital Evidence Laboratory (SFL–9) was able to obtain copies of electronic records from Respondent's system by ''mirroring'' the hard drive. Tr. 62. The records obtained by the SFL–9 investigator included information relating to patients not involved in this proceeding.[28] Tr. 90–93. The SFL–9 provided DI Albert with electronic copies of the records obtained during the execution of the AIW. Tr. 62–63, 94.

16. Government Exhibit 11 is a complete and accurate copy of Respondent's dispensing log for June 1, 2017, to September 7, 2018, which was obtained during the execution of the AIW in September 2018. Tr. 63–66. Government Exhibits 12–13; 15–17; 20–21; 23–24; 26–27; 29–30; 32–33; 35–36; 38–39; 41–43; 47–49, and 51 are correct and accurate copies of documents that were obtained from Respondent's electronic record system by the SFL–9 technician during the execution of the AIW. Tr. 68–86.

17. During the course of the investigation, DI Albert queried the Florida Prescription Drug Monitoring Database (E–FORCSE or PDMP) and obtained information regarding Respondent's dispensing of controlled substance as it was reported to the State of Florida. Tr. 44. Government Exhibits 8–10 are accurate copies of the data obtained from the E–FORSCE database for the dates listed. Tr. 48–51. Government Exhibits 14, 19, 22, 25, 28, 31, 34, 37, 40, 46, and 50 are complete and accurate copies of E–FORSCE information for certain specific enumerated patients. Tr. 68–86. There is no evidence in the record to indicate that the information reported by Respondent to the E–FORSCE database is inaccurate or unreliable.

18. In May 2018, DI Albert served an additional subpoena on Respondent seeking the complete patient record system maintained by Respondent for certain specific patients, as well as any ''other documentation kept by [Respondent] in connection with the filling of prescriptions . . . for these individuals.'' Tr. 88–89; GX 68.

19. Government Exhibit 18 includes all documents and information produced in response to the May 2018 subpoena regarding Patient A.G. Tr. 96; GX 18. Government Exhibit 44 includes all documents and information produced in response to the May 2018 subpoena regarding Patient R.B. Tr. 97–98; GX 44.

20. The Respondent dispensed four to five prescriptions per day on average. Tr. 419.

The Standard of Professional Pharmacy Practice in Florida

21. Dr. Sullivan testified that the standard of professional practice in Florida requires that a pharmacist make sure each prescription is valid and has been issued for a legitimate medical purpose prior to dispensing controlled substances. Tr. 206. As part of this evaluation, Dr. Sullivan testified that a pharmacist must first determine whether the prescription is facially legitimate—whether it includes all of the required information. *Id.* at 208. Then, Dr. Sullivan testified that the pharmacist must attempt to determine whether there is over-utilization or under-utilization; clinical abuse or misuse going on; whether the prescription was issued for a legitimate medical purpose; and whether the prescription puts the patient at ''any potential undue risk of side effects, adverse effects, and/or potentially overdose situations.'' *Id.* at 207–08; *see also* Fla. Admin. Code r. 64B16–27.810 (stating that ''a pharmacist shall review the patient record and each new and refill prescription'' to identify potential concerns such as ''[o]ver-utilization or under-utilization,'' and ''take appropriate steps to avoid or resolve the potential problems''); Fla. Admin. Code r. 64B16–27.831(2)(c) (''When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.'')

22. [Omitted Florida law regarding the maintenance of a patient profile, because I do not think it is relevant to the facts in this case.]

23. Dr. Sullivan testified that a ''red flag'' is a ''warning sign'' that ''there's something potentially wrong with the prescription.'' Tr. 211. Specifically, it is a sign that ''the patient may be either abusing or diverting it.'' *Id.* at 212. Dr. Sullivan testified that these ''red flags'' are well-documented in the pharmacy

[28] I do not agree that DI Albert's testimony supports a finding that the SFL–9 investigator obtained a complete copy of the Respondent's electronic records, as the Government proposed in its post-hearing brief. Gov't PHB, p. 4, ¶ 16 (citing Tr. 90–93). DI Albert's testimony supports a finding that the information ''mirrored'' from the hard-drive included patients other than the eleven involved here, but his testimony does not support the conclusion that the information obtained was a ''complete copy'' of all of the Respondent's records. Tr. 90–93.

community and are known to pharmacists in the State of Florida. *Id.* at 211–14; 235–36.

24. Dr. Sullivan testified that some of these red flags include (1) patients travelling long distances to the pharmacy; (2) certain drug cocktails; (3) high dosages of immediate release pain killers; and (4) cash-paying customers. *Id.* at 214.

25. Dr. Sullivan testified that the prescribing of an opioid pain reliever and benzodiazepine at the same time is a significant red flag. *Id.* at 220–21. Dr. Sullivan noted that the FDA had issued a warning in 2016 regarding the serious health risks posed by the combination of those two medications. *Id.* at 220–21; GX 66. Dr. Sullivan testified that a reasonable pharmacist acting within the usual course of professional practice in Florida would be ''very very reluctant to dispense that combination of drugs'' after the FDA safety warning. Tr. 223.

26. Dr. Sullivan testified that filling a controlled substance prescription early is a red flag. *Id.* at 225–27. He testified that the standard of care required a pharmacist not to fill a Schedule II controlled substance prescription until ''the day of or day before the medication from a previous prescription is supposed to run out.'' Tr. 270–71. While there may be legitimate reasons for a particular prescription to be filled early in ''extreme'' and ''unusual'' cases, there is no legitimate reason for a pharmacist to fill a Schedule II controlled substance prescription early in multiple consecutive months. Tr. 270–71.

27. When a pharmacist identifies one or more red flags, he must undertake an investigation into the prescription before he can fill it. Tr. 227. This may include speaking with the patient and/or speaking with the prescriber. A pharmacist would also be expected to look at the patient profile as well as apply his clinical expertise to the drug, quantity, and strength prescribed. *Id.* The standard of care requires that the pharmacist document these conversations and analyses.[29] Tr. 227–28. [Dr. Sullivan testified that a pharmacist does not look at individual red flags in isolation; rather, he looks at them ''as a collective whole based on what's going on with that prescription at that time.'' Tr. 482, 498. Dr. Sullivan testified that there are some red flags that, ''when taken as a collective whole[,] . . . cannot be resolved.'' Tr. 481. Dr. Sullivan testified that in these circumstances, ''no matter what the patient tells me, what the doctor tells me, any of that, I'm still not filling the prescription.'' Tr. 282. Dr. Sullivan testified that an individual red flag (such as long distances traveled or cash payments) may become unresolvable if it is combined with multiple additional red flags. *Id.* at 473, 475; *see also id.* at 409–11.]

Respondent's Dispensing

Patient A.G.

28. At all times relevant to this matter, Patient A.G. resided at 411 NE 25th Ave., Cape Coral, Florida 33909. GX 15. Patient A.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 55.

29. All of the prescriptions filled by Patient A.G. at Respondent were paid for in cash. GX 14, 17.

30. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.G. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.G. was a ''red flag,'' as was the fact that Patient A.G. was prescribed a ''cocktail of benzodiazepine and opioid'' at the highest strengths of both medications. Tr. 254–55. Dr. Sullivan also observed that Patient A.G. filled multiple prescriptions early. Tr. 257–59.

31. Between June 26, 2017, and August 30, 2018, Respondent filled 30 prescriptions for controlled substances for Patient A.G., including 10 prescriptions for hydromorphone 8 mg; 10 prescriptions for oxycodone 30 mg; 9 prescriptions for alprazolam 2 mg; and 1 prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 17.

32. Between December 20, 2018, and April 12, 2019, Respondent filled 10 prescriptions for controlled substances for Patient A.G., including 5 prescriptions for oxycodone 30 mg and 5 prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 14.

33. Respondent maintained a patient profile for Patient A.G. The only pharmacist note in the profile for Patient A.G. stated: ''Doctor OK to Receive Medication in Compound Capsule Form.'' Govt. Ex. 15.

34. Dr. Sullivan testified that the notes contained the Patient A.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified.*[H] Tr. 258.

35. Dr. Sullivan further testified that the answers provided on the Medical Questionnaire were not sufficient to resolve any of the specific red flags that he identified. Tr. 260–63. [Dr. Sullivan testified that the red flags raised by Patient A.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 256–57, 267–68.]

Patient A.H.

36. At all times relevant to this matter, Patient A.H. resided at 1001 NE 6th Place, Cape Coral, Florida 33909. GX 20. Patient A.H.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 56.

37. All of the prescriptions filled by Patient A.H. at Respondent were paid for in cash. GX 19, 21.

38. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient was a ''red flag,'' as was the fact that Patient A.G. was prescribed a ''cocktail of benzodiazepine and opioid'' at the highest strengths of both medications. Tr. 268–69.

39. Between January 4, 2018, and August 16, 2018, Respondent filled 11 prescriptions for controlled substances for Patient A.H., including six prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 21.

40. Between September 11, 2018, and April 18, 2019, Respondent filled at least seven prescriptions for controlled substances for Patient A.H., including seven prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 19.

41. Respondent maintained a patient profile for Patient A.H. The patient profile for Patient A.H. contained no pharmacist notes or comments. GX 20. In Dr. Sullivan's opinion, Patient A.H.'s patient profile was insufficient to resolve any of the red flags that he identified. Tr. 272. [Dr. Sullivan testified that the red flags raised by Patient A.H.'s prescriptions were not

[29] [Footnote omitted.]

[*H] The Findings of Fact Section discusses Respondent's efforts to document the resolution of red flags. This discussion has minimal relevance to my Decision, because I have concluded that the combination of red flags presented by each prescription in this case could not have been resolved by a pharmacist operating within the usual course of professional practice based on the credible and unrebutted testimony of the Government's expert. However, I have retained this discussion to provide context for Respondent's dispensing to each patient.

resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 269, 273.]

Patient B.S.

42. At all times relevant to this matter, Patient B.S. resided at 117 Zobora Circle, Fort Myers, Florida 33913. GX 23. Patient B.S.'s residence is approximately 150 miles (one-way) from Respondent's registered address. GX 57.

43. All of the prescriptions filled by Patient B.S. at Respondent were paid for in cash. GX 22, 24.

44. Dr. Sullivan examined the dispensing data and the patient profile for Patient B.S. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient B.S. was a ''red flag,'' as was the fact that Patient B.S. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 274–75.

45. Between August 22, 2017, and August 23, 2018, Respondent filled 19 prescriptions for controlled substances for Patient B.S., including 12 prescriptions for hydromorphone 8 mg; six prescriptions for alprazolam 2 mg; and one prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 24.

46. Between December 20, 2018, and April 22, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient B.S., including two prescriptions for hydromorphone 8 mg, four prescriptions for oxycodone 30 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 22.

47. Respondent maintained a patient profile for Patient B.S. The patient profile for Patient B.S. contained no pharmacist notes or comments. GX 23.

48. Dr. Sullivan testified that the notes contained in Patient B.S.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 277. [Dr. Sullivan testified that the red flags raised by Patient B.S.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 274, 276–77.]

Patient C.R.

49. At all times relevant to this matter, Patient C.R. resided at 2907 Jackson Street, Fort Myers, Florida 33901. GX 26. Patient C.R.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 58.

50. All of the prescriptions filled by Patient C.R. at Respondent were paid for in cash. GX 25, 27.

51. Dr. Sullivan examined the dispensing data and the patient profile for Patient C.R. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient C.R. was a ''red flag,'' as was the fact that Patient C.R. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 279–80.

