DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–41]

Pharmacy 4 Less; Decision and Order

On July 5, 2018, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Pharmacy 4 Less, (hereinafter, Respondent) of Altamonte Springs, Florida. Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed to revoke its DEA Certificate of Registration (hereinafter, COR) No. FP5459082, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was held in Orlando, Florida, on November 5–7, 2018, and continued in Arlington, Virginia, on February 25, 2019. On May 22, 2019, Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ) issued the Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD), and on June 11, 2019, the Government timely filed exceptions (hereinafter, Govt Exceptions) to the Recommended Decision. On June 23, 2019, the Respondent filed what it styled as a response to the Government's Exceptions (hereinafter, Resp Exceptions).[*A] According to the ALJ, the Respondent Pharmacy did not request an extension of time to file exceptions, nor did it request an extension of time to file a response to the Government's Exceptions pursuant to 21 CFR 1316.66(c). *See* ALJ Transmittal Letter dated June 25, 2019. Even though Respondent did none of those things, I have decided to address the Exceptions filed by Respondent as part of my review of the record.[*B] Having reviewed the entire record, I find the Respondent's Exceptions are without merit and I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.[*C]

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FP5459082 issued to Pharmacy 4 Less. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application for renewal or modification of this registration by Pharmacy 4 Less in Florida. This Order is effective November 1, 2021.

Anne Milgram,

Administrator.

The Government's Exceptions

The Government, though in agreement with much of the ALJ's opinion, filed exceptions to the RD on June 11, 2019. The Government described its primary concern as being delay caused by the ALJ's conditional admission of documents and proffer testimony, and asked that I ''specify the manner in which the ALJ is to balance the risk of delay with the risk of being reversed, and to, where appropriate, allow only limited proffers.'' Govt Exceptions, at 3. The presiding ALJ has the ''duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order'' and has the power to ''[r]eceive, rule on, exclude, or limit evidence.'' 21 CFR 1316.52 and (f). In other words, he possesses discretion to ''regulate the course of the hearing.'' 5 U.S.C. 556(c)(5) (West 2021). As such, I decline to broadly instruct ALJs in the manner requested by the Government.

Next, the Government alleged that the ALJ erroneously admitted Respondent Exhibits 18–37, which consisted of due diligence files for the patients at issue in this case which had been updated by Respondent after the dates relevant to this case (and after a Government subpoena for these same records). Govt Exceptions, at 3–6. The Government conceded that the records could have been relevant to establish remedial measures taken by Respondent Pharmacy, but argues that they would have been relevant only if Respondent Pharmacy first accepted responsibility for its actions. *Id.* The Government alleges that the ALJ's admission of RX 18–37, even conditionally, was improper without Respondent first establishing responsibility or proffering that acceptance of responsibility was forthcoming. As I have already discussed, I decline to instruct the ALJs on how to balance the risk of delay against the need to receive evidence as it lies within their discretion, because every case will be different. Here, the ALJ ultimately found that the Respondent Pharmacy did not accept responsibility for its actions, but it would have been difficult for the ALJ to have reached that conclusion at the beginning of the evidentiary hearing.

The remainder of the Government's exceptions are addressed in the relevant sections of the RD as footnoted below.

The Respondent's Exceptions

On June 23, 2019, the Respondent filed its exceptions to the Recommended Decision. Exceptions ''shall 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, the Respondent's Exceptions not only fail to comply with this regulatory requirement, but also lack evidentiary support in the Administrative Record. Some of Respondent's Exceptions [*D] repeat facts which were already raised at the hearing in this matter and addressed by the ALJ in the adopted Recommended Decision herein.

Most of Respondent's Exceptions introduce evidentiary facts that Respondent Pharmacy appears to be offering to establish remedial measures.[*E] Many of these facts are not

[*A] Despite the title, Respondent's filing appears to assert its own Exceptions to the RD rather than respond to the Government's Exceptions.

[*B] My decision to consider the Respondent's Exceptions is based on the particular circumstances of this case, including but not limited to, the withdrawal of Respondent's counsel after the conclusion of the hearing.

[*C] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy, I have corrected an occasional citation, and I have made minor, non-substantive, grammatical changes. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with an asterisk and a letter.

[*D] Respondent's Exceptions ¶ 1 asserting that starting doses for opioid patients were not high and that the Pharmacy had detailed medical records; ¶ 7 regarding the initial inventory; ¶ 8 asserting the accuracy of the perpetual inventory; ¶ 12 claiming the opioid naivety red flag was resolved by checking e-FORCSE. Respondent's Exceptions, at 2–3.

[*E] Respondent's Exceptions ¶ 4 asserting that the pharmacy can now bill insurance companies and that 80% of the Schedule II controlled substances prescriptions it fills are through insurance now; ¶ 5 asserting the pharmacy now fills only 10% of the Schedule II controlled substances prescriptions it was filling in 2015 and 2016, admitting they filled too many Schedule II prescriptions in the past and claiming they are not ''extremely due diligent in filling;'' ¶ 6 asserting that the pharmacy does not fill prescriptions from a neighboring pain doctor who will not share medical records; ¶ 7 asserting that Respondent Pharmacy passed every Department of Health inspection from 2015 to 2019; ¶ 9 asserting that Patient A.R. has been discharged; ¶ 11 asserting

supported by the record and were not under oath or subject to cross examination when they were presented for the first time in Respondent's Exceptions. Moreover, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79188, 79202–03 (2016).'' As Respondent Pharmacy has failed to unequivocally accept responsibility for its actions, the purported remedial measures offered by Respondent in its Exceptions, even if they were part of the evidentiary record, would have no impact on my decision in this case.

Similarly, the Respondent's Exceptions contained a number of factual assertions regarding Owner Richard Sprys' purported work with law enforcement bodies to report illegal pharmacy operations and provide testimony, seemingly for the DEA in one instance, to hold those pharmacies accountable. *Id.* at 3. None of these facts were given under oath and none were subject to cross-examination; therefore, they are simply not part of the evidentiary record. Even if Respondent's assertions had been appropriately submitted through testimonial evidence, they could only have been relevant in assessing whether Respondent Pharmacy could be entrusted with a registration. Here, as Respondent Pharmacy has failed to unequivocally accept responsibility for its actions, such assertions would have had no impact on my decision.

The remainder of the Respondent's Exceptions are addressed in their relevant sections of the Recommended Decision as footnoted below.

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

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

The Assistant Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause,[1] dated July 5, 2018, seeking to deny the Respondent's Certificate of Registration, number FP5459082, on the ground that the Respondent's registration would be inconsistent with the public interest, pursuant to 21 U.S.C. 824(a)(4), and as defined in 21 U.S.C. 823(f). The Respondent requested a hearing on August 2, 2018,[2] and prehearing proceedings were initiated.[3] A hearing was conducted in this matter on November 5–7, 2018, in Orlando, Florida, and resumed on February 25, 2019, at the DEA Hearing Facility in Arlington, Virginia.

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

In the OSC, the Government contends that the DEA should revoke the Respondent's DEA COR because it failed to comply with 21 U.S.C. 824(a)(4) and its registration is inconsistent with the public interest, *see* 21 U.S.C. 823(f). Specifically, the Government alleges the following:

1. The Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes and repeatedly filled prescriptions in the face of obvious red flags of diversion, in violation of both federal and state law (including 21 CFR 1306.06, 1306.04(a); *Wheatland Pharmacy,* 78 FR 69411, 69445 (2013); Fla. Admin. Code r. 64B16–27.810, 64B16–27.831[4]), specifically from at least October 27, 2015 to at least June 19, 2017, to at least ten different patients. ALJ Ex. 1 at ¶¶ 2–4.

2. The Respondent routinely filled Schedule II controlled substances without resolving the ''red flag'' of patients with ''very high starting dosages,'' both with respect to the individual dose being prescribed and with respect to the number of tablets being prescribed, which is potentially fatal for a patient. ALJ Ex. 1 at ¶ 5.

3. The Respondent routinely filled controlled substance prescriptions without resolving the ''red flag'' of immediate release pain medication over long periods of time. A chronic pain patient should be moved to a long acting medication. ALJ Ex. 1 at ¶ 6.

4. The Respondent routinely filled controlled substance prescriptions without resolving the ''red flag'' of extremely high cash prices. ALJ Ex. 1 at ¶ 7.

5. The Respondent routinely filled prescriptions without resolving the ''red flag'' for patients who traveled long distances to visit the Respondent's pharmacy. ALJ Ex. 1 at ¶ 8.

6. The Respondent would fill prescriptions without resolving the ''red flag'' for drug combinations that needed to be questioned, such as the combination of buprenorphine and oxycodone. ALJ Ex. 1 at ¶ 9.

Treatment of Patients

Patient A.E.

From November 19, 2015, to at least June 1, 2017, the Respondent filled at least 21 prescriptions for hydromorphone for A.E. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.E.'s prescriptions were for 84 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength.

b. A.E. filled his prescriptions for short acting hydromorphone since at least November 19, 2015, even though hydromorphone is not prescribed for long-term use or chronic conditions.

c. A.E. paid cash for his prescriptions at inflated prices, paying $500.00 for 84 tablets of hydromorphone 8 mg, approximately $5.95 per pill, at a time when legitimate pharmacies were charging approximately $1.50.

Patient A.R.

From March 17, 2016, to at least June 7, 2017, the Respondent filled at least 17 prescriptions for oxycodone for A.R. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.R. filled his prescriptions for immediate release oxycodone since at least March 17, 2016, even though oxycodone is not prescribed for long-term use or chronic conditions.

b. A.R. drove extremely long distances to fill oxycodone prescriptions. A.R. drove approximately 37 miles southwest to visit the prescribing doctor, an additional 17.9 miles further southwest

that Patient A.V. was successfully taken off of opioids. Resp Exceptions, at 2–3.

[1] ALJ Ex. 1.

[2] ALJ Ex. 2.

[3] ALJ Ex. 3.

[*F] All references to ''Acting Administrator'' have been changed to ''Administrator.''

[4] It was noted that there was a scrivener's error by the Government citing to r. 64B16–27.821. The Government later corrected the cite to reflect the correct citation to r. 64B16–27.831.

to the Respondent's pharmacy, an additional 45.4 miles to A.R.'s home, for a total of 97.3 miles round-trip to fill the oxycodone prescriptions.

Patient A.V.

From April 12, 2016, to at least April 10, 2017, the Respondent filled at least 9 prescriptions for buprenorphine and at least 12 prescriptions for oxycodone for A.V. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.V.'s prescriptions were for 112 tablets of oxycodone 20 mg and 60 tablets buprenorphine 8 mg, which are large amounts of tablets at a high dosage strength.

b. A.V. was filling prescriptions for opioid withdrawal at the same time he was filling a prescription for an opioid.

c. A.V. filled his prescriptions for short acting oxycodone since at least April 12, 2016, even though oxycodone was not prescribed for long-term use or chronic conditions.

Patient B.F.

From October 27, 2015, to at least May 15, 2017, the Respondent filled at least 17 prescriptions for hydromorphone and at least 5 prescriptions for oxycodone for B.F. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. B.F.'s prescriptions were for 84 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength.

b. B.F. filled his prescriptions for short acting hydromorphone since at least October 27, 2015, even though hydromorphone is not prescribed for long-term use or chronic conditions.

c. B.F. paid cash for his prescriptions at inflated prices, paying $490.00 for 84 tablets of hydromorphone 8 mg, approximately $5.93 per pill, at a time when legitimate pharmacies were charging approximately $1.50.

Patient B.N.