52. Between July 19, 2017, and August 30, 2018, Respondent filled 13 prescriptions for controlled substances for Patient C.R., including six prescriptions for oxycodone 30 mg, six prescriptions for alprazolam 1 mg, and one prescription for morphine sulfate 30 mg. Information regarding the controlled substances dispensed to Patient C.R. is accurately set forth in Government Exhibit 27.

53. Respondent maintained a patient profile for Patient C.R. The only pharmacist note in the profile for Patient C.R. stated: ''Script has wrong birthdate on it. Dr[.] has now update[.]'' GX 26.

54. Dr. Sullivan testified that the notes contained the Patient C.R.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. at 281.

Patient J.D.

55. At all times relevant to this matter, Patient J.D. resided at 229 NW 15th Place, Cape Coral, Florida 33993. GX 29. Patient J.D.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 59.

56. All of the prescriptions filled by Patient J.D. at Respondent were paid for in cash. GX 28, 30.

57. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.H. was a ''red flag,'' as was the fact that Patient A.G. was prescribed the highest strengths of hydromorphone. Tr. 283.

58. Between January 15, 2018, and September 4, 2018, Respondent filled ten prescriptions for controlled substances for Patient J.D., including nine prescriptions for hydromorphone 8 mg and one prescription for methadone 10 mg. Information regarding the controlled substances dispensed to Patient J.D. is accurately set forth in Government Exhibit 30.

59. In addition, Dr. Sullivan noted that Respondent dispensed two immediate release narcotic pain relievers (hydromorphone 8 mg and methadone 10 mg) to Patient J.D. on March 24, 2018. Dr. Sullivan testified that dispensing two immediate release narcotic pain relievers on the same day was ''a red flag in and of itself.'' Tr. 283–84.

60. Respondent maintained a patient profile for Patient J.D. The only pharmacist note in the profile for Patient J.D. stated: ''Next Fill 7/5/18!!! Watch fill dates!!!!!!'' GX 29.

61. Dr. Sullivan testified that the notes contained in Patient J.D.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 287–88. [Dr. Sullivan testified that the red flags raised by Patient J.D.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 284, 288–89.]

Patient J.M.

62. At all times relevant to this matter, Patient J.M. resided at 3004 30th Street SW, Lehigh Acres, Florida 22976. GX 32. Patient J.M.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 60.

63. All of the prescriptions filled by Patient J.M. at Respondent were paid for in cash. GX 31, 33.

64. Dr. Sullivan examined the dispensing data and the patient profile for Patient J.M. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient J.M. was a ''red flag,'' as was the fact that Patient J.M. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 289–90.

65. Between June 22, 2017, and September 7, 2018, Respondent filled 23 prescriptions for controlled substances for Patient J.M., including eight prescriptions for oxycodone 30 mg; six prescriptions for hydromorphone 8 mg; and nine prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient J.M. is accurately set forth in Government Exhibit 33.

66. Respondent maintained a patient profile for Patient J.M. The patient profile for Patient J.M. contained no pharmacist notes or comments. GX 32.

67. Dr. Sullivan testified that the notes contained the Patient J.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 290. [Dr. Sullivan testified that the red flags raised by

Patient J.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 290–91.]

Patient M.M.

68. At all times relevant to this matter, Patient M.M. resided at 1145 W Walnut Street, Lakeland, Florida 22815. GX 35. The prescriptions that Patient M.M. filled at Respondent were issued by a practitioner located at 1670 San Carlos Blvd., Fort Myers Beach, Florida 22931. GX 36.

69. Patient M.M.'s residence is approximately 130 miles (one-way) from the prescriber's location. GX 61. All of the prescriptions filled by Patient M.M. at Respondent were paid for in cash. GX 34, 36.

70. Between June 6, 2017, and August 16, 2018, Respondent filled 14 prescriptions for controlled substances for Patient M.M., including 14 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 36.

71. Between January 3, 2019, and April 16, 2019, Respondent filled at least 5 prescriptions for controlled substances for Patient M.M., including 5 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 34.

72. Dr. Sullivan examined the dispensing data and the patient profile for Patient M.M. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient M.M. from her home to her physician was a ''red flag,'' as was the fact that Patient M.M. was prescribed the highest available strength of hydromorphone.[30] Tr. 292–95.

73. Respondent maintained a patient profile for Patient M.M. The patient profile for Patient M.M. contained no pharmacist notes or comments. GX 35.

74. Dr. Sullivan testified that the notes contained in Patient M.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 300. [Dr. Sullivan testified that the red flags raised by Patient M.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 299–300.]

Patient N.B.

75. At all times relevant to this matter, Patient N.B. resided at 2132 SE 5th Place, Cape Coral, Florida 33990. GX 38. Patient N.B.'s residence is approximately 135 miles (one-way) from Respondent's registered address. GX 62.

76. All of the prescriptions filled by Patient N.B. at Respondent were paid for in cash. GX 37, 39.

77. Between June 21, 2017, and August 14, 2018, Respondent filled 19 prescriptions for controlled substances for Patient N.B., including 12 prescriptions for hydromorphone 8 mg, four prescriptions for alprazolam 2 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 39.

78. Between September 14, 2018, and April 10, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient N.B., including five prescriptions for oxycodone 30 mg, three prescriptions for alprazolam 1 mg, and one prescription for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 37.

79. Dr. Sullivan examined the dispensing data and the patient profile for Patient N.B. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient N.B. was a ''red flag,'' as was the fact that Patient N.B. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 301–02, 305.

80. Respondent maintained a patient profile for Patient N.B. The only pharmacist note in the profile for Patient N.B. stated: ''Doctor OK Patient to Receive Medication in Compound Capsule Form.'' GX 38.

81. Dr. Sullivan testified that the notes contained in Patient N.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 306. [Dr. Sullivan testified that the red flags raised by Patient N.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 302–07.]

Patient R.B.

82. At all times relevant to this matter, Patient R.B. resided at 2512 Pauldo Street, Fort Myers, Florida 33916. GX 41. Patient R.B.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 63.

83. All of the prescriptions filled by Patient R.B. at Respondent were paid for in cash. GX 40, 43.

84. Between June 28, 2017, and August 16, 2018, Respondent filled 24 prescriptions for controlled substances for Patient R.B., including 12 prescriptions for hydromorphone 8 mg, 11 prescriptions for alprazolam 2 mg, and one prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 43.

85. Between September 12, 2018, and April 15, 2019, Respondent filled at least 10 prescriptions for controlled substances for Patient R.B., including five prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 40.

86. Respondent maintained a patient profile for Patient R.B. The patient profile for Patient R.B. contained no pharmacist notes or comments. GX 41.

87. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.B. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.B. was a ''red flag,'' as was the fact that Patient R.B. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 310–11.

88. Dr. Sullivan testified that the notes contained in Patient R.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 313. [Dr. Sullivan testified that the red flags raised by Patient R.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 311, 313, 321.]

Patient R.G.

89. At all times relevant to this matter, Patient R.G. resided at 1915 NE 5th Street, Cape Coral, Florida 33909. GX 47. Patient R.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 64.

90. All of the prescriptions filled by Patient R.G. at Respondent were paid for in cash. GX 46, 49.

91. Between June 28, 2017, and September 7, 2018, Respondent filled 29 prescriptions for controlled substances for Patient R.G., including 17 prescriptions for oxycodone 30 mg, and 12 prescriptions for alprazolam 2 mg. Information regarding the controlled

[30] For reasons explained later in this Recommended Decision, I am not accepting Dr. Sullivan's opinion that the roundtrip distance from M.M.'s home to the prescriber's office, to the Respondent, and back home, is a red flag, as proposed by the Government. Gov't PHB, pp. 20–21, ¶ 101.

substances dispensed to Patient R.G. is accurately set forth in Government Exhibit 49.

92. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.G. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.G. was a ''red flag,'' as was the fact that Patient R.G. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 322–23.

93. Respondent maintained a patient profile for Patient R.G. The only pharmacist note in the profile for Patient R.G. stated: ''Watch Fill Dates!!!!!!!!!!!'' GX 47.

94. Dr. Sullivan testified that the notes contained in Patient R.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 328. [Dr. Sullivan testified that the red flags raised by Patient R.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 322–23, 326, 328–29.]

Patient R.L.

95. At all times relevant to this matter, Patient R.L. resided at 135 SW 29th Terrace, Cape Coral, Florida 33914. GX 51. Patient R.L.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 65.

96. All of the prescriptions filled by Patient R.L. at Respondent were paid for in cash. GX 50, 52.

97. Between June 21, 2017, and September 4, 2018, Respondent filled 16 prescriptions for controlled substances for Patient R.L., including 14 prescriptions for hydromorphone 8 mg, one prescription for oxycodone 30 mg, and one prescription for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 52.

98. Between December 27, 2018, and April 16, 2019, Respondent filled at least five prescriptions for controlled substances for Patient R.L., including five prescriptions for oxycodone 30 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 50.

99. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.L. and identified multiple ''red flags.'' Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.L. was a ''red flag,'' as was the fact that Patient R.L. was prescribed opioids at the highest strengths available. Tr. 330–31.

100. Respondent maintained a patient profile for Patient R.L. The only pharmacist note in the profile for Patient R.L. stated: ''Next Fill 6/10/18—10 Days Early March & April—Told Him This 5/11/18 GD[.]'' GX 51.]

101. Dr. Sullivan testified that the notes contained in Patient R.L.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) the red flags that he identified. Tr. 335. [Dr. Sullivan testified that the red flags raised by Patient R.L.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 332, 335–36.]

Compounding

102. Respondent repeatedly dispensed both commercially-available tablet and compounded capsule forms of controlled substances to the same patients, indicating that those patients did not have a legitimate therapeutic need for the compounded form. *See, e.g.,* Tr. 256, 290, 297, 321, 325, 326.

103. In May 2012, then-TFO Jeffrey Shearer conducted an interview with Respondent's owner regarding the compounding that he was doing at Respondent. Tr. 183.

104. Respondent's owner indicated that his formulary was designed to ensure that the compounded product was ''essentially similar'' to the commercially-produced product. Respondent's owner stressed that his compounded product had the same ''bioavailability'' as the commercially available product. Tr. 184–85.

105. TFO Shearer observed that Respondent's owner was compounding thousands of dosage units at one time. Respondent's owner explained that he did so because it was ''cost effective'' to produce large volumes at the same time. Tr. 185.

106. Respondent's owner told TFO Shearer that some of his customers did not want the compounded capsules, but that Respondent's owner assured the patients that the capsules and the tablets were ''the same, that they would have the same effect.'' Tr. 185–86.

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 [and unresolvable] red flags of diversion, and in violation of state law under the Florida Administrative Code, and state requirements for the minimum standard of care, and its 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). The Government also alleges that the Respondent engaged in a pattern of manufacturing controlled substances without proper registration.

In the adjudication of a revocation or suspension of a DEA COR, 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 20,727, 20,734 (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 38,363, 38,364 (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,* 419 F.3d at 482–83; *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Krishna-Iyer,* 74 FR 463 (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 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,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (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

The Government alleges that the Respondent filled numerous prescriptions for eleven patients that raised red flags of drug abuse and/or diversion, to include drug cocktails; early fills; traveling long distances; prescriptions for the highest strengths of oxycodone, hydromorphone, and alprazolam; paying in cash; and dispensing compounded capsules without therapeutic justification. ALJ Ex. 1, pp. 4–7. The Government further alleges that [the red flags presented by these prescriptions were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice.][*1] *Id.* The Government claims that by filling these eleven patients' controlled substance prescriptions, 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.* [Omitted for relevance.]

With respect to each patient, the Government presented documentary evidence and testimony from its pharmacy expert, Dr. Sullivan, that the Respondent filled numerous controlled substance prescriptions that raised red flags, including drug cocktails, early fills, long distance, highest strengths, and cash payments. The Government further presented evidence that [the red flags presented by these prescriptions could not have been resolved by a pharmacist acting in the usual course of professional practice.] Finally, the Government proved the Respondent compounded medication without therapeutic justification.

I will now turn to the evidence the Government presented for each patient. After examining the evidence for each patient, I will determine whether the Government has presented a *prima facie* case that the Respondent filled these prescriptions in violation of federal and state law.

Patient A.G.

From January 2018 to April 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to A.G. on six occasions. GX 14. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.G. on three occasions. *Id.*

Dr. Sullivan testified that the Respondent filled several prescriptions for A.G. before his prior month's supply of medication ran out. Tr. 257. For example, the Respondent filled oxycodone and alprazolam prescriptions for A.G. on January 17, 2019, the 28th day after dispensing a 30-day supply of each drug to him on December 20, 2018 (2 days early). ALJ Ex. 42,[31] p. 12; GX 14. The Respondent filled an alprazolam prescription for A.G. on February 14, 2019, the 28th day after dispensing a 30-day supply on January 17, 2019 (2 days early). *Id.* The Respondent filled another oxycodone prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 28-day supply on March 20, 2019 (5 days early). *Id.* The Respondent also filled an alprazolam prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 30-day supply on March 20, 2019 (7 days early). *Id.* These prescriptions should not have been filled early unless the Respondent documented a good reason for doing so. Tr. 257.

Patient A.G.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 10; GX 55. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist.[32] Tr. 254.

[*1] I have modified this paragraph to clarify that the Government alleged that the red flags presented by the prescriptions in this case could not have been resolved by a pharmacist acting within the usual course of professional practice. Because the Government presented sufficient evidence to support this allegation, I do not need to consider the Government's alternative claim that Respondent failed to take adequate steps under Florida and federal law to resolve the red flags.

[31] Because the Government structured its direct examination of Dr. Sullivan by using the demonstrative exhibit for ease of reference, I will cite to that document as well as the Government Exhibit from which the information is derived. I will mark the demonstrative exhibit as ALJ Exhibit 42. I will treat the demonstrative exhibit similar to a summary of voluminous records under Federal Rule of Evidence 1006. The demonstrative exhibit, however, was never introduced into evidence, so it is being used as a guide or aid for review of the record. Thus, the admitted evidence trumps the demonstrative exhibit with respect to any inconsistency between the two.

[32] Although we do not know if A.G., in fact, travelled 131 miles from his home to the Respondent each time he filled a prescription there, the Respondent knew he lived that far away, and was therefore on notice of a well-established red flag of drug abuse and/or diversion. This is true of ten of the eleven patients. The fact that the patients lived over 100 miles away is a red flag even if the patients did not travel that distance each time they

From June 2017 to August 2018, the Respondent dispensed ten prescriptions each for oxycodone, hydromorphone, and alprazolam. ALJ Ex. 42, p. 11; GX 17. Each of these prescriptions, except for one alprazolam prescription, was written for the highest commercially available strength of the drug. *Id.;* Tr. 255. All of the oxycodone prescriptions dispensed during this time period were for 30 mg dosage units, the highest strength available of oxycodone. *Id.* All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.* Nine of the ten alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 256.

In addition to these red flags, patient A.G. paid for all of his prescriptions in cash. GX 14; GX 17. Dr. Sullivan testified that paying in cash is a red flag.[33] Tr. 214.

Although patient A.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient A.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 256–57, 267–68.]

Patient A.H.

From January 2018 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.H. on five occasions. ALJ Ex. 42, p. 15; GX 21.

The Respondent provided three early fills of hydromorphone prescriptions for A.H. from February to March 2019. Tr. 270–71; ALJ Ex. 42, p. 16; GX 19. The Respondent dispensed hydromorphone to A.H. on February 15, 2019, the 24th day after dispensing a 30-day supply on January 22, 2019 (6 days early). *Id.* The Respondent also dispensed hydromorphone to A.H. on February 27, 2019, the 12th day after dispensing a 30-day supply on February 15, 2019 (18 days early). *Id.* The Respondent then dispensed hydromorphone to A.H. on March 14, 2019, the 15th day after dispensing a 30 day-supply on February 27, 2019 (15 days early). *Id.* Filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 271. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. *Id.*

Patient A.H.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 14; GX 56; Tr. 268. Dr. Sullivan opined that this distance is a red flag. Tr. 268.

From January 2018 to August 2018, the Respondent dispensed six prescriptions of hydromorphone and five prescriptions of alprazolam. ALJ Ex. 42, p. 15; GX 21. Each of these prescriptions was written for the highest strength of the drug. *Id.;* Tr. 269. All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.* All of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 269.

In addition to these red flags, patient A.H. paid for all of his prescriptions in cash. GX 19; GX 21. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient A.H. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 272; GX 20; ALJ Ex. 42, p. 17. [Dr. Sullivan testified that the red flags raised by Patient A.H.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 269, 273.]

Patient B.S.

From August 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to B.S. on five occasions. ALJ Ex. 42, p. 19; GX 24; Tr. 274. From December 2018 to March 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to B.S. on three occasions. ALJ Ex. 42, p. 20; GX 22; Tr. 276–77.

Dr. Sullivan also pointed out the duplicative therapy that the Respondent dispensed in January and February 2019. Tr. 276; ALJ Ex. 42, p. 20. After dispensing a 30-day supply of oxycodone to B.S. on January 31, 2019, only five days later the Respondent dispensed a 28-day supply of hydromorphone. *Id.* Then only two weeks later, the Respondent dispensed another 30-day supply of oxycodone to B.S. *Id.* Oxycodone and hydromorphone are potent immediate-release narcotic pain killers. Tr. 276. The fact that B.S. presented overlapping prescriptions for different immediate-release opioids with duplicative therapy was a red flag of abuse and/or diversion. *Id.*

Patient B.S.'s home address was located about 148 miles from the Respondent. ALJ Ex. 42, p. 18; GX 57; Tr. 273–74. Dr. Sullivan opined that this distance is a red flag. Tr. 273–74.

From August 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 7 prescriptions of alprazolam. ALJ Ex. 42, p. 19; GX 24; Tr. 274. All but one of these prescriptions was written for the highest commercially available dosage strength of the drug. *Id.* All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* All but one of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength of alprazolam. *Id.* From December 2018 to April 2019, the Respondent dispensed four

visited the pharmacy. The focus is on the information the Respondent knew, and the Respondent knew the patients lived over 100 miles away because it had their addresses on the prescriptions. According to Dr. Sullivan, this information should have aroused the Respondent's suspicion. The remaining patient (M.M.) lived approximately 134 miles from his prescriber's office, which represents its own red flag of long distance travel to obtain the prescription. Tr. 291–94.

[33] The Respondent argues that it did not view cash payments as suspicious because it did not accept insurance as a form of payment. Resp't PHB, at 19–20, 35. I am not convinced by this argument for two reasons. First, the Respondent did not provide any direct evidence that the only form of payment it accepted during the relevant time period was cash. Rather, it drove at this issue indirectly by asking hypothetical questions such as how would the Respondent get paid if it did not have contracts with insurance carriers or pharmacy benefit managers. Tr. 443–44. Second, even if the only form of payment that the Respondent accepted was cash, the fact that a patient was willing to pay in cash should still have aroused the Respondent's suspicion since it is a [part of the standard of professional practice of pharmacy as testified by Dr. Sullivan. Tr. 221–225.] The fact that the patients in this case were willing to pay in cash was even more concerning given the other red flags that they raised. Dr. Sullivan testified that paying in cash for controlled substances remains suspicious when it occurs with the other red flags involved here, even if the pharmacy did not take insurance. Tr. 475–76. [DEA has consistently relied on the testimony of pharmacy experts in finding that cash payments are a red flag of diversion or abuse. *See, e.g., Edge Pharm.,* 81 FR 72,092, 72,103, 72,111–12 (2016) (crediting Florida pharmacy expert's testimony that paying in cash or cash equivalent, such as by credit or debit card, creates a suspicion that a controlled substance may be abused or diverted).]

prescriptions of oxycodone and one prescription of hydromorphone. ALJ Ex. 42, p. 20; GX 22; Tr. 276. All four of the oxycodone prescriptions were written for 30 mg, the highest strength of oxycodone. *Id.* The hydromorphone prescription was written for 8 mg, the highest strength of hydromorphone. *Id.* Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 274, 276–77.

[Text omitted.] *[J] [34] *Id.*

In addition to these red flags, patient B.S. paid for all of his prescriptions in cash. GX 22; GX 24. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient B.S. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 277–78; GX 23; ALJ Ex. 42, p. 21. [Dr. Sullivan testified that the red flags raised by Patient B.S.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 274, 276–77.]

Patient C.R.

From July 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to C.R. on five occasions. ALJ Ex. 42, p. 23; GX 27; Tr. 280. On one of these occasions, the Respondent dispensed morphine tablets in addition to oxycodone and alprazolam. *Id.*

Patient C.R.'s home address was located about 134 miles from the Respondent. ALJ Ex. 42, p. 22; GX 58; Tr. 279. Dr. Sullivan opined that this distance is a red flag. Tr. 279.

From July 2017 to August 2018, the Respondent dispensed six prescriptions of oxycodone. ALJ Ex. 42, p. 23; GX 27; Tr. 279–80. Each of these six oxycodone prescriptions were for 30 mg dosage units, the highest strength available of oxycodone. *Id.*

In addition to these red flags, patient C.R. paid for all of her prescriptions in cash. GX 25; GX 27. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient C.R. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 281–82; GX 24; ALJ Ex. 42, p. 23. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient C.R.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 279–83.]

Patient J.D.

On one occasion the Respondent dispensed a drug cocktail of hydromorphone and methadone to J.D. Tr. 283–84; ALJ Ex. 42, p. 26; GX 30. Dr. Sullivan testified that taking these two immediate-release narcotic pain killers at the same time put J.D. ''at extreme risk of overdose.'' Tr. 284.

The Respondent provided three early fills of hydromorphone prescriptions for J.D. from May to June 2018. Tr. 284–87; ALJ Ex. 42, p. 27; GX 30. The Respondent dispensed hydromorphone to J.D. on May 30, 2018, the 20th day after dispensing a 30-day supply on May 10, 2018 (10 days early). *Id.* The Respondent also dispensed hydromorphone to J.D. on June 15, 2018, the 16th day after dispensing a 30-day supply on May 30, 2018 (14 days early). *Id.* The Respondent then dispensed hydromorphone to J.D. on June 30, 2018, the 15th day after dispensing a 30 day-supply on June 15, 2018 (15 days early). *Id.* Dr. Sullivan testified that filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285. He testified that a pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271.

Patient J.D.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 25; GX 59; Tr. 283. Dr. Sullivan opined that this distance is a red flag. Tr. 283.

From January 2018 to September 2018, the Respondent dispensed nine prescriptions of hydromorphone. ALJ Ex. 42, p. 26; GX 30; Tr. 283–84. Each of these nine hydromorphone prescriptions were for 8 mg dosage units, the highest strength available of hydromorphone. *Id.*

In addition to these red flags, patient J.D. paid for all of her prescriptions in cash. GX 28; GX 30. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.D. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 287–88; GX 29; ALJ Ex. 42, p. 28. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient J.D.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 284, 288–89.]

Patient J.M.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to J.M. on five occasions. ALJ Ex. 42, p. 30; GX 33; Tr. 289–90. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to J.M. on three occasions. *Id.*

Patient J.M.'s home address was located about 144 miles from the Respondent. ALJ Ex. 42, p. 29; GX 60; Tr. 289. Dr. Sullivan opined that this distance is a red flag. Tr. 289.