From January 22, 2016, to at least June 2, 2017, the Respondent filled at least 9 prescriptions for hydromorphone and at least 10 prescriptions for oxycodone for B.N. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. B.N.'s prescriptions were for 100 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength. In September 2016, B.N. switched to 120 tablets of oxycodone 30 mg, which is an even higher number of tablets at the highest dosage strength of oxycodone.

b. B.N. filled his prescriptions for immediate release oxycodone and hydromorphone since at least January 22, 2016, even though oxycodone and hydromorphone are not prescribed for long-term use or chronic conditions.

c. B.N. paid cash for his prescriptions at inflated prices, paying up to $640.00 for 100 tablets of hydromorphone 8 mg, approximately $6.40 per pill, at a time when legitimate pharmacies were charging approximately $1.50. Similarly, B.N. paid prices up to $650.00 for 120 tablets of oxycodone 30 mg, approximately $5.51 per pill, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient K.Y.D.[5]

From February 4, 2016, to at least June 12, 2017, the Respondent filled at least 17 prescriptions for oxycodone and at least 17 prescriptions for morphine sulfate for K.Y.D. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. K.Y.D.'s prescriptions for hydromorphone were for 84 tablets of oxycodone 30 mg, which is a large amount of tablets at the highest dosage strength.

b. K.Y.D. paid cash for his prescriptions at inflated prices, paying up to $290.00 for 84 tablets of oxycodone 30 mg, approximately $3.45 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient K.E.D.

From October 26, 2015, to at least June 7, 2017, the Respondent filled at least 20 prescriptions for oxycodone for K.E.D. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. K.E.D.'s prescriptions for oxycodone were for 112 tablets of oxycodone 20 mg, which is a large amount of tablets at a high dosage strength.

b. K.E.D. filled his prescriptions for immediate release oxycodone since at least October 26, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

c. K.E.D. paid cash for his prescriptions at inflated prices, paying up to $430.00 for 112 tablets of oxycodone, approximately $3.83 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient R.R.

From October 28, 2015, to at least May 30, 2017, the Respondent filled at least 21 prescriptions for oxycodone for R.R. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. R.R.'s prescriptions for oxycodone were for 112 tablets of oxycodone 15 mg, which is a large amount of tablets at a high dosage strength.

b. R.R. filled his prescriptions for immediate release oxycodone since at least October 28, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

Patient R.V.

From November 17, 2015, to at least June 19, 2017, the Respondent filled at least 21 prescriptions for oxycodone for R.V. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. R.V.'s prescriptions for oxycodone were for 112 to 120 tablets of oxycodone 20 mg, which is a large amount of tablets at a high dosage strength.

b. R.V. filled her prescriptions for immediate release oxycodone since at least November 17, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

Patient V.W.

From November 30, 2015, to at least May 31, 2017, the Respondent filled at least 20 prescriptions for oxycodone for V.W. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. V.W.'s prescriptions for oxycodone were for 84 to 112 tablets of oxycodone 15 mg, which is a large amount of tablets at a high dosage strength.

[5] There are two patients with the same initials, K.D. In pretrial filings, the Government and Respondent referred to these patients as K.D.1 and K.D.2. However, the Government and Respondent referred to different patients as K.D.1 and K.D.2 (*i.e.,* the Government's K.D.1 was Respondent's K.D.2). At the hearing, the parties discussed this issue and decided to refer to these two patients by the first two letters in their first name. All of the Government's pre-trial filings referring to K.D.1 are now discussed as K.Y.D. All of the Government's pre-trial findings referring to K.D.2 are now discussed as K.E.D. The opposite is true for the Respondent.

b. V.W. filled his prescriptions for immediate release oxycodone since at least November 30, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

c. V.W. paid cash for his prescriptions at inflated prices, paying up to $400.00 for 112 tablets of oxycodone, approximately $3.57 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Recordkeeping Violations

1. The Respondent did not have an initial inventory, when requested by DEA during an on-site inspection of June 6, 2017, in violation of 21 CFR 1304.11(b).

2. The Respondent's biennial inventory failed to indicate whether it was taken at the opening or closing of business as required by 21 CFR 1304.11(a).

3. The Respondent's pharmacist on duty, Amy Mincy, stated that the biennial inventory was performed over several days, in violation of 21 CFR 1304.11(a).

4. The Respondent's pharmacist on duty during the June 6, 2017 on-site inspection admitted to using the pharmacy owner's, Mr. Richard Sprys, CSOS credentials to order controlled substances in violation of 21 CFR 1311.30(a) & (c).

5. The Respondent's receiving records showed that the Respondent failed to create an electronically linked record of a quantity and date received for its controlled substances in violation of 21 CFR 1305.22(g). The Respondent also possessed 89 invoices without the date of receipt recorded in violation of 21 CFR 1304.22(c).

The Hearing

Preliminary Matters

At the outset of the hearing, the Government confirmed that it was not going forward with pursuing any independent violation against the Respondent for a delay by the Respondent in complying with the July 2018 administrative subpoena. Tr. 14–15.[6] This Tribunal also noticed the Government that if it intended to assert a new allegation or expand the charges, it must inform this Tribunal at the time the new matter is broached at the hearing. *Id.* at 15–16. This would also give the Respondent the opportunity to either litigate the issue by consent or to object to the new allegation. *Id.* at 15–16. No supplemental allegations were broached by the Government.

The Respondent noted that they would be withdrawing their motion to suppress evidence, a motion that this tribunal had only preliminarily ruled upon. *Id.* at 17; ALJ Ex. 35. This Tribunal noted that the preliminary evidentiary rulings were for guidance and that the parties would still need to make their objections at the time of the hearing to preserve those objections. Tr. 17. The Respondent further requested that this Tribunal take official notice of 21 CFR 1304.21(a) and 21 U.S.C. 827(a)(3), to which this Tribunal acceded. *Id.* at 17–18. Next, the Respondent made preliminary objections as to authentication, failure to meet the business records exception, and improper burden shifting as to Government's Proposed Exhibits 9, 11, and 13. *Id.* at 18–19. This Tribunal carried those objections over to the hearing. *Id.* at 19. Then, the Respondent clarified that Government's Proposed Exhibit 25 had been ruled inadmissible and excluded.[7] *Id.* at 20. The Respondent then discussed a number of other matters related to proposed exhibits, which will be later discussed. *Id.* at 20–22. Finally, the Respondent objected to Government's Proposed Exhibit 26, which objection was also carried to the hearing. *Id.* at 23.

Government's Opening Statement

In the Government's Opening Statement, it previewed that the DEA conducted an audit of Pharmacy 4 Less on June 6, 2017. *Id.* at 25. The Government intended to explain the on-site audit through the testimony of DI1, including the findings from the audit, and explain the record keeping and regulatory violations that were discovered. *Id.* at 25. The Government also intended to offer the testimony of Dr. Hamilton regarding his review of the prescriptions and due diligence files that Pharmacy 4 Less maintained and how the Respondent filled prescriptions for controlled substances without resolving red flags. *Id.* at 25. Finally, the Government argued that the Respondent had not accepted responsibility for any of the alleged violations. *Id.* at 25–26.

Respondent's Opening Statement

In the Respondent's Opening Statement, it described Pharmacy 4 Less as a small, independent pharmacy. *Id.* at 27. Pharmacy 4 Less has two pharmacists and a low volume of patients. *Id.* at 27. The Respondent contrasted it from Publix, the pharmacy where Dr. Hamilton is employed. *Id.* at 27–28. The Respondent stated that Pharmacy 4 Less cannot purchase in volume like other retail pharmacies, and cannot sell at the same prices as other larger pharmacies. *Id.* at 28.

The Respondent described Mr. Richard Sprys, the owner and operator of Pharmacy 4 Less. *Id.* at 28. The Respondent detailed Mr. Sprys' community involvement in his capacity as a pharmacist, and how he has previously testified as a witness in several cases for the Government in whistleblower cases against pharmacies. *Id.* at 28. The Respondent further asserted that Mr. Sprys has always attempted to cooperate with the Government, including the process involving the July 9, 2018 administrative subpoena. *Id.* at 28–29. The Respondent also described Ms. Amy Mincy, another pharmacist that works at Pharmacy 4 Less, including her extensive background and experience as a pharmacist. *Id.* at 30.

The Respondent described the June 6, 2017 on-site inspection of Pharmacy 4 Less. *Id.* at 29. The Respondent asserted that the DEA diversion investigators related to Ms. Mincy, the pharmacist on-site at the time of the inspection, that the inspection would only last ten to fifteen minutes when the inspection actually lasted over six hours. *Id.* at 29.

The Respondent asserted that the Government's portrayal that the Respondent has not accepted responsibility is misplaced. *Id.* at 30. The Respondent stated that they submitted a corrective action plan (which the DEA rejected), they have modified their behavior, they have reduced the number of patients they see and fill prescriptions for, and they have implemented a number of other remedial changes. *Id.* at 30.

The Respondent further described the treatment of patients when they visit Pharmacy 4 Less. *Id.* at 30–32. The Respondent asserted that each patient receives specialized attention by the pharmacists because of Pharmacy 4 Less's small size. *Id.* at 31. The Respondent also stated that not only does Pharmacy 4 Less contact patients' doctors to resolve red flags, but Pharmacy 4 Less goes beyond that of other pharmacies because they will request and keep medical records of their patients to assist in the resolution of red flags. *Id.* at 31–32.

Finally, the Respondent stressed that while Pharmacy 4 Less may not be

[6] Tr.—Refers to the hearing transcript. The number(s) immediately following refer to the transcript page numbers.

[7] GX 25 consisted of over 1000 pages of an Excel spreadsheet involving records of patients additional to the ten patients who are the subject of the allegations. GX 25 was ruled inadmissible as generally irrelevant. The Government was permitted to reconstitute the exhibit reflecting only the ten subject patients. The Government's substitute exhibit was introduced as GX 35.

perfect, they keep their practice above-average. *Id.* at 32. The Respondent maintains that before and after the DEA on-site inspection, Pharmacy 4 Less has a clean record with the Florida Department of Health for their on-site inspections. *Id.* at 32.

Government's Case in Chief

The Government presented its case in chief through the testimony of two witnesses. First, the Government presented the testimony of a Diversion Investigator (hereinafter DI1). Secondly, the Government presented the testimony of its expert, Dr. Thomas D. Hamilton.

Diversion Investigator DI1

DI1 has been a Diversion Investigator for approximately seven years. *Id.* at 33. He is currently assigned to the Orlando District Office, in Orlando, Florida. *Id.* at 33. DI1 described his training and experience at the DEA Academy and in the field at the Baltimore and Orlando offices, including experience in at least 50–70 pharmacy investigations. *Id.* at 34–35.

DI1 first met with the staff at Pharmacy 4 Less on June 6, 2017. *Id.* at 37. He explained that Diversion Investigators[8] were doing regulatory inspections and Pharmacy 4 Less was randomly picked for a regulatory inspection. *Id.* at 37. When they arrived, the DIs showed their credentials and presented Ms. Amy Mincy, a pharmacist at Pharmacy 4 Less, with a DEA Form 82 Notice of Inspection.[9] *Id.* at 37–38; GX 30.[10] The form was signed by Ms. Mincy and the DIs began their on-site inspection. Tr. 38–39.

The DIs began by asking questions about Pharmacy 4 Less's customer base and prescriptions, and looked at the prescriptions records, log books, and other required records. *Id.* at 39. When DI1 asked Ms. Mincy about inventories, she could not locate the initial inventory; so Mr. Richard Sprys, the owner of Pharmacy 4 Less, was contacted via speakerphone by Ms. Mincy to determine where the initial inventory could be located. *Id.* at 39–40.[11] DI1 asked Mr. Sprys over the phone if Pharmacy 4 Less had an initial inventory, and Mr. Sprys replied that it did not. *Id.* at 40.