From June 2017 to September 2018, the Respondent dispensed nine prescriptions of alprazolam, eight prescriptions of oxycodone, and six prescriptions of hydromorphone. ALJ Ex. 42, p. 30; GX 33; Tr. 289–90. All of these prescriptions were for the highest strength available of the drug. All of the nine alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.* All of the eight oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id.* All of the six hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.*

In addition to these red flags, patient J.M. paid for all of her prescriptions in cash. GX 31; GX 33. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 290; GX 32; ALJ Ex. 42, p. 31. [Dr. Sullivan testified that the red flags raised by Patient J.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 290–91.]

Patient M.M.

The Respondent provided three early fills of hydromorphone prescriptions for M.M. from January to March 2019. Tr. 299–300; ALJ Ex. 42, p. 34; GX 34. The Respondent dispensed hydromorphone to M.M. on January 24, 2019, the 21st day after dispensing a 28-day supply on January 3, 2019 (7 days early). *Id.* The Respondent also dispensed hydromorphone to J.D. on February 19, 2019, the 26th day after dispensing a 30-

*[J] As referenced herein, the ALJ did not find that Dr. Sullivan's testimony regarding the ibuprofen prescriptions was factually supported. I find it unnecessary given the strength of the other evidence in this case to reach this issue, and therefore, I am omitting the references to this testimony as irrelevant.

[34] [Texted omitted where footnote was included.]

day supply on January 24, 2019 (4 days early). *Id.* The Respondent then dispensed hydromorphone to J.D. on March 15, 2019, the 24th day after dispensing a 30-day supply on February 19, 2019 (6 days early). *Id.* Dr. Sullivan testified that filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285, 300. He testified that a pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300.

Patient M.M.'s home address was located about 38 miles from the Respondent. GX 60, pp. 5–6; Tr. 292–93. The concern about the distance M.M. would have had to travel, however, was the distance from his home to the prescribing doctor's office. Tr. 293–94. Patient M.M.'s home was located about 134 miles from the office of the doctor who issued him controlled substance prescriptions. GX 61, pp. 1–3. Dr. Sullivan opined that the distance from M.M.'s home to the doctor's office is a red flag.[35] Tr. 292–94.

From June 2017 to August 2018, and from January to April 2019, the Respondent dispensed 14 and 5, respectively, hydromorphone prescriptions to patient M.M. ALJ Ex. 42, p. 33–34; GX 34; GX 36; Tr. 295. All of these 19 prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.*

Dr. Sullivan also pointed out the red flag raised by M.M.'s prescriptions for folic acid 0.4 mg. Tr. 295–96; ALJ Ex. 42, p. 33; GX 36. From June 2017 to August 2018, the Respondent dispensed folic acid 0.4 mg to M.M. on eight occasions. *Id.* Folic acid is a vitamin and 0.4 mg of folic acid is a dose that could be obtained over-the-counter without a prescription. Tr. 295. Dr. Sullivan opined that it is common for doctors who unlawfully prescribe controlled substances to add low doses of non-controlled medication to make their controlled substance prescribing appear legitimate. *Id.* For the same reasons I gave earlier with respect to B.S., however, I do not accept Dr. Sullivan's testimony in this regard.

[35] I am not accepting Dr. Sullivan's testimony that the roundtrip distance from M.M.'s home to the doctor's office, and then to the Respondent, and then back home, is a red flag. Tr. 293. There was no evidence M.M. ever made that round trip. The 38 miles from M.M.'s home to the Respondent is not overly suspicious on its face. I believe the Government withdrew its allegation as to that distance. I will, however, accept Dr. Sullivan's testimony that the 134 miles from M.M.'s home to the doctor's office is a red flag. Tr. 294.

Dr. Sullivan also observed a concerning lapse in M.M.'s opioid prescriptions from July 2018 to January 2019. Tr. 297–98; ALJ Ex. 42, p. 34; GX 34. After M.M. filled a hydromorphone prescription in July 2018, M.M. did not present another prescription until January 2019, when she presented a prescription for 8 mg dosage units of hydromorphone, the highest strength of that drug. *Id.* The seven-month lapse in hydromorphone prescriptions followed by a prescription for the highest strength of hydromorphone should have raised a red flag because returning abruptly to such a high dose after not taking it for seven months would have put M.M. at ''heightened risk for overdose.'' *Id.*

In addition to these red flags, patient M.M. paid for all of her prescriptions in cash. GX 34; GX 36. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient M.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 300–01; GX 35; ALJ Ex. 42, p. 35. [Dr. Sullivan testified that the red flags raised by Patient M.M.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 299–300.]

Patient N.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to N.B. on six occasions. ALJ Ex. 42, p. 37; GX 39; Tr. 302. From September 2018 to January 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to N.B. on two occasions, and a cocktail of alprazolam and hydromorphone on one occasion. ALJ Ex. 42, p. 38; GX 37; Tr. 305.

The Respondent provided two early fills of prescriptions for N.B. from January to March 2019. Tr. 303–04; ALJ Ex. 42, p. 38; GX 37. First, the Respondent dispensed oxycodone and alprazolam to N.B. on January 16, 2019, the 27th day after dispensing a 30-day supply of each drug on December 20, 2018 (3 days early). *Id.* Then, the Respondent dispensed oxycodone to N.B. on March 13, 2019, the 19th day after dispensing a 28-day supply on February 22, 2019 (9 days early). *Id.* A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304.

Patient N.B.'s home address was located about 137 miles from the Respondent. ALJ Ex. 42, p. 36; GX 62; Tr. 301. Dr. Sullivan opined that this distance is a red flag. Tr. 301.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone to N.B. ALJ Ex. 42, p. 37; GX 39; Tr. 302. All of these 12 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* In addition, the Respondent also dispended four prescriptions of alprazolam in 2 mg dosage units, the highest strength of alprazolam. *Id.* Dr. Sullivan also pointed out that on one occasion the Respondent dispensed alprazolam to N.B. in 2 mg and 1 mg dosage units. *Id.* He testified that aking the same controlled substance in two different strengths is a red flag. *Id.*

[Text omitted, *see supra* n.*J.]

Dr. Sullivan also observed a concerning two-month gap in N.B.'s opioid prescriptions in October and November 2018. Tr. 304–05; ALJ Ex. 42, p. 38; GX 37. N.B. presented a prescription for hydromorphone in September 2018 and then presented an oxycodone 30 mg prescription in December 2018, but did not present any opioid prescriptions to the Respondent in October and November. *Id.* Dr. Sullivan testified that not taking opioids for two months and then starting up again on the highest strength of oxycodone is concerning and puts the patient at heightened risk of overdose. Tr. 297–98, 304–05. This lapse in filling opioid prescriptions raises a red flag. *Id.*

In addition to these red flags, patient N.B. paid for all of her prescriptions in cash. GX 37; GX 39. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient N.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 306–07; GX 38; ALJ Ex. 42, p. 39. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient N.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 302–07.]

Patient R.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.B. on twelve occasions. ALJ Ex. 42, p. 41; GX 43; Tr. 311.

The Respondent provided one early fill of hydromorphone to R.B. On February 18, 2019, the Respondent dispensed hydromorphone to R.B. on

February 18, 2019, the 27th day after dispensing a 31-day supply of hydromorphone on January 22, 2019 (4 days early). ALJ Ex. 42, p. 42; GX 40; Tr. 312.

Patient R.B.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 40; GX 63; Tr. 307. Dr. Sullivan opined that this distance is a red flag. Tr. 307.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 12 prescriptions of alprazolam to R.B. ALJ Ex. 42, p. 41; GX 43; Tr. 311. All of the 12 hydromorphone prescriptions were for 8 mg dosage units, the highest commercially available strength of hydromorphone. *Id.* Eleven of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.*

As with patients M.M. and N.B., Dr. Sullivan also observed a concerning three-month gap in R.B.'s opioid prescriptions in October, November, and December 2018. Tr. 312; ALJ Ex. 42, p. 42; GX 40. R.B. presented a prescription for hydromorphone in September 2018 and did not present another hydromorphone prescription to the Respondent until January 2019.[36] *Id.* A three-month lapse in opioid treatment renders the patient opioid naïve and puts the patient at heightened risk of overdose upon resumption of opioid treatment. Tr. 297–98, 304–05, 312. This lapse in filling opioid prescriptions raises a red flag. *Id.*

Dr. Sullivan also observed that R.B.'s PDMP report revealed evidence of pharmacy shopping, which Dr. Sullivan considered significant. Tr. 316–17. The PDMP report showed that R.B. filled controlled substance prescriptions at five different pharmacies, to include the Respondent. Tr. 316–17; GX 44, p. 5.

In addition to these red flags, patient R.B. paid for all of her prescriptions that were filled by the Respondent in cash. GX 40; GX 43. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214. Although R.B. always paid in cash at the Respondent, she used insurance to purchase controlled substance prescriptions at other pharmacies on three occasions. GX 44, pp. 4–5; Tr. 317–19. Dr. Sullivan noted that a patient does not break the law by alternating between paying in cash and using insurance. Tr. 319. It is, however, another red flag that a pharmacist should resolve. Tr. 318–19. When a pharmacist evaluates the red flag raised by a patient paying in cash for controlled substances, it would be relevant to consider the fact that the patient was using insurance to fill prescriptions at another location. Tr. 318.

Although patient R.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 313; GX 41; ALJ Ex. 42, p. 43. [Dr. Sullivan testified that the red flags raised by Patient R.B.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 311, 313, 321.]

Patient R.G.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to R.G. on twelve occasions. ALJ Ex. 42, p. 45; GX 49; Tr. 322–24.

The Respondent provided multiple early fills of prescriptions for R.G. from February to May 2018. Tr. 326–28; ALJ Ex. 42, p. 46; GX 49. The Respondent dispensed alprazolam and oxycodone to R.G. on February 21, 2018, the 23rd day after dispensing a 30-day supply of each drug on January 29, 2018 (7 days early). *Id.* The Respondent again dispensed alprazolam and oxycodone to R.G. on March 19, 2018, the 26th day after dispensing a 30-day supply of each drug on February 21, 2018 (4 days early). *Id.* The Respondent then dispensed alprazolam to R.G. on April 17, 2018, even though the doctor instructed that the prescription should not be filled until April 20, 2018 (3 days early). *Id.* The Respondent dispensed oxycodone to R.G. on May 8, 2018, the 21st day after dispensing a 30-day supply of oxycodone on April 17, 2018 (9 days early). *Id.* A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304, 328.

Patient R.G.'s home address was located about 131 miles from the Respondent. ALJ Ex. 42, p. 44; GX 64; Tr. 322. Dr. Sullivan opined that this distance is a red flag. Tr. 322.

From June 2017 to September 2018, the Respondent dispensed 17 prescriptions of oxycodone and 12 prescriptions of alprazolam to R.G. Tr. 322–24; ALJ Ex. 42, p. 45; GX 49. All of these 29 prescriptions were for the highest strength of the drug. *Id.* All of the 17 oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id.* All of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id.*

In addition to these red flags, patient R.G. paid for all of his prescriptions in cash. GX 46; GX 49. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 328–29; GX 47; ALJ Ex. 42, p. 47. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient R.G.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 322–23, 326, 328–29.]

Patient R.L.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.L. on one occasion. ALJ Ex. 42, p. 49; GX 52; Tr. 331.

The Respondent provided four early fills of hydromorphone to R.L. from February to May 2018. Tr. 333–34; ALJ Ex. 42, p. 51; GX 52. First, the Respondent dispensed hydromorphone to R.L. on February 26, 2018, the 25th day after dispensing a 30-day supply of hydromorphone on February 1, 2018 (5 days early). *Id.* The Respondent dispensed hydromorphone to R.L. again on March 22, 2018, the 24th day after dispensing a 30-day supply of hydromorphone on February 26, 2018 (six days early). *Id.* Then the Respondent dispensed hydromorphone to R.L. on April 17, 2018, the 26th day after dispensing a 30-day supply of hydromorphone on March 22, 2018 (4 days early). *Id.* The Respondent also dispensed hydromorphone to R.L. on May 11, 2018, the 24th day after

[36] Patient R.B.'s PDMP report indicates that the hydromorphone prescription he received from the Respondent in September 2018 was for a 120-day supply. GX 40; ALJ Ex. 42, p. 42. If that were true, the gap in opioid prescriptions from September 2018 to January 2019 would not raise any concern because the September 2018 prescription would have lasted four months. That number, however, must have been incorrectly reported to the PDMP. In fact, the September 2018 prescription was written for a 30-day supply, not 120-days as reported in the PDMP. This becomes evident by comparing the PDMP report to the actual prescription, which is one of the few hard-copy prescriptions in evidence. The PDMP report indicates that the Rx number for the September 2018 hydromorphone prescription (10th from the top) is 5011489 and was issued by Dr. L. GX 40. The corresponding prescription bearing the same Rx number on the fill sticker is located at Government Exhibit 44, pages 6–7 (prescription at top right corner). That prescription was written by Dr. L. for 120 tablets of hydromorphone 8 mg, to be taken one tablet every 6 hours (or 4 tablets per day). GX 44, p. 6. A 120-tablet prescription with these instructions would last one month, not four months. Thus, R.B.'s three month lapse in filling opioid prescriptions at the Respondent remains a concern that the Respondent should have addressed.

dispensing a 30-day supply of hydromorphone on April 17, 2018 (6 days early). *Id.* Filling four consecutive hydromorphone prescriptions early is a red flag. Tr. 271, 285, 300, 334. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 334.

Patient R.L.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 48; GX 65; Tr. 330. Dr. Sullivan opined that this distance is a red flag. Tr. 330.

From June 2017 to September 2018, the Respondent dispensed 14 prescriptions of hydromorphone, one prescription of oxycodone, and one prescription of alprazolam to R.L. Tr. 331–32; ALJ Ex. 42, p. 49; GX 52. All of these 16 prescriptions were for the highest strength of the drug. *Id.* All of the 14 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id.* The oxycodone prescription was for 30 mg dosage units, the highest strength of oxycodone. *Id.* The alprazolam prescription was for 2 mg dosage units, the highest strength of alprazolam. *Id.* From December 2018 to April 2019, the Respondent dispensed five prescriptions of oxycodone to R.L. in 30 mg dosage units, the highest strength of oxycodone. Tr. 331–32; ALJ Ex. 42, p. 50; GX 50.

In addition to these red flags, patient R.L. paid for all of his prescriptions in cash. GX 50; GX 52. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.L. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription. Tr. 334–36; GX 51; ALJ Ex. 42, p. 52. [Omitted for relevance. Dr. Sullivan testified that the red flags raised by Patient R.L.'s prescriptions were not resolvable, and that a pharmacist operating in the usual course of professional practice would not have filled them. Tr. 332, 335–36.]

Analysis of Dispensing Evidence for All Eleven Patients

[Analysis omitted for brevity and relevance.] *K [37] [38] [39] [40] [41] [42] [43]

[As discussed in more detail *infra,* the Government's evidence showed that Respondent repeatedly filled controlled substances prescriptions for eleven patients that raised numerous red flags of drug abuse and diversion. These red flags included early fills, long distances traveled, cash payments, dangerous drug cocktails, and high-strength narcotics. Dr. Sullivan offered credible and unrebutted expert testimony that, for each of these customers, these red flags could not have been resolved by a reasonable pharmacist acting within the usual course of his professional practice. Thus, by filling these prescriptions, Respondent violated its corresponding responsibility and filled prescriptions outside the usual course of professional practice, in violation of 21 CFR 1306.04 and 1306.06. Respondent also violated Florida law, which requires pharmacists to ''exercise[ ] sound professional judgment,'' to conduct a prospective drug use review before dispensing a controlled substance, and to take appropriate steps to avoid or resolve problems with the prescriptions. Fla. Admin. Code rs. 64B16–27.831, 64B16–27.810.]

Analysis of Unlawful Manufacturing Allegation

Finally, the Government alleges that the Respondent engaged in ''manufacturing'' controlled substances, as that term is defined in the CSA, without a separate DEA registration authorizing the manufacture of controlled substances, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). ALJ Ex. 1, ¶ 20–28. Specifically, the Government alleges that the Respondent compounded oxycodone and hydromorphone capsules in such large quantities that this activity constituted manufacturing rather than permissible compounding for individual patients. *Id.*

DEA regulations require registrants to obtain a separate registration for each regulated business activity in which they engage. 21 CFR 1301.13(e). Section 1301.13(e) provides ten separate business activities, to include manufacturing and dispensing.[44] *Id.* at (e)(1)(i), (iv). Each business activity is ''deemed to be independent of each other.'' 21 U.S.C. 1301.13(e). In other words, a registration for one activity does not authorize the registrant to engage in another activity. *Id.* To engage in both dispensing and manufacturing, a registrant would need to apply for and obtain separate registrations for each activity. No person or entity may engage in a regulated business activity ''until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person [or entity].'' 21 CFR 1301.13(a).

Requiring separate registrations for manufacturing and dispensing is more than mere formality. In fact, the CSA imposes stricter requirements on manufacturers than dispensers, not to mention a different standard for issuing a sanction. *Wedgewood Village Pharm.,* 71 FR 16,593, 16,594 (2006); *compare* 21 U.S.C. 823(a) (setting forth six public interest factors for manufacturers of Schedule I and II controlled substances), *with* 21 U.S.C. 823(f) (establishing five similar, yet different, public interest factors for practitioners, which includes pharmacies engaged in dispensing). Additionally, the CSA imposes higher

*K I disagree with the ALJ's decision not to credit Dr. Sullivan's testimony that the red flags in this case could not have been resolved by a pharmacist operating in the usual course of professional practice. Because the ALJ did not credit this testimony, his analysis centered on whether Respondent had adequately resolved the red flags with each prescription and whether Respondent had adequately documented the resolution of red flags. RD, at 90–100. The ALJ concluded that he was unable to determine that Respondent had violated its corresponding responsibility for the majority of the prescriptions, because Dr. Sullivan testified that red flags may be resolved in the patient profile or on the face of the prescription, and the Government did not admit copies of the majority of the prescriptions into evidence. *Id.* Instead, the ALJ found that Respondent had violated Florida law—which the ALJ interpreted as requiring pharmacists to resolve red flags in the patient profile—and therefore, that Respondent had dispensed controlled substances outside the usual course of professional practice, in violation of 21 CFR 1306.06. In its Exceptions, Respondent argued that the ALJ's interpretation of Florida law was incorrect, because it does not require pharmacists to document the resolution of red flags. Resp Exceptions, at 8–17.

As discussed in more detail above, it is not necessary for me to resolve this conflict. Because Dr. Sullivan offered credible and unrebutted expert testimony that the prescriptions in this case presented unresolvable red flags of drug abuse and diversion, and that these prescriptions would not have been filled by a pharmacist acting within the usual course of professional practice, I have concluded that Respondent violated Florida and federal law. Thus, I need not determine whether Respondent made adequate attempts under Florida law to resolve red flags and document their resolution. Therefore, I have omitted the RD's discussion of Florida and federal law requirements for documenting the resolution of red flags. I have also omitted the RD's discussion of whether Respondent adequately documented the resolution of red flags in this case.

This section also included a discussion of Florida requirements for conducting a drug utilization review of each controlled substance prescription. This discussion has been incorporated into the section below summarizing the evidence under Factors Two and Four of the public interest analysis.

[37] [Text omitted where footnote was included.]

[38] [Text omitted where footnote was included.]

[39] [Text omitted where footnote was included.]

[40] [Text omitted where footnote was included.]

[41] [Text omitted where footnote was included.]

[42] [Text omitted where footnote was included.]

[43] [Text omitted where footnote was included.]

[44] Although not relevant to this case, the other business activities include distributing, reverse distributing, research (Schedule I), research (Schedules II–V), narcotic treatment programs, importing, exporting, and chemical analysis. 21 U.S.C. 1301.13(e)(1).

standards for recordkeeping, reporting, and security on manufacturing than it does on dispensing. 71 FR 16,594. Manufacturers are also required to obtain a registration annually, whereas dispensers are only required to obtain a registration every three years. *Id.* (citing 21 U.S.C. 822(a)(1)–(2)).

The Respondent is registered with the DEA as a ''retail pharmacy.'' GX 1. Pursuant to this registration, the Respondent may dispense controlled substances in Schedules II–V. *Id.;* 21 CFR 1301.13(e)(1)(iv). The Respondent's registration as a retail pharmacy authorizing it to engage in the regulated activity of dispensing does not permit the Respondent to manufacture controlled substances; thus, any manufacturing it performed would be unlawful. To prevail on its claim that the Respondent manufactured controlled substances, the Government must show by a preponderance of the evidence that the Respondent engaged in an activity that met the CSA's definition of ''manufacturing.''

Although the CSA does not define what the term ''to compound'' means, it does define ''manufacture.'' *[L] *Wedgewood Village Pharm.* v. *DEA,* 509 F.3d 541, 543 (D.C. Cir. 2007) (noting the CSA does not define ''compounding''). ''The term 'manufacture' means the production, preparation, propagation, *compounding,* or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container.'' 21 U.S.C. 802(15) (emphasis added). Importantly, the CSA includes compounding in its definition of manufacturing. *Id.* Not all compounding, however, is considered to be manufacturing. The definition of manufacturing ''does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.'' *Id.* [Omitted.] [45] [46]

*[M] The thrust of the Respondent's argument is that because the CSA does not define compounding, the appropriate question is whether the Respondent complied with Florida law and other federal laws. Resp't PHB, at 37–38. The Respondent argues that it engaged in anticipatory compounding (*i.e.,* compounding before receiving a prescription), which is permissible under Florida law and the Food, Drug, and Cosmetic Act (hereinafter, FDCA).*[N] *Id.* at 37–41. Florida law provides that lawful compounding includes ''[t]he preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.'' Fla. Admin. Code r. 64B16–27.700(1)(a).*[O] [However, as explained herein, the facts on the record do not support a finding that Respondent was compounding in this manner, nor do they support a finding that Respondent was compounding within the usual course of the professional practice of pharmacy in order to meet the CSA's manufacturing exemption.] [Text omitted.] [47]

*[P] The clearest evidence that the Respondent manufactured, rather than compounded for individual patients, comes from the closing inventory conducted by DI Albert and Mr. Clement, Sr., in September 2018. Tr. 52, 54, 56, 165–66; GX 7. The closing inventory documented the number of controlled substances the Respondent had on hand at the time. *Id.* DI Albert observed Mr. Clement, Sr., conduct the inventory and Mr. Clement, Sr., signed off on it. Tr. 56, 166.

The closing inventory shows that on September 10, 2018, the Respondent had 3,546 compounded capsules of hydromorphone 8 mg on hand and 574 compounded capsules of oxycodone 30 mg on hand. GX 7, p. 1. These capsules were sitting in a safe when they were counted. Tr. 56. Several thousand capsules sitting in a safe is not consistent with compounding for an individual patient's therapeutic needs as an incident to dispensing [nor is it consistent with anticipated prescriptions based on routine prescribing patterns as described in Florida law]. It is consistent with manufacturing capsules in bulk and storing them until a prescription is presented.