DI1 next inquired as to whether Pharmacy 4 Less had performed a biennial inventory. *Id.* at 40–41. Ms. Mincy provided DI1 with a document purported to be a biennial inventory. *Id.* at 41. DI1 concluded that the document did not comply with DEA regulations as the purported biennial inventory did not include a statement that it had been completed either at the opening or closing of business.[12] *Id.* at 41–42. Further, DI1 claimed that Ms. Mincy had indicated that she had completed it over several days. *Id.* at 41. DI1 indicated that biennial inventories need to be completed either at the opening or closing of business and it needs to be notated on the biennial inventory. *Id.* at 41–42. DI1 claimed that during this exchange, Ms. Mincy said, ''what was [I] supposed to do, shut down the pharmacy?'' *Id.* at 42. As part of his later audit of the pharmacy's inventories, DI1 did not use the biennial inventory because he could not verify its accuracy due to the issues he had discovered during his review. *Id.* at 56, 61, 66, 154–56.

DI1 then inquired of Ms. Mincy as to recordkeeping and CSOS records.[13] *Id.* at 42. DI1 asked Ms. Mincy how Pharmacy 4 Less documents and records their ordering of controlled substances and validation of a prescription's legitimacy. *Id.* at 43.[14] When DI1 asked Ms. Mincy to produce the CSOS records (including records of receipt for Schedule 2s), he observed that Ms. Mincy proceeded to a laptop in the pharmacy to log into the CSOS system. *Id.* at 45. DI1 asked Ms. Mincy if she had her own CSOS credentials (which DI1 asserted is required for anyone accessing the CSOS system and cannot be shared with anyone else). *Id.* at 46. In response, Ms. Mincy stated she did not have her own credentials and did not have a power of attorney for anyone else's credentials. *Id.* at 46. Ms. Mincy stated to DI1 that she was using Mr. Richard Sprys credentials to log onto CSOS. *Id.* at 46.

DI1 later contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters, to determine which personnel at Pharmacy 4 Less had access to the CSOS system. *Id.* at 47–48. Mr. Jewell ran a report and the report stated that Ms. Mincy received her own CSOS credentials in July 2018. *Id.* at 48–49; GX 29.[15]

DI1 described the audit[16] of Pharmacy 4 Less's records and inventories.[17] Tr. 53–85, 919–26; GX 4, 31, 32.[18] DI1 conducted an audit of Pharmacy 4 Less's records and inventories at a starting date of January 1, 2017. Tr. 55–56. DI1 selected this date because Pharmacy 4 Less maintained handwritten Schedule 2 controlled substance logs, there was no initial inventory, and the investigating DIs were unsure of how accurate the biennial inventory was. *Id.* at 56, 61. For example, DI1 had used the pharmacy's handwritten perpetual inventory forms for Methadone 10 mg tablets and Oxycodone 30 mg tablets during the audit, which had been provided to DI1 by Ms. Mincy during the on-site inspection on June 6, 2017. *Id.* at 56–60; GX 31, 32.[19]

DI1 explained that under DEA regulations, records need to be readily retrievable and maintained at the pharmacy. Tr. 86. It does not satisfy the regulations that records may later be retrieved. *Id.* at 86. He discovered that

[8] DI1 was accompanied by Group Supervisor DI2 during the on-site inspection. Tr. 41.

[9] A Notice of Inspection is a DEA Form evidencing a voluntary consent to search.

[10] GX—Government's Exhibit.

[11] Richard Sprys was not present at Pharmacy 4 Less during the on-site inspection on June 6, 2017. Tr. 40.

[12] *See* 21 CFR 1304.11(a).

[13] CSOS—Controlled Substance Ordering System.

[14] DI1 asserted during his testimony that when a pharmacy orders and receives controlled substances on-site, they are required to notate that they received them with the date and the initials of the person that received them. Tr. 44.

[15] The Respondent objected to admission of GX 29 on the basis of lack of authentication and not meeting the exception of a business record. Tr. 49. DI1 made it clear that he did not personally produce this record, but requested it from Mr. Jewell. *Id.* at 49–50. This Tribunal noticed that it appears to be a government record and did not appear to have any indication of inaccuracy or unreliability. *Id.* at 50. The Respondent argued that portions of the document appeared to have inaccuracies as related to Mr. Sprys, but agreed that if the Government was only offering the document as related to Ms. Mincy, it would not object if the rest of the document was blackened out to only show Ms. Mincy's records. *Id.* at 50–52. The Government agreed that it was only offering the document for Ms. Mincy's records on the top line and would not object to blackening out Mr. Spry's records. *Id.* at 51–52. This Tribunal admitted GX 29 on that basis as altered and is only considering GX 29 for the top line as related to Ms. Mincy's records. *Id.* at 51–52.

[16] The audit occurred both at the pharmacy and later during a review of Pharmacy 4 Less's records. Tr. 100.

[17] DI1 was later asked about his receipt and possession of records obtained from the pharmacy during the June 6, 2017 on-site inspection. Tr. 949–54; Proposed RX 10 (not offered into evidence) (The Government also had a standing objection to this line of questioning as outside the scope of redirect examination. Tr. 951.). Proposed RX 10 was a DEA–12, a receipt of items taken by the DIs after their inspection. Tr. 951. The DEA–12 forms indicated that the DEA had taken possession of six California folders containing C–2 prescriptions, and 13 manila folders containing C–2 invoices. Tr. 951–53.

[18] The Government initially offered GX 4 during the first portion of the hearing in Orlando, Florida. Tr. 67. The Respondent conducted voir dire and objected that it was unreliable. Tr. 68–81. This Tribunal initially admitted the exhibit. Tr. 81–85. However, this Tribunal reconsidered its ruling and found that GX 4 in its then present condition would not be helpful to the factfinder. Tr. 146. This Tribunal then afforded the Government the opportunity to resubmit GX 4 at a later time. Tr. 146–48. During the portion of the hearing in Arlington, Virginia, the Government reintroduced a corrected version of GX 4. Tr. 925. The Respondent did not object and the corrected version of GX 4 was admitted. Tr. 925–26.

[19] For a full discussion of how DI1 conducted his audit, *see* Tr. 61–67.

Pharmacy 4 Less did not have readily retrievable records available during the June 6, 2017 on-site inspection. *Id.* at 87.[20]

Following the June 6, 2017 on-site inspection, DIs[21] returned to Pharmacy 4 Less again on June 21, 2017. *Id.* at 88. Ms. Mincy was again at the pharmacy, and Mr. Richard Sprys joined them later that day. *Id.* at 88. DI1 stated that he discussed his findings from the initial on-site inspection and audit (including the invoices and prescriptions) with Mr. Sprys and Ms. Mincy during this second visit. *Id.* at 88. During the discussion, DI1 asked Mr. Sprys and Ms. Mincy how they determined whether prescriptions were for a legitimate medical purpose, based on a review of the records the DIs had retrieved during the first on-site inspection. *Id.* at 89–90. The pharmacists (both Mr. Sprys and Ms. Mincy) responded that they checked E–FORCSE, the Florida prescription monitoring program website, and that they would verify prescriptions by contacting the doctor's office and/or requesting patient medical files. *Id.* at 90–91. When asked how this information is documented, one of the pharmacists (DI1 could not remember if it was Mr. Sprys or Ms. Mincy) provided a red folder that they maintained. *Id.* at 91–92. The red folder contained screenshots from the computer system, Rx30.[22] Tr. 92. The red folder contained information related to multiple patients. Tr. 93, 119–31; GX 5, 7, 13, 17, 21, 23. DI1 did not find any ''due diligence files'' for Patients A.V., B.F., K.Y.D., or R.R. in the files provided to him by Pharmacy 4 Less. Tr. 131–36.

The following day on June 22, 2017, an administrative subpoena was served on Pharmacy 4 Less, requesting hard copy prescriptions for all Schedules 2–5 controlled substance prescriptions from October 2015 through June 22, 2017, all controlled substance prescription data from Rx30, and all due diligence patient files. Tr. 93–94; GX 2. Pharmacy 4 Less complied by delivering a gray tote container that contained ''California'' folders filled with Schedule 2 hard copy prescriptions, a thumb drive containing all Rx30 data, and the red folder seen during the June 21 on-site inspection. *Id.* at 96. The Schedules 3–5 prescriptions were delivered to the DIs by Pharmacy 4 Less at an unidentified later date. *Id.* at 97. The red folder contained screenshots from the Rx30 program. *Id.* at 96. The red folder also contained the pharmacists' notes on patients, referred to as ''due diligence files.'' *Id.* at 96–97. The ''California'' folders were organized by prescription number, which DI1 sorted through to locate prescriptions for the 10 charged patients at issue in this case. Tr. 97–111; GX 6, 8, 10, 12, 14, 16, 18, 20, 22, 24.[23] DI1 also discussed the Rx30 data retrieved from the thumb drive related to the 10 charged patients. Tr. 111–16; GX 35, 36.[24]

Diversion Investigators (the DIs were not identified by DI1) returned to Pharmacy 4 Less during approximately February 2018. Tr. 136. During this visit, DI1 acquired copies of invoices for controlled substances. Tr. 136. DI1 noted that a few of these invoices violated DEA regulations by failing to provide a date of receipt.[25] thnsp;*G Tr. 136–39.

Another administrative subpoena was served on Pharmacy 4 Less on July 9, 2018. Tr. 95; GX 3.

DI1 was recalled during the second portion of the hearing at the DEA Hearing Facility in Arlington, Virginia. DI1 credibly explained the purpose of the corrected GX 4, and how he arrived at his results during his audit of the pharmacy's records and inventories. Tr. 919–26. DI1 also testified to GX 38—Redacted (Initial Response from Florida E–FORCSE reflecting only the 10 charged patients) and GX 40 (A declaration by DI3 as to an administrative subpoena sent to the Florida E–FORCSE for user history), which was introduced at the second portion of the hearing. Tr. 929–36.[26] DI3 was asked by DI1 to send an administrative subpoena to the Florida E–FORCSE program to request a user history report. *Id.* at 929–30. Based on a follow-up request by DI1, the Florida E–FORCSE personnel reviewed their system to see when Mr. Sprys and Ms. Mincy had accessed the Florida PDMP to look up patients. Tr. 931–32; GX 40, Att. C.

DI1 also offered three arrest records for Patient K.Y.D. Tr. 937; GX 41–43. The arrest records were produced from ''*arrest.org,*'' a public website where members of the public can retrieve arrest information about individuals, which DI1 occasionally uses in the course of his employment. *Id.* at 938–39. DI1 indicated that this website is a tool that pharmacists or doctors can utilize to look up patients to see if they have ever been arrested for controlled substance violations. *Id.* at 940. According to the records, Patient K.Y.D. had previously been arrested on December 31, 2015, for possession of oxycodone with an intent to sell. *Id.* at 940; GX 43. Patient K.Y.D. had also previously been arrested on May 2, 2016, for operating with a suspended license, possession of Schedule 2 controlled substances, and possession of a Schedule 4 controlled substance. Tr. 941; GX 41. Finally, Patient K.Y.D. had also previously been arrested on February 25, 2017, for possession of a Schedule 2 controlled substance and resisting an officer without violence. Tr. 941–42; GX 42.[27]

Dr. Thomas Hamilton, Pharm. D.

Dr. Hamilton received his Doctor of Pharmacy degree at Nova Southeastern University in Fort Lauderdale. Tr. 167. He has worked as a pharmacist for 18 years. *Id.* at 169; GX 27. After being licensed in 1999, he worked for a short time at a small pharmacy before beginning full-time at Publix pharmacy as a pharmacist. Tr. 172. He served in

[20] DI1 explained that ''readily retrievable'' means that when DIs go into a pharmacy to perform an audit or to review a record, the pharmacy should be able to provide those records within a reasonable time. Tr. 87.

[21] DI1 noted that on this second visit, he was present, along with DI Debbie George, Group Supervisor Linda Stocum, and Division Program Manager of the State of Florida, Susan Langston. Tr. 88.

[22] Rx30 is a computer software that Pharmacy 4 Less used to maintain their inventory, the dispensing of controlled substances, and as DI1 testified, patient profile screens where the pharmacist can input notes about the patient, including information about the patient, treatment, injuries, and other diagnosis notes. Tr. 92–93. The Respondent identified this as the patient record maintenance form (PRM). *Id.* at 93.