The Respondent argues that no evidence of record proves that it ''produced significantly large quantities of any drug.'' Resp't PHB, at 41. Whether the 4,120 capsules stored in the Respondent's safe on September 10, 2018, constitutes a ''significantly large'' quantity is beside the point. Whether the Respondent produced a large or small amount of compounded capsules, however, is relative, and my finding on this allegation has nothing to do with the amount of capsules produced. [Omitted.] [48]

This is especially true when the Respondent typically filled only two to four prescriptions per day. Tr. 508. The rough math shows that four thousand compounded capsules could be enough for two weeks of dispensing. Considering that a month's supply of oxycodone would be roughly 112 tablets (GX 18, p. 6) and a month's supply of hydromorphone would be roughly 120 tablets (GX 44, p. 6), the Respondent had enough oxycodone capsules on hand to fill approximately 5 prescriptions and enough hydromorphone capsules on hand to fill about 29 prescriptions. Together, this would approximate the number of prescriptions the Respondent typically saw over the course of two weeks. This lends further support to my conclusion that the amount of compounded capsules the Respondent had on hand on September 10, 2018, is [more

*[L] Respondent argues in its Exceptions that it was permitted to compound under the definition of ''dispense'' in the CSA. Resp Exceptions, at 17–22. However, as the ALJ stated,

> [u]nder the CSA, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the *lawful order* of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or *compounding* necessary to prepare the substance for such delivery.'' 21 U.S.C. 802(10) (emphases added).

RD, at 105. Respondent has not demonstrated that there was a lawful order of a practitioner to prepare the substance for such delivery to fall under the definition of ''dispense.''

[45] [Text omitted where footnote was included.]

[46] [Text omitted where footnote was included.]

*[M] RD's discussion was relocated.

*[N] The RD contained an analysis of the FDCA requirements in rebuttal of Respondent's assertion, but declined to make a finding as to whether Respondent was in compliance. RD, at 107–09. As the RD noted, the FDCA does not have a direct impact on DEA's interpretation of the CSA manufacturing provision. *Id.*

*[O] Even if Florida law were controlling in this case, there is no evidence that Respondent's compounding was permissible under Florida law. Although Florida Law permits what the Respondent describes as ''anticipatory compounding,'' there are plain language restrictions in the regulation that require the preparation to be in anticipation of prescriptions. As described herein, the facts of this case contradict the Respondent's claim that its compounding was in compliance with this law. Respondent also cited to Fla. Admin. Code r. 64B16–27.700(1)(c) that permits ''the preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis,'' but the evidence shows that Respondent typically contacted the physicians for permission to substitute compounded capsules when the prescriptions were written for tablets. The Respondent has presented no evidence or argument to support that physicians were specifically prescribing the compounded product, which appears to be what is required by this section of Florida code. Furthermore, there is no evidence that this section, or the other section of the Florida code, permits the Respondent to compound without an individualized patient need in accordance with the usual course of professional practice.

[47] [Text omitted where footnote was included.]

*[P] RD's discussion was relocated.

[48] [Text omitted where footnote was included.]

consistent with manufacturing than dispensing compounding within the scope of the CSA.]

In addition to the closing inventory, the Government also points to statements made by Mr. Clement, Sr., in 2012. Gov't PHB, at 46. In May 2012, during execution of an administrative inspection warrant (AIW) at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. Tr. 183. Mr. Clement, Sr., was not in custody at the time and was free to leave. *Id.* In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183–84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2–$10 per pill. *Id.* In other words, $1,100 worth of powder could produce at least $12,000 worth of dosage units. Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it was cost effective. Tr. 184–85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id.* Mr. Clement, Sr., also told TFO Shearer that he persuaded patients to take capsules even if they did not want them because capsules have the same effect as tablets.[49] Tr. 185–86.

Although these statements were made in 2012, they demonstrate that the Respondent had a system in place to compound thousands of capsules at a time. Tr. 184–85. These statements also demonstrate that the Respondent's motive for mass-compounding thousands of capsules per batch was cost effectiveness, rather than patients' unique therapeutic needs. Tr. 184–86. These statements provide additional support to the conclusion that the Respondent's compounding was cost-driven rather than patient-driven, and that the Respondent was, therefore, manufacturing and not compounding as the CSA understands those terms.

[49] While reliable hearsay statements may be admissible in these administrative proceedings, Mr. Clement, Sr.'s, statements to TFO Shearer in 2012 are not hearsay. They enjoy enhanced credibility as they would qualify as statements by a party opponent and would, therefore, be excluded from the definition of hearsay. Fed. R. Evid. 801(d)(2). [Respondent argues that this conversation was six or seven years ago and to rely on it would be arbitrary and capricious. Resp't Exceptions, at 3. This conversation lends further support for a finding that has other support in the record. Also, I note that Respondent did not refute this evidence through the testimony of Mr. Clement, Sr.]

The Government also points to the batch records obtained pursuant to the 2017 subpoena. Gov't PHB, at 46; Tr. 27. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id.* The batch records indicate how many capsules were used in the production of each batch. Tr. 38, 40–41. The batch records in Government Exhibit 5 document the production of hydromorphone 8 mg. The batch records in Government Exhibit 6 document the production of oxycodone 30 mg. The hydromorphone batch records show that the Respondent ''compounded'' from 600 to 2,400 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 5. The oxycodone batch records show that the Respondent ''compounded'' from 600 to 1,800 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 6. These numbers are consistent with the number of compounded capsules found during the 2018 closing inventory and with Mr. Clement, Sr.'s, statements to TFO Shearer in 2012. [When viewed with the other facts,] these numbers are also consistent with manufacturing rather than [dispensing] compounding.

Furthermore, the Respondent's dispensing records also demonstrate that the patients for whom the Respondent compounded oxycodone and hydromorphone did not have valid therapeutic needs for compounded medication. Dr. Sullivan explained that the definition of compounding in the practice of pharmacy is to ''make[ ] a drug . . . from scratch, make it in a finished form from an unfinished form, to meet the individual, unique therapeutic needs of a patient.'' Tr. 230. Compounding would be necessary, he continued, if the patient had an allergy to the commercially available version or if the patient needed a unique dose or strength that was not available in the mass-produced product. Tr. 230–31. [Omitted. Dr. Sullivan also testified that the dosage units dispensed in GE–11, at 7, demonstrated that 90,179 dosage units of the compounded 8 milligram hydromorphone capsules. Tr. 248. He testified that ''[t]here cannot be that many patients that need to have compounded hydromorphone 8 milligram tablets to meet the unique therapeutic needs of the patient. In [his] opinion, that's manufacturing.'' Tr. 249; *see also* Tr. 250 (same for oxycodone).]

Dispensing records, however, show that the Respondent dispensed both commercially manufactured tablets and compounded capsules to the same patient. The fact that the Respondent dispensed both commercially available tablets and compounded capsules of the same controlled substances to the same patients indicates that the patients lacked ''unique therapeutic needs'' for the compounded version. Tr. 231, 256. For example, the Respondent dispensed seven prescriptions of oxycodone 30 mg tablets to patient A.G. from June 2017 to August 2018. ALJ Ex. 42, p. 11. During that same time period, the Respondent also dispensed to A.G. three prescriptions of oxycodone 30 mg compounded capsules. *Id.* A note dated March 13, 2017, in A.G.'s profile states that a doctor approved dispensing medication to A.G. in compounded capsules. GX 15, p. 1; ALJ Ex. 42, p. 13. After March 2017, however, the Respondent continued dispensing both tablets and compounded capsules to A.G. ALJ Ex. 42, p. 11. Thus, even if a doctor approved of A.G. taking compounded capsules, it was not for a therapeutic or medical reason because he continued to alternate between capsules and tablets. [Dr. Sullivan testified that nothing in the record demonstrated that there was a therapeutic need for the compounded medication. Tr. 258–59].

In another example, the Respondent dispensed both tablets and compounded capsules to patient R.G. to fill the same oxycodone prescription. GX 49; Tr. 325–26. Dr. Sullivan opined that R.G. clearly had no valid therapeutic need for compounded capsules since he also took the tablet form of the same drug. Tr. 326. Patient R.G. also received oxycodone in capsules on 15 occasions from June 2017 to September 2018, and in tablets on 2 occasions during the same time period. ALJ Ex. 42, p. 45. As Dr. Sullivan observed, the fact that the Respondent dispensed oxycodone to R.G. in both capsule and tablet forms, and dispensed capsules and tablets together on one occasion, demonstrates that the Respondent was not compounding for R.G. in response to a unique therapeutic need for compounded capsules. Tr. 325–26. Furthermore, no profile for any of the patients documents an allergy or other reason that would have necessitated compounded capsules. Tr. 339; GX 15, 20, 23, 26, 29, 32, 35, 38, 41, 47, 51.

Dr. Sullivan pointed out numerous other instances where the Respondent's dispensing history demonstrated that patients lacked legitimate therapeutic justification for compounded capsules. From January 2018 to December 2018, the Respondent dispensed compounded capsules of hydromorphone 8 mg to A.H. on eight occasions: January 4;

February 15; March 5; April 3; May 2; August 16; September 11; and December 5. ALJ Ex. 42, pp. 15–16; GX 19; GX 21. The Respondent then dispensed tablets of hydromorphone 8 mg to A.H. on the following five occasions in 2019: January 22; February 15; February 27; March 14; and April 18. *Id.* The fact that the Respondent dispensed capsules of hydromorphone to A.H. on eight occasions in 2018 and then tablets of hydromorphone on five occasions in 2019 demonstrates that A.H. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him. Tr. 255–56, 258–59, 269.

Dr. Sullivan noted a lack of therapeutic justification to compound hydromorphone for B.S. since he received hydromorphone in both tablets and capsules. Tr. 274. From August 2017 to August 2018, the Respondent filled 12 hydromorphone prescriptions with compounded capsules for B.S.: August 22, 2017; September 27, 2017; October 18, 2017; November 15, 2017; December 12, 2017; January 4, 2018; January 29, 2018; February 28, 2018; March 26, 2018; April 23, 2018; May 22, 2018; and August 24, 2018. ALJ Ex. 42, p. 19; GX 24. On February 5, 2019, the Respondent filled a hydromorphone prescription for B.S. with tablets. ALJ Ex. 42, p. 20; GX 22. The fact that the Respondent dispensed hydromorphone tablets to B.S. in 2019 shows that B.S. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him on 12 occasions in 2017 and 2018. Tr. 255–56, 258–59, 269, 274.

The Respondent dispensed oxycodone capsules and tablets to C.R., indicating that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255–56, 258–59, 269, 274, 279–80. On July 19, 2017, and October 26, 2017, the Respondent filled oxycodone prescriptions for C.R. with compounded capsules. ALJ Ex. 42, p. 23; GX 27. The Respondent then filled four oxycodone prescriptions for C.R. with tablets: March 6, 2018; April 19, 2018; July 12, 2018; and August 28, 2018. *Id.*

Dr. Sullivan observed that J.M. alternated between tablets and capsules of oxycodone, demonstrating that there was no valid therapeutic need for the Respondent to compound oxycodone capsules for her. Tr. 290. First, the Respondent dispensed oxycodone tablets to J.M. on January 25, 2018, and then filled J.M.'s next oxycodone prescription with compounded capsules on March 1, 2018. ALJ Ex. 42, p. 30; GX 33; Tr. 290. The next month the Respondent switched back to oxycodone tablets on April 4, 2018, followed by oxycodone capsules on April 19, 2018, and then switched back again to tablets on May 16, 2018. *Id.* The fact that the Respondent alternated between dispensing oxycodone tablets and capsules to J.M. demonstrates that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255–56, 258–59, 269, 274, 279–80, 290.

Dr. Sullivan observed that the Respondent dispensed oxycodone tablets and compounded capsules to M.M. Tr. 295, 297. From June 2017 to August 2018, the Respondent filled 14 oxycodone prescriptions for M.M. with compounded capsules. Tr. 295, 297; ALJ Ex. 42, pp. 33–34; GX 34; GX 36. From January 2019 to April 2019, the Respondent filled five oxycodone prescriptions for M.M. with tablets. *Id.* The fact that the Respondent dispensed compounded oxycodone capsules to M.M. for over a year and then switched to dispensing oxycodone tablets to her for several months demonstrates that there was no valid medical reason for the Respondent to have compounded oxycodone for her. Tr. 255–56, 258–59, 269, 274, 279–80, 290, 295, 297.

Dr. Sullivan observed that the Respondent compounded hydromorphone capsules for N.B. without any apparent therapeutic justification. Tr. 302. From June 2017 to August 2018, the Respondent filled twelve hydromorphone prescriptions for N.B. with compounded capsules. ALJ Ex. 42, p. 37; GX 39.

Dr. Sullivan pointed out that the Respondent compounded hydromorphone capsules for R.B. without any apparent medical justification. Tr. 311, 319–20. From June 2017 to January 2019, the Respondent filled 14 hydromorphone prescriptions for R.B. with compounded capsules. GX 40; GX 43; ALJ Ex. 42, pp. 41–42. At least three of those prescriptions were originally written for tablets and were substituted for capsules by the Respondent. Tr. 319–20; GX 44, pp. 6–7. The Respondent then dispensed hydromorphone tablets to R.B. on three occasions from February to April 2019. ALJ Ex. 42, p. 42; GX 40. The fact that the Respondent dispensed tablets and capsules of hydromorphone to R.B., switching prescribed tablets to capsules, demonstrates that there was no valid therapeutic reason for the Respondent to compound hydromorphone for R.B. Tr. 311, 319–21.

Lastly, Dr. Sullivan noted that the Respondent compounded capsules of hydromorphone for R.L. without any apparent medical justification. Tr. 331; ALJ Ex. 42, p. 49; GX 52. From June 2017 to September 2018, the Respondent filled 14 hydromorphone prescriptions for R.L. with compounded capsules. *Id.*

[Contrary to the Respondent's contention, due to the credible and unrebutted testimony of the Government's expert witness, Respondent's compounding cannot fall into the CSA's exception to the definition of manufacturing ''in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.'' *Q 21 U.S.C. 802(15). Dr. Sullivan's testimony was clear that the compounding here was outside the course of professional practice, because there was no individualized therapeutic need for the compounded capsules, as evidenced by the quantities dispensed and the alternating of compounded capsules and commercially available product and the lack of documentation or other support demonstrating any individualized need. Further, as described above, Respondent's reliance on Florida law is unavailing for many

*Q In finding that Respondent engaged in manufacturing, the ALJ relied primarily on a statutory interpretation of ''incident to'' and determined that the compounding in this case would not be considered ''incident to'' the dispensing. RD, at 103–06. I find that it is unnecessary to rely on a statutory interpretation of ''incident to'' in this case, because the evidence on the record clearly establishes that this compounding was not in the course of professional practice, which the statute states plainly is required for the exception to the manufacturing definition to apply. In analyzing this issue, the ALJ discussed the Agency's decision in *Wedgewood,* which clarifies that to use a dispensing registration for compounding the important consideration is that the compounding is ''for a specific patient on a patient by patient basis.'' *Id.* (citing *Wedgewood Village Pharm.,* 71 FR 16,593, 16,595 (2006)). It is noted that *Wedgewood* was appealed and remanded, based primarily on the Agency's interpretation of distribution—not manufacturing, *Wedgewood Village Pharmacy* v. *DEA,* 509 F.3d 541, 550–52 (D.C. Cir. 2007) and therefore, that the Agency's interpretation in *Wedgewood* regarding what constitutes manufacturing remains intact; however, I also find it unnecessary to rely on prior Agency interpretation in this case, because, again, the statute is clear regarding the requirement that such compounding must be in the course of professional practice. My conclusions rely on Dr. Sullivan's testimony that patients must have a specific need for compounded capsules and other support in the record that the usual course of professional practice requires such a need. As discussed in more detail herein, the record does not demonstrate that Respondent's customers had individualized needs. The RD also provided examples where courts, including the Supreme Court, have defined the term ''compounding'' to require individualized patient need. RD, at 105, n.45, and 116. Although not in the context of the CSA, these interpretations further support Dr. Sullivan's credible and unrebutted testimony regarding the course of the professional practice and the lack of individualized need for compounded capsules in this case.

reasons. Although Florida law permits compounding based on routine, regularly observed prescribing patterns, there is nothing in Florida law to suggest that this anticipation would negate the professional practice of pharmacy requirement for there to be individualized therapeutic need, which the record has repeatedly demonstrated was lacking with regard to these compounded capsules.*R *See* Fla. Admin. Code r. 64B16–27.700(1)(a).]

In sum, the evidence paints a picture of a pharmacy mass-compounding bulk quantities of oxycodone and hydromorphone in thousands of capsules per batch. The evidence further reveals the Respondent's motive for doing so: Profit rather than patient need. The evidence shows that the Respondent's ''compounding'' was not incidental to the act of dispensing and was not in the course of its professional practice. [Omitted]. Thus, the Respondent engaged in manufacturing thousands of controlled substance dosages over a period of several years without the proper registration. For these reasons, the Government's allegation that the Respondent illegally manufactured controlled substances is SUSTAINED. ALJ Ex. 1, pp. 8–10, ¶ 20–28. [Although I find that this constitutes a separate violation of federal law, which I consider under Factor Four below, I also find that there is more than enough evidence of other violations in this case to support a sanction of revocation, even if I had not sustained this allegation.]

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[50] 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 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *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.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

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.[51] The Government has also raised one allegation under Factor Five.

[Factors Two and Four are often analyzed 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). Factor Two analysis focuses on an applicant's acts that are inconsistent with the public interest, rather than on an applicant's neutral or positive acts and experience. *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career'') (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state controlled substance laws. 21 U.S.C. 823(f)(4). Factor Four analysis focuses on violations of state and federal laws and regulations. *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009) (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.,* 74 FR 10,083, 10,090–91 (2009).] *S 52

Standard of Care as to Charged Violations *T

[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.

*R Although stated in a different context, there is further support for this finding in *Department of Health, Petitioner* v. *Discovery Experimental and Development, Inc., Respondent Discovery Experimental and Development, Inc., Petitioner,* 2003 WL 1921003 (April 18, 2003), where a Florida Administrative Law Judge stated that Fla. Admin. Code r. 64B16–27.700 ''requires patient specific compounding of medicinal drugs, on a per prescription basis where there is an established patient-physician relationship, and the patient has been made aware that a pharmacist will prepare the compounded drug.'' *Id.* at n.14). Although the portion of the Florida regulation cited to by Respondent would permit advance preparation of compounded drugs under state law, there is no evidence that Florida intended it to permit a pharmacy to compound drugs without a specific therapeutic need. In fact, the Government's expert opined that such compounding is not within the course of professional practice of pharmacy, and in his opinion, constitutes manufacturing.

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

[51] 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).

*S For brevity and keeping with recent cases, I have removed the RD's legal analysis of Factors Two and Four and replaced it with this text.

[52] [Text omitted where footnote was included.]

*T This section was modified to clarify the analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

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 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28,667, 28,670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

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

In this matter, the Government did not allege that Respondent dispensed the prescriptions at issue having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated its corresponding responsibility by filling prescriptions that raised red flags that were so strongly indicative of drug abuse and diversion that they could not have been resolved by a pharmacist acting in the usual course of professional practice. ALJ Ex. 1, pp. 4–7. 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.*[U] Additionally, DEA has consistently held, based on the credible testimony of pharmacy experts, that prescriptions may raise red flags that are so strongly indicative of diversion that they cannot be resolved by a pharmacist acting within the usual course of professional practice, and should not be filled.*[V] DEA has also held that a pharmacist who fills prescriptions that present unresolvable red flags engages in knowing diversion of controlled substances.*[W]

[Text omitted for brevity.]*[X]

The Government has introduced a preponderance of evidence to prove that the Respondent dispensed numerous controlled substance prescriptions for at least eleven patients that raised red flags of drug abuse and/or diversion. These

*[U] *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] *See, e.g., Pharmacy Doctors Enterprises,* 83 FR 10,286, 10,888 (2018) (crediting expert testimony that certain red flags were ''not resolvable''); *The Medicine Shoppe,* 79 FR 59,504, 59,507–08 (2014) (same); *Holiday CVS, LLC,* 77 FR 62,316, 62,319 (2012) (same); *cf. Edge Pharmacy,* 81 FR 72,092, 72,112 n.54 (2016) (noting that ''many of the prescriptions presented unresolvable red flags'').

*[W] *The Medicine Shoppe,* 79 FR at n.10.

*[X] 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)).

red flags included early fills, long distances traveled, cash payments, dangerous drug cocktails, and high-strength narcotics, among others. [Dr. Sullivan offered credible and unrebutted testimony that these red flags could not have been resolved by a reasonable pharmacist acting within the usual course of his professional practice. Therefore, I find that the Respondent filled prescriptions for controlled substances that the pharmacists knew 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 outside the usual course of professional practice in violation of 21 CFR 1306.06.*[Y]

Further, the Government introduced evidence that Respondent violated Florida law by repeatedly filling prescriptions that raised unresolvable red flags. 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.

Respondent violated Fla. Admin. Code rs. 64B16–27.810 and 64B16–27.831 by repeatedly filling prescriptions that presented unresolvable red flags. Based on Dr. Sullivan's credible expert testimony, as supported by Florida law and prior Agency Decisions, a pharmacist acting in accordance with Florida law would have declined to fill these prescriptions after conducting a prospective drug use review.]

The Respondent failed to rebut or discredit the Government's case. The Respondent did not introduce any documentary evidence and it only offered the testimony of a single witness, who failed to convincingly rebut the Government's evidence. In light of the record as to this factor, I find that the Government has overwhelmingly proven that the Respondent failed to comply with federal and state law with respect to its corresponding responsibility for the prescriptions in evidence.

Furthermore, I find that the Government has sponsored a preponderance of evidence to show that the Respondent engaged in unlawful manufacturing of controlled substances without the proper DEA registration, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1301.13(e). Thus, the Government has introduced evidence against the Respondent with respect to two aspects of the controlled drug supply chain, dispensing and manufacturing. The totality of this evidence demonstrates a concerning lack of compliance with applicable federal and state law 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 this factor significantly favors revoking the Respondent's registration.*[Z]

[Section omitted for brevity and relevance.] *[AA] [53] [54]

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 364, 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007).*[BB] 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.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995); *Medicine Shoppe,* 73 FR 387; *see also Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (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 62,316, 62,346 (2012); *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801 (2015).

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 owner and pharmacist-in-charge never testified at the hearing in order to accept responsibility. Instead, the Respondent's sole witness, a pharmacy tech, never admitted that the Respondent committed any wrongdoing. The Respondent's post-hearing brief is silent on this issue. Resp't PHB, p. 29, ¶ (i); p. 32, ¶ (ii); p. 36, ¶ (iii). [In its

*[Y] I have omitted the RD's discussion of Respondent's efforts (or lack thereof) to document a resolution of the red flags in this case.