[23] These exhibits were admitted with the qualification that these exhibits only contained the Schedule 2 hard copy prescriptions for each of the 10 charged patients, not all of the prescriptions. Tr. 102–11. [The Government noted, that ''some of the prescriptions here are not Schedule 2s, but [the Government did] not litigat[e] those prescriptions,'' and they are therefore not relevant to the Government's *prima facie* case. Tr. 103.]

[24] GX 35 is a narrowed version of Government's Proposed Exhibit 25, which was previously ruled inadmissible during prehearing proceedings. GX 35 only included information related to the 10 charged patients. Tr. 116–18. *See* ALJ Ex. 32.

[25] The Respondent conducted voir dire of DI1 on this point and argued that 21 CFR 1305 only applies to Schedule 2 controlled substances. Tr. 140–45. For further analysis, *see infra* section ''Date of Receipt on Invoices.''

[*G] DI clarified his testimony to say that ''only a few of them actually contained the . . . date of receipt;'' specifically, there were only ''four that contain[ed] the actual date of receipt,'' and ''eighty-five'' were not properly dated. Tr. 137–38.

[26] GX 38—Redacted was admitted and substituted in place of the original GX 38. Tr. 934. GX 40, p. 1, Att. A, and Att. C. were also admitted into evidence. Tr. 935–36.

[27] The Respondent objected and argued that the arrest records were unreliable and irrelevant to this matter. This Tribunal found that these records were available to the public, and not being offered for the truth of the matter of the arrests, but as a resource that an individual such as a doctor or pharmacist would be confronted with if they accessed this website. They were admitted over objection. Tr. 942–43. Reviewing such arrest websites is not required by the relevant standard of care, nor is it something that Dr. Hamilton or the other pharmacists did at Publix Pharmacies. Tr. 1022–23.

various capacities at Publix, including Pharmacist, Assistant Manager of the Pharmacy, and Pharmacy Manager. GX 27. He also served as a ''fixer,'' or a temporary Pharmacy Manager, who would ''clean up'' pharmacies. Tr. 169. Dr. Hamilton later transitioned to a Pharmacy Supervisor, in which he oversaw up to 40–45 *[H] pharmacies, in hiring, firing and daily operations. Tr. 170. Additionally, Dr. Hamilton evaluated stand-alone, independent pharmacies for purchase by Publix Supermarkets. *Id.* at 170. This evaluation included review of the drug invoices, the filled prescriptions, and the nature of the pharmacy's overall business. *Id.* at 170–71. In order to spend more time with his young family, Dr. Hamilton decreased his responsibilities with the company, gave up his supervisory role, and now serves as a Pharmacy Manager of a single pharmacy with Publix. *Id.* at 286–87.

In connection with the investigation into Pharmacy 4 Less, Dr. Hamilton reviewed the materials sent to him by the Government, which included prescriptions (front and back), related patient medical notes, and patient addresses. *Id.* at 177, 380–81. Additionally, Dr. Hamilton reviewed prescription pricing via GoodRx. *Id.* at 177–78. Dr. Hamilton noticed ''red flags'' in connection with the reviewed prescriptions. *Id.* at 178. ''Red flags'' are concerns resulting from the review of the prescription. *Id.* at 178–79. These concerns can be resolved through some investigation by the pharmacist, such as speaking with the patient, reviewing the medical history, or checking with the prescriber. *Id.* at 179. Dr. Hamilton noted that the resolution of the ''red flag'' had to be documented in the file as part of the Florida Standard of Care,*[I] noting, ''[i]f it's not documented, there's no evidence that . . . it was resolved *[or a phone call was made, or an answer was given].'' *Id.* at 179–81, 306, 318, 337, 1006–11, 1016.[28]

Dr. Hamilton indicated the source of pharmacy standards in Florida included ''Florida Regulation 64B,'' [29] and guidance from the National Board of Pharmacy Association. *Id.* at 180, 351–58. Dr. Hamilton noted these standards are enforced by the Board of Pharmacy in Florida. *Id.* at 180.

Dr. Hamilton explained that if the prescription involved a controlled substance, that in itself was a red flag. *Id.* at 182. The strength of medication and the duration of the medication therapy was a concern, which needed to be addressed. *Id.* The pricing structure of the controlled substance represented a concern, as well as the distance of travel. *Id.* at 182, 360–61.

Dr. Hamilton noted ''red flags'' in a prescription to Patient A.E., for 84 tablets of 8 mg. of hydromorphone. *Id.* at 183–84; GX. 6, pp. 1–2, GX. 5; RX 18, pp. 1–2, RX 19.[30] Dr. Hamilton noted that 8 mg was the highest dosage made of hydromorphone, a Schedule 2 controlled substance. Tr. 184. Further, the number of dosage units prescribed, 84, was also concerning. *Id.* at 184. Dr. Hamilton noted that, based on the records, the first ''red flag'' involving a dangerously high dosage level, had not been resolved. *Id.* at 186. Dr. Hamilton noted the absence of any information relating to the patient's prescribing history suggesting the patient was acclimated to this significant dosage, and not ''opiate naïve'' to this dosage. *Id.* at 188–90, 316–17. Dr. Hamilton indicated the Florida standard of care required the starting date of the prescribed medication to be disclosed on the face of the prescription or in a note readily available to the pharmacist. *Id.* at 186–87, 350–51, 392–94. Dr. Hamilton acknowledged that a pharmacist had access to the Florida PDMP, or ''E–FORCSE'' database, which contained prescribing history. *Id.* at 348–49.

Dr. Hamilton noted that an identical prescription for hydromorphone was issued to A.E. for two more consecutive months. Tr. 191–92; GX 6, pp. 3–6. Dr. Hamilton noted the Florida standard of care regarding ''individualization'' required that the pharmacist consider whether an extended high dosage of controlled medication should be continued or should be reduced. Tr. 192–93. Dr. Hamilton expected to see a reduction in dosage over time, or an explanation by the pharmacist for continuing to dispense the same high dosage. *Id.* at 1013–14. Dr. Hamilton noted there was no evidence that any reevaluation of the patient's continued need for this strong medication had been made. *Id.* at 193. The fact that the patient was on immediate release tablets further heightened the ''red flag.'' GX 28, p. 6. Dr. Hamilton explained that immediate release tablets typically addressed acute versus chronic or long-term conditions, as suggested here by ongoing prescriptions for hydromorphone. Tr. 193–94, 1013–14. This ''red flag'' was not resolved on the face of the prescription, or in the medical notes. Tr. 194; GX 5, GX 6, pp. 5–6. Dr. Hamilton was also concerned by the cash purchase of the prescription and the ''extremely high prices'' paid, of $5.95 per pill. Tr. 194, 199; GX, 28, p. 6.

Dr. Hamilton explained that medications are typically priced at the ''average wholesale price'' plus 20%. Tr. 195. Dr. Hamilton explained that the appropriate price *[J] of 8 mg. of hydromorphone was $1.50 per tablet. He cautioned that this was an approximation by reviewing pharmacy prices in his area, both of big chain pharmacies as well as independents. *Id.* at 195, 326, 330–31. Dr. Hamilton opined that prices per pill from wholesalers would be fairly consistent across the state. *Id.* at 195, 1011–13. However, he noted that, at the retail level, the purchase of just a few pills could result in an extremely high price per pill versus the purchase of a large number of pills. Tr. 198.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to A.E. *See* GX 5 and RX 18, 19. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the GX 18, 19 version, his previous opinions as to A.E.'s dispensing remained the same. Tr. 957–65. As related to the differences

*[H] Amended pursuant to Tr. 170.

*[I] Throughout the case, the Government's expert and all parties appear to have used the phrases ''standard of care'' and ''corresponding responsibility'' and ''standard of pharmacy practice'' interchangeably. The testimony regarding the requirement to resolve red flags is clearly related to Respondent Pharmacy's corresponding responsibility under 21 CFR 1306.04. The interchangeable use of this terminology does not impact my ultimate finding that Respondent Pharmacy 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 the standard of pharmacy practice and corresponding responsibility herein.

[28] *[Omitted for clarity. The ALJ found that the Government did not allege a separate violation regarding the documentation of the resolution of red flags, but instead chose to consider such lack of documentation as an inference supporting a finding that the red flag was not resolved. In this case, I find that the Government's expert credibly testified that documenting the resolution of red flags was required by the standard of professional practice in Florida. Furthermore, the issue of whether documentation was required by the standard of practice in Florida was thoroughly addressed by both parties at the hearing. *See id.* 179–81, 434–38, 1007–08. I find that it is unimportant to find an independent violation related to the lack of documentation, because such lack of documentation already supports the overall finding that Respondent filled these alleged prescriptions in violation of its corresponding responsibility and outside the usual course of professional practice in Florida.]

[29] *See* West's Florida Administrative Code, Title 64. Department of Health, Subtitle 64b16, Chapter 64B16–27—Pharmacy Practice.

[30] Dr. Hamilton compared GX 5 with RX 18.

*[J] Dr. Hamilton referred to it as ''the market retail price.'' Tr. 195.

between the Government and Respondent versions of the same records, Dr. Hamilton conceded that the Respondent versions could be updated versions of the Government versions. *Id.* at 1019–20. Dr. Hamilton observed that updating medical records was required by the standard of care. *Id.* at 1020.

Turning to patient A.R., Dr. Hamilton noted a prescription for 112 tablets of 15 mg of oxycodone represented several ''red flags'', citing significant dosage, high quantity, frequency of prescribed usage (4 times daily), and high price.[31] *Id.* at 204–05, 329; GX 8, pp. 1–2; RX 20. Dr. Hamilton was unable to find that these ''red flags'' were resolved on the face of the prescription or on the ''information sheet'' within the patient record. Tr. 205–06; GX 7. Dr. Hamilton explained that, although the patient's ''information sheet'' contained information relating to diagnoses and medical conditions, it did not include information justifying the long-term use of the subject oxycodone prescription. Tr. 206, 329–30; GX 28, pp. 12–14. As relates to price per pill, Dr. Hamilton estimated the retail price to be approximately 90 cents. Tr. 330–31. The next prescription for A.R. also involved 15 mg of oxycodone, but for 140 tablets at a directed frequency of 5 times per day at a price of $350. Tr. 207–08; GX 8, pp. 3–4. Dr. Hamilton noted the distance between A.R.'s residence and the prescribing doctor's office and Pharmacy 4 Less. Tr. 208. Dr. Hamilton estimated A.R. lived approximately 40 miles from the prescribing doctor, and another 13 miles further to the subject pharmacy. *Id.* at 209. Dr. Hamilton indicated this distance represented a ''red flag,'' which went unresolved within the subject records. Tr. 209–10, 332–37; GX 7, GX 8, p. 3.

The next two prescriptions for A.R., which Dr. Hamilton indicated disclosed the same ''red flags'' were identical prescriptions for 15 mg of oxycodone, for 140 tablets, but at a price of $340. Tr. 212–14; GX 8, pp. 5–6, 33–34.

[31] Patient A.R. paid $280 for 112 pills of oxycodone in connection with this prescription, or $2.50 per pill. *[Later, Patient A.R. paid between $340 and $350 for 140 pills of oxycodone, or approximately $2.43–$2.50 per pill. GX 8, at 3–6, 33–34.]

*[Omitted based on further review of the record]. Dr. Hamilton opined the subject oxycodone prescriptions for A.R. remained unresolved within the records reviewed, and were thus below the standard of care in Florida. Tr. 215–16; GX 7.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to A.R. *See* GX 7 and RX 20, 21. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the GX 20 and 21 version, his previous opinions as to A.R.'s dispensing remained the same. Tr. 965–69.