*[Z] As found herein, there is substantial record evidence that Respondent dispensed controlled substances prescriptions outside the usual course of the professional practice in Florida and in violation of its corresponding responsibility and in violation of state law. There is also substantial record evidence that Respondent manufactured controlled substances outside the usual course of professional practice and without the proper registration. I, therefore, have concluded that Respondent engaged in misconduct that supports a determination that its registration is inconsistent with the public interest. *See Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,903 (2018).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). At the time the Government issued the OSC, the Government had clear evidence that Respondent repeatedly filled prescriptions that presented a combination of red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice, which establishes ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registration. *Id.*

*[AA] The Government argued that I should consider under Factor Five that ''Respondent's business consisted almost entirely of dispensing controlled substances to customers who exhibited one or more significant red flags.'' Gov't Posthearing, at 39–40. The ALJ declined to consider this conduct under Factor Five. RD, at 130–31. I find that the Government has provided substantial evidence related to Factors Two and Four to support my finding that Respondent's continued registration is inconsistent with the public interest and that the appropriate remedy in this case is revocation. Therefore, I decline to consider the Government's evidence under Factor Five.

[53] [Text omitted where footnote was included.]

[54] [Text omitted where footnote was included.]

*[BB] This sentence was relocated for clarity, and text was omitted for brevity.

opening statement, Respondent previewed its failure to accept responsibility]. Respondent argued that the Government had failed to satisfy its burden; accused the DEA of never intending to clearly or objectively evaluate the evidence; attacked the credentials of the Government's expert; claimed that the Respondent exercised appropriate judgment when dispensing the relevant controlled substance prescriptions in compliance with Florida law; and complained about the so-called ''ivory tower aspirational'' 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

*[CC] 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 38363, 38364 (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 law and state standards of practice [by filling prescriptions that presented unresolvable red flags].*[DD] Respondent repeatedly dispensed high-strength schedule II opioids, sometimes dangerously combined with high-strength benzodiazepines, to patients who raised multiple red flags of diversion. [These red flags included paying in cash, filling prescriptions early, filling dangerous combinations of high-strength narcotics and benzodiazepines, and traveling between two and five hundred miles round trip to Respondent. The Government's expert credibly testified that the rationales that the patients offered for traveling such extraordinary distances should have concerned the pharmacists. Patient A.G. wrote on his questionnaire that he traveled two hundred and eighty miles roundtrip for ''quick and good service,'' GX 18; and Patient R.B. wrote that she traveled the same distance because ''[i]t's cheaper and [she has] found that they are good people.'' GX 44, at 1. Dr. Sullivan testified that the red flags raised by these prescriptions were so strongly indicative of drug abuse and diversion that a pharmacist acting in the usual course of professional practice would not have filled them. Respondent's decision to repeatedly turn a blind eye to these red flags] constitutes egregious misconduct because it allowed for the potential of unchecked diversion of controlled substances into illegitimate channels.

[Omitted for brevity.] *[EE]

In addition to the severity of the Respondent's dispensing misconduct, the Respondent also unlawfully manufactured thousands of capsules of schedule II controlled substances without being registered with the DEA as a manufacturer. As noted earlier, registered manufacturers of controlled substances are held to higher standards than practitioners with respect to recordkeeping, reporting, security, and frequency of renewing registration. Thus, manufacturing controlled substances without the DEA's blessing enabled the Respondent to produce thousands of dosage units of controlled substances over several years in the absence of regulatory monitoring. As with unlawful dispensing, unlawful manufacturing is an egregious violation and warrants the revocation of registration.

I further find that 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 [ignoring glaring red flags of drug abuse and diversion], and despite engaging in a regulated activity without obtaining approval from the DEA to engage in that activity. 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.

Advice of Counsel

When the DEA executed an AIW at the Respondent in September 2018, the Respondent's owner and pharmacist-in-charge, Mr. Clement, Sr., refused to speak to DI Albert upon advice of counsel to not answer any questions. Tr. 168, 173, 177. The Respondent has an absolute right to seek advice of counsel, and no adverse inference from obtaining advice of counsel may be drawn. It does not provide, however, any defense to actions taken, including failing to eventually respond to DEA inquiries following consultation with counsel, or lack of cooperation with the DEA's investigation.

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 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. As just discussed, the Respondent does not appear to believe it has done anything wrong. [Text 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. [Omitted for relevance.] *[FF]

*[CC] Omitted for brevity.

*[DD] Paragraph modified for consistency with my finding that the prescriptions in this case presented a combination of red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice.

*[EE] 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).

*[FF] I have omitted the ALJ's discussion of Respondent's failure to cooperate with DEA investigators during inspections. Although cooperation with law enforcement can be relevant to sanction determinations, it is not necessary for me to consider this evidence in this case. I find that revocation is the appropriate remedy based on the

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. FP2302076 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: May 5, 2020.

Mark M. Dowd,

U.S. Administrative Law Judge

The Respondent's Exceptions *[GG]

On May 26, 2020, Respondent filed its exceptions to the Recommended Decision. DEA regulations require that Exceptions ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, Respondent's Exceptions not only fail to comply with this regulatory requirement, but they also lack evidentiary support in the Administrative Record. Additionally, some of Respondent's Exceptions repeat arguments that were already raised in Respondent's Posthearing Brief, and were adequately addressed by the ALJ in the adopted Recommended Decision.

Exceptions #1 and 2

In the first two Exceptions, Respondent argues that the ALJ erred in concluding that approximately thirty of the documents that the Government admitted into evidence were accurate and reliable. Resp Exceptions, at 5–8. These documents consist of: (1) Dispensing data, prescription records, and other patient records that DEA downloaded from Respondent's computers during the September 2018 AIW; and (2) dispensing data that DEA obtained from Florida's controlled substance dispensing database, E–FORSCE. *Id.* Because all of these records were generated by Respondent, and Respondent has not identified any specific concerns with the accuracy of these records, I find that these Exceptions are without merit.

The only record evidence that Respondent identifies as potentially undercutting the reliability of these records is Mr. Clement, Jr.'s testimony that Respondent's computers were inoperable when DEA returned them after the search warrant was executed in August of 2019, which precluded Respondent from confirming the accuracy of the records that DEA downloaded. Resp Exceptions, at 6–7 (citing Tr. 515, 517–18). Respondent also argues that DEA did not present ''sufficient evidence to prove the accuracy or reliability of the[se] records,'' because DI—who laid the foundation for each document—did not download the records from Respondent's computers himself, and therefore could not attest to whether any errors were made when the records were extracted.*[HH] *Id.* at 5–6 (citing Tr. 62–65, 134–36).

Respondent, however, has not identified any inconsistencies or errors in the documents that would cause me to question their reliability. For example, Respondent has not identified any particular prescriptions that it believes it did not dispense, or patients to whom it did not dispense.*[II] Moreover, Respondent has not identified any discrepancies between the E–FORSCE dispensing records, which DEA obtained directly from E–FORSCE, and the dispensing records that DEA downloaded from Respondent's computers. It is reasonable for DEA to rely on these records as evidence of Respondent's dispensing, because these are all records that Respondent is required to generate under Florida *[JJ] and federal law.*[KK]

Exception #3

Respondent next 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 8–17. Respondent argues that the RD's conclusion that Respondent violated 21 CFR 1306.04(a) and 1306.06 was dependent on his erroneous conclusion that Florida law requires documentation, and therefore, Respondent argues that these conclusions should be overturned. *Id.*

I do not need to address this Exception because I have concluded above, based on Dr. Sullivan's credible and unrebutted expert testimony, that the prescriptions that Respondent dispensed raised red flags that could not have been resolved by a pharmacist acting within the usual course of professional practice. I have also concluded that, by filling these prescriptions, Respondent violated its corresponding responsibility because the pharmacists knew these controlled substances were not prescribed for

egregiousness of Respondent's conduct and its failure to accept responsibility.

*[GG] Jack Folson, Jr., who identifies himself as a clinical pharmacist in Westland, Michigan, filed a document on June 9, 2020, titled Amicus Brief Concerning the Standard of Practice in Pharmacy, Law and Decision of the Administrative Law Judge. Mr. Folson states that Respondent retained him to review the trial transcript and the RD, and he outlines his disagreements with the RD and Dr. Sullivan's testimony. The ALJ issued an Order Regarding Respondent's Amicus Brief on June 10, 2020. Order, at 1. The Order stated that Respondent had already filed the one set of exceptions it was entitled to file, and that the Amicus Brief was essentially a second set of exceptions that was filed after the May 26, 2020 deadline. *Id.* The ALJ also noted that the Amicus Brief repeatedly cites to materials outside of the record and includes unsworn expert testimony. *Id.* at 2. I agree with the RD's conclusion that the Amicus Brief is a set of untimely exceptions that is not permitted by the agency's adjudicative process. *Id.* at 2. Further the Brief presented evidence that was not on the record of the hearing, which I cannot consider, because doing so would, among other things, deprive the Government of an opportunity to address Respondent's representations and prevent a full credibility assessment. *See Lisa Hamilton,* 84 FR 71,465, 71,466 n.3 (2019). Therefore, I do not consider the Amicus Brief in my Decision.

*[HH] Respondent also argues that the Government did not adequately authenticate these records, but Respondent waived this objection by failing to raise it in writing prior to the hearing and failing to show good cause for not raising it prior to the hearing. *See* 21 CFR 1316.59; *see also* Tr. 64–68. Moreover, Respondent has not raised any noteworthy objections to the authenticity of these records.

*[II] The one error that Respondent identifies in the PDMP data does little to undercut the reliability of the PDMP data, and in fact, it elucidates the suspicious nature of Respondent's dispensing. Resp Exceptions, at 7 (citing RD, at 86 n.36). The PDMP indicates that Respondent prescribed a 120-day supply of hydromorphone to Patient R.B. in September 2018, when in fact the prescription was for a 30-day supply. RD, at 86 n.36. This PDMP error highlights an unexplained lapse in Patient R.B.'s opioid prescriptions, because this patient did not fill another hydromorphone prescription for four months after receiving the 30-day supply. *Id.*

In questioning the PDMP data, Respondent also states that ''the Government's own expert acknowledged that there are errors in the PDMP data.'' Resp Exceptions, at 7. Respondent cites to Dr. Sullivan's testimony—in response to the question of whether he has ''ever encountered . . . a data entry error'' in the PDMP—that he ''know[s] that there are data entry errors in the PDMP. Potential errors.'' *Id.* This testimony is not specific enough to undermine the reliability of the PDMP data, especially because Respondent is required by state law to accurately report each controlled substance that it dispenses to E–FORSCE. *See* Fla. Stat. § 893.055(3)(a) (2019) (requiring certain information to be reported to E–FORSCE each time a controlled substance is dispensed, including the date the prescription was filled; the patient's name and other identifying information; and the name, quantity, and strength of the controlled substance dispensed).

*[JJ] *See* Fla. Stat. § 893.055(3)(a).

*[KK] *See generally* 21 CFR 1304.04; *see also* Tr. 492 (DI's testimony that pharmacists must keep accurate dispensing logs).

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 the red flags were unresolvable, I find that it is irrelevant whether Respondent took adequate steps under Florida law to document any attempts to resolve the red flags.

Exception #4

Respondent's final Exception restates, nearly verbatim, arguments that it made in its Posthearing brief. *Compare* Resp Exceptions, at 17–21 *with* Resp Posthearing, at 36–41. I find that the RD adequately addresses these arguments, and I agree with the RD's conclusion that Respondent engaged in illegal manufacturing. I therefore find that this Exception is without merit.

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. FP2302076 issued to Pronto Pharmacy, LLC. 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 Pronto Pharmacy, LLC 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 all controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective December 20, 2021.

Anne Milgram,

Administrator.

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