As to Patient B.F., Dr. Hamilton reviewed a series of prescriptions for hydromorphone 8 mg, 84 count, 3 times daily. Tr. 216–22; GX 12, pp. 13–14, 17–18, 21–22, 25–26; RX 24. The ''red flags'' revealed included the controlled substance itself, the dosage at the highest available, the high quantity (84 tablets), the immediate release, the ongoing length of time it is being prescribed, and the high price ($490).[32] Tr. 216–22.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to B.F., RX 24, 25. Dr. Hamilton noted references to a discharge date of May 15, 2017, a reference to liver cancer, stage 3, and the last fill of the subject prescription on May 15, 2017. Tr. 976–77. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to B.F.'s dispensing. *Id.* at 975–80.

As to Patient B.N., Dr. Hamilton identified ''red flags'' related to a series of prescriptions for hydromorphone. *Id.* at 223. The first was of 8 mg, 90 count, priced at $580. Tr. 222–23; GX 14, pp. 1–2; GX 13; RX 26. Dr. Hamilton reiterated the hydromorphone itself represented an unresolved ''red flag,'' as well as the dosage, quantity and cost. Tr. 223, 226. The second and third prescriptions for hydromorphone, again with the same unresolved a ''red flags,'' involved 8 mg, 100 count, priced at $640. Tr. 224–28; GX 14, pp. 3–6; GX 13. The fourth hydrocodone prescription, again with the same unresolved ''red flags,'' involved 8 mg, 100 count, priced at $600. Tr. 229–30; GX 14, pp. 15–16. This prescription prompted an additional ''red flag'' as it represented ongoing prescribing of hydromorphone without demonstrated justification. Tr. 230. Dr. Hamilton reviewed a prescription for oxycodone, 30 mg (the highest dosage available), 120 count, priced at $600. *Id.* at 231–32. Dr. Hamilton opined the medication itself represented a ''red flag,'' as well as the dosage, the quantity and the cost. *Id.;* GX 14, pp. 19–20, GX 13. Additionally, transitioning from hydromorphone to oxycodone required an explanation, which was not contained within the records reviewed by Dr. Hamilton. Tr. 232. A second prescription for oxycodone for B.N., for 30 mg, quantity 40, had the same unresolved ''red flags.'' Tr. 233; GX 14, pp. 21–22. As this represented the second consecutive prescription for oxycodone, an additional ''red flag'' was raised regarding the ongoing unjustified prescribing. Tr. 233–34. The next two oxycodone prescription for B.N. involving the same unresolved ''red flags,'' involved 30 mg, 120 count, priced at $600.*[K] Tr. 234–36; GX 13; GX 14, pp. 23–24, 37–38.

[32] Eighty-four tablets at $490 equals $5.83 per tablet. *[The ALJ then found that Dr. Hamilton estimated the expected retail price to be $0.90 per pill citing to Tr. 218–22 and GX 28, p. 11, but the record does not support this finding. Dr. Hamilton originally testified that hydromorphone had an estimated retail price of $0.90, Tr. 218; however, after he refreshed his recollection with his expert report he stated, ''I might have misspoke at $0.90. It's a little bit more expensive for [D]ilaudid, or [h]ydromorphone . . . .'' Tr. 222. Dr. Hamilton's export report stated that the estimated retail price of hydromorphone was approximately $1.50 per pill. GX 28, at 11. Dr. Hamilton also testified elsewhere in the record that the market retail price for hydromorphone was $1.50 per pill. *See e.g.* Tr. 195–97. Moreover, albeit in a different context, Dr. Hamilton testified that to the extent numbers appearing in his expert report differed from numbers to which he was testifying based on his recollection, the numbers in the expert report would be ''[m]ore accurate.'' Tr. 209. Based on the entirety of the record, I find that Dr. Hamilton estimated the expected retail price of hydromorphone to be $1.50 per pill.]

*[K] Dr. Hamilton also testified that additional prescriptions falling between the November 11, 2016, and June 2, 2017, prescriptions had the same unresolved ''red flags.'' Tr. 236.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to B.N., GX 13 and RX 26, 27. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 26 and 27 version, his previous opinions as to B.N.'s dispensing remained the same. Tr. 980–85.

As to patient K.Y.D., Dr. Hamilton identified a series of oxycodone prescriptions with unresolved ''red flags.'' Tr. 237; GX16, pp. 1–2, 5–6, 9–10, 63–64; RX 30, 31, pp. 2–4. The first three involved a dosage of 30 mg, quantity 84, price $290. Tr. 237–39 *[For these prescriptions, Dr. Hamilton testified that the red flags included the highest strength dosage, high quantity, frequency of prescribed usage (3 times daily), and high price.] By the third prescription, it also triggered an additional ''red flag'' involving the ongoing unjustified prescribing of oxycodone. Tr. 239. The fourth example for the identical prescription triggered the same unresolved ''red flags.'' [*L] *Id.* at 240.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to K.Y.D., RX 30, 31. Dr. Hamilton noted references to a discharge date of June 12, 2017. Tr. 990–91. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to K.Y.D.'s dispensing. Tr. 990–94.

As to Patient K.E.D., Dr. Hamilton determined there were unresolved ''red flags'' involved in a series of oxycodone prescriptions. The first was for 20.5 mg, quantity 112, for $430. Tr. 241–45; GX 17, GX 18, pp. 1–2, 3–4, 5–6, 41–42; RX 28, RX 29, p. 2. For the first, the dosage of 20.5 mg represents a dosage outside common dosage units, and would have been a compounded dosage, a ''red flag'' in itself. Tr. 242. *[Additionally, Dr. Hamilton noted that the quantity, and price were unresolved red flags for this prescription. *Id.*] The second and third oxycodone prescription noted were for 20 mg, 112 quantity, priced at $430. Tr. 244–45. Again, the medication itself represented a ''red flag,'' as well as the dosage, quantity and price. Tr. 245. The fourth oxycodone prescription was identical to the second and third, except that the price was $400. Tr. 245–46. *[In addition to the ''red flags'' identified with the prior two prescriptions,] the fourth prescription triggered the ''red flag'' of an extended prescription without apparent justification.[*M] *Id.* at 246.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to K.E.D. *See* GX 17; RX 28, 29. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 28 and 29 version, his previous opinions as to K.E.D.'s dispensing remained the same. Tr. 986–90.

As to Patient R.R., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 247–50; GX 20, pp. 1–6, 41–42; RX 32, p. 1; RX 33, p. 5. The first prescription was of 18 mg, 112 quantity, priced at $250. Tr. 247. The first ''red flag'' is that the dosage has been compounded, without explanation. *Id.* The high quantity is a ''red flag,'' as well as the high price paid. *Id.* The second and third prescriptions involved 15 mg, quantity of 112, priced at $270. Tr. 248. The fourth prescription is identical to the second and third, except for the price was $260. Tr. 249–50. The third and fourth prescriptions *[had the same unresolved red flags as the earlier prescriptions, and] additionally triggered a ''red flag'' as extended prescriptions without apparent justification.[*N] *Id.*

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to R.R. *See* RX 32, 33. Dr. Hamilton noted references to a discharge date of May 2, 2017, yet another prescription fill on May 30, 2017. Tr. 994–95. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to R.R.'s dispensing. *Id.* at 994–97.

As to Patient R.V., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 251–56; GX 21; GX 22, pp. 27–28, 31–32, 34–35, 78–79; RX 34, p. 1; RX 35. The first prescription was for 20 mg, 112 quantity, priced at $340. Tr. 251; GX 28. The first ''red flag'' was the high dosage. Tr. 251. The next ''red flag'' was the quantity. *Id.* And the third was the high price paid. *Id.* *[Dr. Hamilton testified that there was no evidence on either the face of the prescription or in the patient record for R.V. that these ''red flags'' were resolved. *Id.* at 251–52.] The second prescription was identical to the first *[and had the same unresolved ''red flags.'']. *Id.* at 253. The third was identical to the first two, except that it was priced at $310. *Id.* The third prescription *[had the same unresolved red flags as the earlier prescriptions, and] had the additional ''red flag'' as an extended prescription without apparent justification. *Id.* The fourth prescription for oxycodone was of 20 mg, quantity 120, priced at $340 *[and had the same unresolved red flags as the third].[*O] *Id.* at 254–55.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to R.V. *See* GX 21 and RX 34, 35. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 34 and 35 version, his previous opinions as to R.V.'s dispensing remained the same. Tr. 997–1001.

As to Patient V.W., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 256–60; GX 23, GX 24, pp. 1–2, 3–4, 5–6, 41–42; RX 36. The first prescription was for 15 mg, quantity of 84, priced at $300. Tr. 256. The first ''red flag'' was the relatively high dosage. Tr. 256. The next ''red flag'' was the quantity. *Id.* And the third was the high price paid. *Id.* The second prescription involved 15 mg, quantity 112, priced at $400. Tr. 257. The third prescription was identical to the second, but was priced at $350. Tr. 258. The third prescription had *[the same unresolved ''red flags'' as prior prescriptions based on the dose and quantity] and additional [unresolved] ''red flags'' *[because the prescription was written for four times a day and filled for only three times a day and] as an extended prescription without apparent justification. *Id.* The fourth prescription was identical to the third, except priced at $285. *Id.* at 259. *[The fourth prescription shared the ''red flags'' arising based on the dose, quantity, price, and ''length of time for immediate-release medication.'' [*P] *Id.* at 259–60.

[*L] Dr. Hamilton also testified that additional prescriptions issued between March 31, 2016, and June 12, 2017, had the same unresolved ''red flags.'' Tr. 241.

[*M] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 18 issued between December 21, 2015, and June 7, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 246.

[*N] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 20 issued between December 21, 2015, and May 30, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 250.

[*O] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 22 issued between January 11, 2016, and June 19, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 255.

[*P] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 24 issued between January 25, 2016, and May 21, 2017, and opined that each had the same red flags as the fourth prescription discussed herein and that none of those red flags were resolved. Tr. 260.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to V.W. *See* GX 23 and RX 36, 37. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 36 and 37 version, his previous opinions as to R.V.'s dispensing remained the same. Tr. 1001–04.

As to Patient A.V., Dr. Hamilton discovered a series of controlled substance prescriptions that were filled by Pharmacy 4 Less despite unresolved ''red flags.'' Tr. 261–67; GX 10, pp. 1–2, 3–4, 5–6, 9–10, 15–16, 37–38, 41–42, 43–44, 45–46, 47–48, 59–60; RX 22. The first such prescription involved 29 tablets of 8 mg of buprenorphine. Tr. 261–62. The second prescription, filled 9 days after the buprenorphine was filled, involved 112 tablets of oxycodone, 20 mg each, priced at $290. Tr. 262. The oxycodone prescription itself presented ''red flags,'' which needed to be resolved, as discussed earlier, including the drug itself, the large quantity, the relatively high dosage, and the price. *Id.* Additionally, Dr. Hamilton observed the 20 mg oxycodone was being prescribed in conjunction with the buprenorphine. *Id.* at 263. Buprenorphine is used to wean someone off of an opiate, such as oxycodone. *Id.* The prescribing of buprenorphine along with an opioid prescription creates a ''red flag,'' which needs to be resolved. *Id.* at 262–63. The acceptable protocol would be to introduce the buprenorphine as the dosage of oxycodone is reduced, until the oxycodone is completely replaced by the buprenorphine. *Id.* at 262–65. Here, the buprenorphine is introduced, yet nine days later the 20 mg of oxycodone was filled, which is inconsistent with the typical detoxification protocol, and can present some contraindication issues. *Id.* at 266–67. Additionally, detoxification would require physician monitoring. *Id.* at 265. Dr. Hamilton noted there was no indication in the reviewed records [*Q] *[that the ''red flag'' was resolved]. *Id.* at 265–66. Another 8 mg buprenorphine prescription of 60 tablets was filled almost two months after the first buprenorphine prescription. *Id.* at 267–68. On the same day, a second identical prescription for 20 mg of oxycodone was filled, triggering the same set of ''red flags'' as previously described *[and, according to Dr. Hamilton, there was no documentation that those ''red flags'' were resolved]. *Id.* at 268–69. This second prescription for oxycodone,[*R] *[according to Dr. Hamilton, raised the same unresolved ''red flags'' as the first one, and an additional unresolved ''red flag'' because the medication dosage and frequency remained unchanged and ''[y]ou would see a de-escalation of medication with a patient going through detox.'' *Id.* at 268–69. The next month saw a repeat of an 8 mg buprenorphine prescription *[for 60 tablets], along with a 20 mg prescription for oxycodone, thus repeating the same unresolved ''red flags.'' *Id.* at 271–72. Less than one month later, dual prescriptions for 8 mg of buprenorphine and 20 mg of oxycodone were filled, repeating the same unresolved ''red flags'' as described earlier. *Id.* at 271–73. Additionally, as to the oxycodone, the repeated prescribing created the unresolved ''red flag'' related to *[the length of time] without a reduction in dosage. *Id.* at 273–74. Dr. Hamilton addressed another set of dual prescriptions for 8 mg of buprenorphine and 20 mg of oxycodone, thus repeating the same unresolved ''red flags'' discussed earlier.[*S] *Id.* at 274–77.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to A.V. *See* RX 22, 23. Dr. Hamilton noted references to a consultation with Dr. Seaford, to ''tapering'' and to ''detox.'' Tr. 970–72. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to A.V.'s dispensing. *Id.* at 970–75.

Again on rebuttal, Dr. Hamilton confirmed that nothing in the testimony of Mr. Parrado or Ms. Mincy has caused Dr. Hamilton to change his previously offered opinions in this case. *Id.* at 1004–05. Dr. Hamilton did agree with Mr. Parrado's observation that it was proper to fill a pain prescription up to a month after the patient was released from the hospital. *Id.* at 1017. Dr. Hamilton further commended the Respondent's practices of maintaining medical records within their pharmacy files. *Id.* at 1015–16.

Respondent's Case in Chief

The Respondent presented its case through the testimony of two witnesses. First, the Respondent presented the testimony of Ms. Amy Mincy (Ms. Mincy). Second, the Respondent presented the testimony of its expert, Robert M. Parrado (Mr. Parrado).

Ms. Amy Mincy, R.Ph.[33]

Ms. Mincy testified to the following. Several of Ms. Mincy's claims were contested by the government and will be discussed later. As background, Ms. Mincy graduated from Mercer University in Atlanta, Georgia, and has been a pharmacist since 1983. Tr. 569. She is licensed in the State of Florida and has inactive licenses in Tennessee and Virginia. *Id.* She has worked for a number of pharmacies for varying lengths of time, including independent pharmacies, as a relief pharmacist, and as a pharmacy consultant, over the course of her career. *Id.* at 569–76, 579–83; RX 1.[34] She has also previously been disciplined by the Florida Board of Pharmacy for filling a prescription for her mother, was placed on probation, and successfully completed the terms of her probation in 1998. *Id.* at 579–82. She began working as a pharmacist at Pharmacy 4 Less in January 2016. *Id.* at 576–77. She is one of two pharmacists that works at Pharmacy 4 Less, along with Mr. Sprys. *Id.* at 577. She works at Pharmacy 4 Less four days per week, Monday through Thursday, with Mr. Sprys working on Friday. *Id.* at 822.

Ms. Mincy was working as the pharmacist on duty at Pharmacy 4 Less on June 6, 2017, when the DEA conducted its on-site inspection at the pharmacy. *Id.* at 584. She testified that DI1 and another Diversion Investigator (hereinafter DI2) arrived at the pharmacy sometime between 10:00 a.m.–12:00 p.m. that day. *Id.* at 585. She did not know the DEA was planning to conduct the on-site inspection that day. *Id.* at 585–86. She was told that the inspection would take between 20–30 minutes or up to an hour. *Id.* at 586.[35] She related that Mr. Sprys' son, William Sprys, was also in the pharmacy. *Id.* at

[*Q] The ALJ found that ''Dr. Hamilton noted that there was no indication in the reviewed records that the physician was monitoring any attempted detoxification.'' I have omitted the finding because I do not see support for it in the record and find it to be irrelevant. The record is clear that Dr. Hamilton did not see any documentation of resolution of the ''red flag,'' which is ultimately the fact at issue in this case.

[*R] The ALJ found that the second prescription ''highlighted the 'red flag' relating to the absence of any evaluation as to the reduction in the dosage or frequency of the oxycodone.'' I have revised this finding to quote Dr. Hamilton.

[*S] Dr. Hamilton testified collectively regarding the remaining prescriptions for buprenorphine and oxycodone in GX 10 issued between August 2, 2016, and February 13, 2017, and opined that each oxycodone prescription had the same red flags as the other oxycodone prescriptions discussed herein and that there was no documentation that these red flags were resolved. Tr. 276.

[33] Ms. Mincy testified the entire day of November 7, 2018. She was recalled to the stand during the second portion of the hearing at the DEA Hearing Facility in Arlington, Virginia on February 25, 2019, for the remainder of her testimony.

[34] Ms. Mincy's CV was admitted over objection with the corrections noted through Ms. Mincy's testimony. Tr. 584.

[35] When asked, Ms. Mincy said that it was primarily DI1 that spoke to her and asked her questions during the inspection. Tr. 586. She stated that DI2 was primarily observing. Tr. 587.

587. William Sprys acts as the administrator for the pharmacy, but is not a registered pharmacist, so he primarily handles clerical administrative duties. *Id.* at 587–88.

During the inspection, Ms. Mincy was handed a DEA Form 82, Notice of Inspection. Tr. 589; GX 30. She was uneasy about consenting to an inspection because she only works as an independent contractor at Pharmacy 4 Less, not as a regular employee. Tr. 590–91. She asked to contact Mr. Richard Sprys to ask about the form and whether she should consent and sign the form. *Id.* at 591–92. She had William Sprys contact Mr. Richard Sprys on the telephone because Richard was out of the country at the time of the inspection. *Id.* at 592. The DIs were also present during the telephone call. *Id.* She spoke to Mr. Richard Sprys on speakerphone about the DEA inspection and the DIs request to inspect the pharmacy. *Id.* Mr. Sprys then gave permission and directed Ms. Mincy to sign the form. *Id.* at 592–93. Ms. Mincy then signed the Form 82. Tr. 594.

After signing the form, Ms. Mincy was taken into a separate room in the pharmacy. *Id.* at 596. DI1 asked to see the pharmacy's perpetual inventory. *Id.* at 598. DI1 proceeded to count pills of controlled substances contained in the pharmacy. *Id.* DI1 asked for the perpetual inventory pages for January 1, 2017, through June 6, 2017. Tr. 604–05. The perpetual inventory was handwritten and was designed to keep track of the pharmacy's prescription inventory. Tr. 630–31; RX 31 (Methadone), 32 (Oxycodone).

He then requested the pharmacy's biennial inventory. Tr. 605–06, 773–74; GX 37; RX 38.[36] The pharmacy keeps its inventories in a binder that is located inside the locked medication room. Tr. 607. The Respondent's version of the biennial inventory indicated that it was completed on April 26, 2017, at 8:00 a.m. by Ms. Mincy and Mr. Sprys. *Id.* at 617–18, 767–73; RX. 38, pp. 1, 2, 3, 8–16. The inventory was completed by entering the drug room, verifying the number of pills, scanning the prescription bottles, and verifying their entry into the pharmacy's computer system. Tr. 626–27. Ms. Mincy testified she completed the biennial inventory in about three hours. *Id.* at 628. Ms. Mincy indicated her understanding that the biennial inventory must be completed either in the morning before the start of business or at the end of the day at the close of business, and that it was completed before the opening of business. *Id.* at 620–21, 817–19. The biennial inventory was kept inside a binder with the C–2 perpetual inventory. *Id.* at 622. The biennial inventory was later sent by the pharmacy to DI1 after he left it at the pharmacy following the inspection. *Id.* at 638–42; 782–88. She indicated she was not aware that a biennial inventory containing Schedule 2 prescriptions needed to be separate from an inventory containing Schedules 3 through 5 prescriptions. *Id.* at 818. To complete the biennial inventory, she would open the narcotic cabinet and would hand-count the Schedule 2 pills inside. *Id.* at 820–21.

For the inventories in the pharmacy, Ms. Mincy would keep a perpetual inventory of the prescriptions that had been filled. *Id.* at 628–34; GX 31, 32. The perpetual inventories were usually filled out by Ms. Mincy, but were sometimes updated by Mr. Sprys. Tr. 628–29. Every time a prescription was filled, it would be noted by either Mr. Sprys or Ms. Mincy so that they could keep up with their inventory that was on hand. *Id.* at 631. These were provided by Ms. Mincy to DI1 when he asked to see the pharmacy's inventory to determine if it was correct. *Id.* at 634–35. Ms. Mincy explained from the perpetual inventories how it can be determined how many pills were currently in the inventory. *Id.* at 635.

DI1 also asked to see the pharmacy's computer software, including print-outs and reports. *Id.* at 609–11. DI1 then requested to inspect the pharmacy's CSOS system. *Id.* at 612–13. CSOS is the pharmacy's electronic controlled substance ordering system. *Id.* at 611, 865–66. The pharmacy uses the CSOS system sourced through AmerisourceBergen. *Id.* at 612. Ms. Mincy showed DI1 the steps to order, but could not order because she did not have CSOS credentials at the time of the inspection. *Id.* at 613, 839–40, 867. Each authorized user receives an individual code that must be kept confidential to that user. *Id.* at 613. When showing the program to DI1, Ms. Mincy stated she did not put in any credentials because she did not have any at the time. *Id.* at 615, 867–68. DI1 then accused her of ordering with Mr. Richard Spry's credentials, which she promptly denied. *Id.* at 615. DI1 then proceeded to take all the original copies of the pharmacy's Schedule 2 prescriptions and some of the Schedules 3–5 prescriptions from January 1, 2017, to June 6, 2017. *Id.* at 615–17, 891–93, 894–96; RX 59, 60.[37] Ms. Mincy could not explain how there were differences between the original copy of RX 59 she had maintained at the pharmacy and the version that the Government had introduced into evidence, as the version the Government had seized on June 6, 2017. Tr. 901–903; *compare* GX 26, pg. 50 *with* RX 59.

Ms. Mincy would use the Florida E–FORCSE system as part of her resolution of red flags. Tr. 642–43. It is used to assist medical personnel in keeping track of medications individuals are taking. *Id.* at 642, 870–71. It contains a log of a patient's controlled substances that are disbursed from a prescription written by a doctor and filled by a pharmacist. *Id.* Pharmacies upload prescriptions daily into the E–FORCSE system. *Id.* at 643. E–FORCSE contains prescriptions for Schedules 2–4 controlled substances. *Id.* Ms. Mincy would use it daily and prior to every fill of a new prescription for clients. *Id.* at 643. E–FORCSE allows a pharmacist to immediately access a patient's name, date of birth, address, and the aforementioned prescriptions. *Id.* at 645. It also allows a pharmacist to see which pharmacies a patient goes to, or if the patient is doctor shopping or trying to fill prescriptions early. Tr. 645.

At the pharmacy each morning, either Mr. Sprys or Ms. Mincy would log on to the E–FORCSE system and it would be left open on the computer to be accessed. *Id.* at 871. Ms. Mincy understood that when E–FORCSE started, it was permissible to use another person's login since the pharmacy manager or pharmacist would log in first thing in the morning and it could be used throughout the day under that person's login information. *Id.* at 903–908.[38] The login systems for CSOS and E–FORCSE are two separate systems. *Id.* at 872. CSOS is regulated directly by the DEA and individual authorization and access has to be

[36] Each version was admitted following the Government's voir dire and request to admit GX 37 if this Tribunal were to admit RX 38. The Government agreed to redact the pricing information contained at the Respondent's request. Tr. 775–82. However, the Government later requested to withdraw the original GX 37 and offer an alternative version of GX 37, with only pages 1–7 considered for record. Tr. 912–17.

[37] Testimony related to RX 59 and 60 were objected to by the Government for lack of notice and being beyond the scope of cross-examination that was conducted on November 7, 2018. This Tribunal permitted the Respondent to make a record of the testimony for the Administrator's consideration, but sustained the Government's objection as to being beyond the scope of cross examination. Tr. 885–91, 893, 896–900.

[38] Ms. Mincy explained that this is why sometimes another person's E–FORCSE number would appear on the search records when she had actually done the search. Tr. 908–09. There was further testimony about the pharmacy's use of E–FORCSE and Ms. Mincy's understanding of its use, along with discussion about proposed RX 57. Tr. 903–09. However, proposed RX 57 was later withdrawn by the Respondent and GX 38 (redacted) was used instead after its introduction during DI1's rebuttal testimony. Tr. 927–34; 1024–25.

granted by the DEA. *Id.* at 872. Ms. Mincy had a key and certificate specific to her that had to be used to access the CSOS system. *Id.* at 872. On the other hand, E–FORCSE could be properly accessed by either Mr. Sprys or Ms. Mincy and could be left open on the computer for either person to access. *Id.* at 872.

Ms. Mincy would turn away patients if she found discrepancies on the E–FORCSE, and did so, up to 10 to 12 times per month. *Id.* at 646. She would turn them away if she suspected their ID was not legitimate, if they were also filling their prescriptions somewhere else, if it appeared they were doctor shopping, or if there were signs of diversion or abuse. *Id.* at 647. She would also call the patient's doctor and discuss the patient's medical needs and the prescriptions that had been provided to her. *Id.* at 648. She would send patients away if there were discrepancies between the identification provided and the information provided on the prescription. *Id.* at 648. She would also look to see if any of the patients had overdosed, which would help her determine whether to fill a prescription. *Id.* at 841. She would also investigate whether there was any indication that any of the patients were selling their prescribed medications. *Id.* at 841–45.[39] She would then place a sticker on the prescription to signify that she had resolved any potential red flags for the prescription. *Id.* at 648–49, 827–28.

Ms. Mincy was familiar with each of the 10 charged patients in this matter. *Id.* at 649. She has filled prescriptions for controlled substances for each of the 10 subject patients. *Id.* at 830. She would try to resolve red flags for each of the 10 subject patients by using the previously discussed methods, including determining whether any of them were opiate naïve.[*T] *Id.* at 813–14. One way she would do so was by accessing E–FORCSE. *Id.* at 814, 831.[40] Her E–FORCSE number is *[redacted]. *Id.* at 831. She conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. *Id.* at 815–16. She had medical release forms for Patient K.Y.D., but not for the other 9 charged patients. *Id.* at 828–29. Ms. Mincy confirmed she had previously reviewed E–FORCSE in relation to the 10 charged patients. *Id.* at 875–79. Ms. Mincy indicated that while the policy at the pharmacy was presently (at the time of the hearing) to run each controlled substance patient through E–FORCSE, it had previously been only to run each Schedule 2 prescription. *Id.* at 880–81.

The pharmacy used the Rx30 computer software to fill prescriptions. *Id.* at 650. This was an internal system the pharmacy used to collect information, such as patient's names, addresses, phone numbers, allergies, and diagnostic codes. *Id.* at 650–51, 687–90; *see, e.g.,* GX 5; RX 18, p. 1; RX 19. It is also used to input information related to the patient's doctor, prescriptions, directions for the prescriptions, and number of days for the supply. Tr. 652. Each prescription was entered into the program one at a time, even if the doctor had put multiple substances on a single prescription form. *Id.* at 652–53. The Rx30 program would flash red with an alert if there was a contra-indication that something in the prescription did not match with the information on file to let Ms. Mincy know that some follow up was necessary. *Id.* at 652–54.

The pharmacy maintained patient record maintenance files through their internal system. *Id.* at 687–90, 706–09, 713–16, 722–31, 733–67; RX 18–37. These records were also used to maintain due diligence on the pharmacy's patients and resolve red flags as they arose. *Id.* at 707–08, 840–41.

Ms. Mincy had been present at Pharmacy 4 Less during inspections by the Florida Department of Health, including on February 28, 2017. *Id.* at 657–58. Ms. Mincy assisted the DOH inspector throughout the state inspections. *Id.* at 659–60. There were no deficiencies found during the February 28, 2017 inspection. *Id.* at 662; RX 15. She was also present during an inspection of the pharmacy on September 5, 2017. Tr. 669, 674. This inspection was done by the Board of Pharmacy. *Id.* at 667, 671–72. Ms. Mincy was given an inspection report at the end of that inspection, although the inspection report appeared to be incomplete. Tr. 675–81; RX 14.

At the end of the DEA inspection, DI1 took ten ''California folder'' files of Schedule 2 prescriptions dated between January 1, 2017, through June 6, 2017. Tr. 799–801. A ''California file'' consists of bundles of prescriptions that the pharmacy keeps for its records. *Id.* at 801. DI1 later requested twenty-four additional ''California files'' from Mr. Sprys. *Id.* at 801–02. The pharmacy kept a receipt that documented originals of the Schedule 2 prescriptions in the pharmacy. Tr. 802–03; RX 12.

Ms. Mincy was present during the inventory taken by DI1 on June 6, 2017. Tr. 835. She signed a DEA closing inventory sheet, confirming that the drug counts were correct. Tr. 835–37; GX 39.[41]

Mr. Robert M. Parrado, BPharm., R.Ph.

Robert Parrado graduated from the University of Florida in 1970 with a B.S. in Pharmacy. Tr. 401. Mr. Parrado has been licensed in Florida as a Pharmacist since 1971. *Id.;* RX 5, at 1. He was formerly licensed as a Consulting Pharmacist by the State of Florida up until 1989, which involved work with institutional facilities. Tr. 401; RX5, at 1. Mr. Parrado has received several awards over the years: The R.Q. Richards Award from the Florida Pharmacy Association for pharmaceutical public relations, and the Generation Rx Award in the field of prescription drug abuse and drug diversion from Cardinal Health. Tr. 402. He is presently President and CEO of Parrado Pharmacy Consultants, Inc., which involves pharmacy consulting with pharmacies, pharmacists, and with government agencies. *Id.* at 402–03; RX 5. Mr. Parrado previously worked for CVS Pharmacy from 2000 to 2009 as a Pharmacist. Tr. 403. For nine months in 2007, Mr. Parrado was a Regional Acquisition Specialist, involved in acquiring independent pharmacies by CVS. *Id.* Prior to working for CVS, Mr. Parrado worked for approximately three years for Eckerd Drugs and Albertson's. *Id.* at 404. Previously, Mr. Parrado worked for St. Joseph's Hospital as an Inpatient Staff Pharmacist, during which time he consulted with physicians on a daily basis. *Id.* Prior to St. Joseph's, Mr. Parrado was the Director of Pharmacy at Centro Hispano Hospital in Tampa. *Id.* at 404–05. Prior to that, for a few months, Mr. Parrado worked as a Pharmacist at SupeRx Drugs. *Id.* at 405.

From 2001 to 2004, Mr. Parrado was a member of the Florida Board of

[39] The Government confronted Ms. Mincy with arrest records of Patient K.Y.D. during its cross-examination. She was surprised to hear that he had been arrested on December 31, 2015, for possession of oxycodone with intent to sell, and later arrested on February 25, 2017, for possession of a Schedule 2 controlled substance. She said he had later been discharged as a patient and that he was unruly. Tr. 845–84; GX 41–43.

[*T] Ms. Mincy, responded ''No'' to the question ''Did you ever fill any prescription the first time for a patient where it was contra-indicated for the amount because a patient might have been opiate naïve?'' Tr. 649–50.

[40] When asked, Ms. Mincy stated that she had not printed out any documents from E–FORCSE that would show she had looked at the 10 charged patients. Tr. 814–15.

[41] While she could not recall signing the inventory sheet, she stated that it was her signature on the document. Tr. 837.

Pharmacy. *Id.* at 406. From 2003 to 2009, he was on the Board's Accreditation Council on Pharmacy Education. *Id.* As such, Mr. Parrado was involved in the accreditation of Florida schools of pharmacy. *Id.* While on the Board, Mr. Parrado was on the Rules Committee. *Id.* at 407. He also served on the Legislative Affairs Committee, which wrote proposed legislation for presentation to the Florida Department of Health, and for consideration by the Florida legislature. *Id.* During 2004, Mr. Parrado was Chairman of the Florida Board of Pharmacy. *Id.* at 408. Since 2001, Mr. Parrado has been a perpetual member of the National Association of Boards of Pharmacy. *Id.* Mr. Parrado was a member of the National ''Rules Committee,'' which developed ''model rules'' for consideration by individual states. *Id.* at 408–09. For 18 months, ending in 2001, Mr. Parrado was President-elect of the Florida Pharmacy Association. *Id.* at 409. Later, Mr. Parrado served as Speaker of the House of Delegates for the Association. *Id.* at 410. Since 2014, Mr. Parrado has been guest lecturer on pharmacy law at the University of South Florida College of Pharmacy. *Id.* As part of a recurring continuing education course, Mr. Parrado taught ''Resolving Red Flags, Allowing Patients to Legally Obtain Their Lawful Medical Prescriptions.'' *Id.* at 411. He has taught this course at universities, to county and state pharmacy associations, and other professional organizations. *Id.* at 411–12. He has presented to various professional organizations a course on ''Identifying Drug Diversion.'' *Id.* at 412. Mr. Parrado has testified as an expert witness previously, including an estimated eight or nine times as an expert called by DEA. *Id.* at 414–16.

Mr. Parrado had last prescribed a controlled substance approximately three or four years prior to the instant hearing when working as a substitute pharmacist at Genoa Healthcare. *Id.* at 418. Regarding his most recent dispensing of opioids on a regular basis, Mr. Parrado estimated it to be 2011. *Id.* at 419. Mr. Parrado was certified as a pharmacy expert. *Id.* at 431.

As relates to opioid naïve patients, Mr. Parrado described various scenarios in which a patient, even one who has been dispensed opioids in the past but who has been deprived of opioids for a month or two, can become dangerously opioid naïve. *Id.* at 433. To ensure a patient prescribed opioids is not opioid naïve, Mr. Parrado described several tools available to the pharmacist. *Id.* at 433–34. The pharmacist should ask a number of questions to alleviate concerns. *Id.* at 434. He can also reference the E–FORCSE database. *Id.*

Mr. Parrado was critical of the limited records Dr. Hamilton reviewed to form his opinion in this case. *Id.* at 434. Mr. Parrado suggested he would have asked the DEA to share more documentation with him than was shared with Dr. Hamilton. *Id.* at 443.

As related to resolving red flags, Mr. Parrado opined that in addition to consulting the E–FORCSE database, a pharmacist may obtain medical records directly from the physician, or access the ''patient record maintenance'' from the Rx30 computer program. *Id.* at 435–36. As to Dr. Hamilton's opinion that the resolution of ''red flags'' had to be documented under Florida law, either on the prescription or somewhere else readily available to the pharmacist, Mr. Parrado disagreed, claiming there was no such requirement under Florida law. *Id.* at 434, 438. Mr. Parrado conceded documenting the resolution of ''red flags'' may represent the ''best practice.'' [*U] *Id.* at 434. As to the subject documentation, Mr. Parrado observed that most pharmacists do ''document somewhat.'' *Id.* at 435. Most document on the back of the prescription. *Id.* However, if that wasn't possible, Mr. Parrado opined that it was acceptable to ''document'' in a card file system, or in the ''note'' field on your computer system. *Id.* Mr. Parrado also noted he created a computer program, called ''Red Flag Resolver,'' which would preserve such documentation on the computer server. *Id.* Mr. Parrado suggested diagnostic codes could be used on the prescription to demonstrate the medication was justified on the basis of the medical condition. *Id.*

Mr. Parrado explained that to resolve any red flag regarding ''immediate release'' medication, the physician can be consulted. *Id.* at 447–48. Mr. Parrado noted that ''immediate release'' medications are cheaper than the extended release versions, and that the insurance company may not pay for extended release. *Id.* at 448.

Mr. Parrado also disagreed with Dr. Hamilton's estimated price for each pill of oxycodone at .90 cents. *Id.* at 449. Mr. Parrado suggested the price of Schedule 2 controlled substances are often inflated to accommodate the added expenses inherent in dispensing them, such as additionally scrutiny, legwork, record-keeping, and inventories. *Id.* Mr. Parrado conceded that pharmacy pricing was very competitive. *Id.* at 449–50. Mr. Parrado explained that insurance issues can explain why a pharmacy may only accept cash payments [*V] *[omitted]. *Id.* at 450–51. Mr. Parrado explained that ''cash'' in the pharmacy business may include by credit card or even by check. *Id.* at 460.

The only explanations Mr. Parrado could give for a pharmacy charging different prices for the same medication was a potential higher cost from a different wholesaler, the use of discount coupons, or indigent pricing programs. *Id.* at 451–52.

Regarding inordinate travel to fill a prescription, Mr. Parrado agreed it was a red flag, which needed to be resolved. *Id.* at 453. *[But Mr. Parrado did not go on to opine as to whether or not the red flag was resolved with regard to the patient file for A.R. at issue in this case. *Id.*] As to the 8.5 mg prescription for hydromorphone, Mr. Parrado did not recognize it as requiring any investigation.[*W] *Id.* at 454. Prescriptions for compounded medications are a normal part of pharmacy work. *Id.* at 453–54; GX 12, p. 17–18.

As to Patient B.F., who was apparently suffering from stage 3 hepatic cancer, Mr. Parrado opined that absent an inconsistent physical presentation by the patient at the pharmacy, the diagnosis itself resolved any ''red flag'' created by the large amount of opioids prescribed. *Id.* at 455–56.

Mr. Parrado disagreed with Dr. Hamilton's concept of the ''minimum standard of care,'' which Dr. Hamilton attributed to both the Florida Administrative Code, specifically ''Florida Regulation 64B,'' [42] and guidelines from the National Board of Pharmacy Association. *Id.* at 180, 351–58. Mr. Parrado understood the ''minimum standard of care'' as a violation of a law or rule of the Pharmacy Act, or of the Florida

[*U] Mr. Parrado testified that there is ''no regulation that says you have to document . . . It may be a best practice to do that. But it [does not] say you have to.'' Tr. 434. When asked by the ALJ whether ''documenting the resolution of this red flag issue might be the best practice,'' Mr. Parrado testified ''It might be, [it is] a good, I do it.'' *Id.* at 436. Later, Mr. Parrado testified that, ''[y]ou have to resolve the flag . . . . Does it say anywhere that you have to document it? No. Should you? Of course. How are you going to remember; how is your partner coming going to know, because there [are] many pharmacists coming in and out of the pharmacy.'' *Id.* at 438.

[*V] The ALJ further found that the insurance issues can explain why a customer would pay cash. That portion of the finding is neither relevant to the alleged conduct nor did I find support for it in the record. Tr. 450–51.

[*W] Mr. Parrado did not testify in the positive or the negative regarding the need for an investigation, and he was never asked whether an 8.5 mg prescription for hydromorphone raised a red flag that needed to be resolved. Tr. 454.

[42] *See* West's Florida Administrative Code, Title 64. Department of Health, Subtitle 64b16, Chapter 64B16–27—Pharmacy Practice.

Administrative Code. *Id.* at 456. Mr. Parrado did not recognize any violation of the Florida minimum standard of care by Pharmacy 4 Less in the documents he reviewed and interviewing the two pharmacists involved. *Id.* at 456–58. Mr. Parrado reviewed favorable Florida Department of Health Inspection Reports dated February 28, 2017, September 5, 2017. *Id.* at 475–80, 546; RX 14, 15, 16, 17. One of the documents Mr. Parrado reviewed at Pharmacy 4 Less was their biennial inventory completed April 26, 2017. Tr. 489.

Mr. Parrado disagreed with Dr. Hamilton's opinion that 84 or 112 opioid tablets, *[for 30 mg of oxycodone,] represented ''red flags,'' which needed to be resolved. *Id.* at 461–63. He did not consider these to be inordinate amounts. *Id.* at 463.

Mr. Parrado agreed that the simultaneous prescribing of oxycodone and buprenorphine to Patient A.V. represented a ''red flag'' which needed to be resolved. *Id.* at 463. Mr. Parrado was able to resolve it by reviewing the PRM records. *Id.* at 464. It revealed the pharmacy had contacted the physician, who advised he was attempting to wean the patient off of the oxycodone. *Id.* at 463–65.

In reviewing the PRM for each of the ten subject patients, Mr. Parrado found evidence that Pharmacy 4 Less contacted or attempted to contact the physician in each of ten cases to resolve red flags, and that each ''red flag'' described by Dr. Hamilton was properly resolved. *Id.* at 490–92.

Mr. Parrado found none of the dosage units inordinately high, not even the 8 mg of hydromorphone. *Id.* at 491. He actually deemed 15 to 20 mg of oxycodone a ''very low dose,'' in contrast to Dr. Hamilton's assertion that those doses were relatively high. *Id.* at 510. As to the high prices charged, Mr. Parrado disagreed that the subject prices were suspiciously high. *Id.* at 492–93, 534. Mr. Parrado explained that following the crackdown on ''pill mills'' in Florida, opioids became more difficult for patients to obtain. *Id.* at 457, 539. They may have to travel to multiple pharmacies to even find the medication, so they would be willing to pay higher prices for them. *Id.* at 457, 539.

Mr. Parrado did not address the ''red flag'' described by Dr. Hamilton for the ongoing opioid prescriptions without considering a reduction in dosage, ''individualization.'' [*X] *Id.* at 492.

On cross-examination, Mr. Parrado was confronted with Florida Administrative Code Section 64(B)16–27.800, requiring pharmacies to maintain patient records. *Id.* at 495–96. It specifically requires the pharmacy to ''provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing,'' *[and requires that a ''reasonable effort is made to obtain, record and maintain . . . pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' Tr. 496.]

Mr. Parrado indicated the ''red flag'' identified by Dr. Hamilton regarding whether patients could be opioid naïve had been resolved by the subject pharmacists. *Id.* at 497. Mr. Parrado learned this by interviewing the pharmacists, and being satisfied with the steps they *[told Mr. Parrado that they generally] took, including checking with the PDMP. *Id.* at 496–99.

Mr. Parrado did not observe the ten patients increasing their dosage above the norm. *Id.* at 511. Most appeared to remain at ''maintenance levels.'' *Id.* at 511–12.

As to Patient R.V., who, according to the pharmacy notes, was suffering from a neoplasm, Mr. Parrado was not ''concerned'' by a medical record from the pain doctor, which described her condition as cervicalgia resulting from a ''fender bender.'' *Id.* at 516–22, 549; RX 34, p. 1, RX 35, p. 2.

As to Patient B.F., who Mr. Parrado testified was suffering from liver cancer, however, Mr. Parrado was unable to identify the cancer diagnosis by virtue of the diagnostic codes contained in the records. *Id.* at 514. However, he recalled seeing the cancer diagnosis in a medical note. *Id.* at 513–16.

Regarding RX 22, pp. 2–3; GX 10, Mr. Parrado discovered the pharmacists resolved the red flag by speaking with the subject pharmacists, who advised they confirmed they contacted the physician, who advised he was weaning the patient off of oxycodone with buprenorphine. Tr. 522–25. However, in GX 10, it appears the buprenorphine was prescribed for sciatica pain. *Id.* at 524–25. Mr. Parrado dismissed the medical codes as likely erroneous, choosing to rely on the conversation between the pharmacist and the physician. *Id.* at 525–26. As to the nearly one year period of *[unchanged strength] oxycodone prescriptions from April 12, 2016 to April 10, 2017, in conjunction with the buprenorphine intervention, Mr. Parrado recognized it to be a red flag, which would require the pharmacist to investigate by contacting the physician, pursuant to Fla. Admin. Code § 16–27.810. Tr. 526–27. *[Mr. Parrado did not testify specifically as to whether or not this ''red flag'' was in fact resolved with a call to the physician. Tr. 527.]

As to Patient R.R., who apparently suffered a ''broken back'' and fractured tibia from a car accident, Mr. Parrado was not concerned that the patient was discharged from the hospital on May 2, 2017, yet the final prescription was issued on May 30, 2017. *Id.* at 527–28, 551; RX 32, pp. 1–2. Mr. Parrado did not consider a prescription issued a month after discharge unusual, and assumed the patient had not yet found another doctor. Tr. 528. Mr. Parrado was not concerned by the medical report denying any surgical history for R.R., as it was not contradictory of the above pharmacy notes, explaining a broken tibia does not necessarily require surgery. Tr. 529.

As to Patient A.E., although Mr. Parrado reviewed the relevant medical records, which contained some obvious contradictions, including the patient claiming a pain level of 10 of 10, yet the physical examination by the physician showed no physical restrictions. *Id.* at 532. Mr. Parrado did not appear to have evaluated the substance of the medical records, but only the fact that the pharmacist had obtained the records and verified the patient was being treated for pain.[*Y] Tr. 529–32; RX 18, RX 19, pp. 2, 3.

As to Patient K.E.D., who was reportedly suffering from ''chronic pain'' as the result of a ''severe auto accident,'' yet the medical records deny past hospitalization, Mr. Parrado focused on the key findings of ''chronic pain'' and ''auto accident'' and not on contradictions in the medical records. Tr. 532–33, 552; RX 28, 29, p. 3.

As to Patient A.R., who apparently drove 45.4 miles *[one way] to see his physician and to obtain his medications at Pharmacy 4 Less, Mr. Parrado did not find that distance unusual, citing the difficulty in locating pharmacies which carried opioids. Tr. 539. Mr. Parrado conceded he has testified in other cases that driving 40 miles was a red flag. *Id.* at 541–42. Mr. Parrado distinguished his prior testimony as the distance was also part of a suspicious pattern. *Id.* at 542.

[*X] Though Mr. Parrado did not specifically address this red flag, he did testify generally that assuming there were red flags with every one of the patients, those red flags ''seemed to be'' resolved in every case and that he ''saw documentation where they had written down the resolutions.'' Tr. 492.

[*Y] Mr. Parrado testified, that he was not considering the medical records with specificity for their content, but ''was looking to see that they had gotten something from the doctor to help them resolve [red flags]. . . . [he] considered the fact that they had [the medical record], and that the doctor was treating pain and that they had gotten that.'' Tr. 532.

Mr. Parrado conceded that dual prescriptions for hydromorphone and methadone represented a red flag, but one which could be resolved by contacting the physician. *Id.* at 542–43. As to Patient B.F., Mr. Parrado did not consider multiple different opioid prescriptions concerning, explaining that physicians often try different medications to find an effective treatment. *Id.* at 543–44; RX 24, pp. 2–3. Further, Mr. Parrado did not view the simultaneous prescription of methadone and hydromorphone concerning, as methadone could be used as an extended release reliever, while the hydromorphone was an immediate release. *Id.* at 544. Mr. Parrado conceded he had testified previously that that combination was a red flag, but a resolvable red flag. *Id.*

As to Patient A.V., the prescription bore a code for sciatica. *Id.* at 545. Mr. Parrado [*Z] *[testified that the diagnostic code for sciatica was inherently reliable because it was handwritten as opposed to created by a computer.] *Id.* at 545–46, 551; GX 10, p. 15.

Mr. Parrado testified that ''due diligence files'' in a pharmacy would include all information used by the pharmacists to resolve red flags. Tr. 546.

Mr. Parrado's Sur-Rebuttal Testimony

During the second part of the hearing, the Respondent recalled Mr. Parrado to give sur-rebuttal testimony to the Government's rebuttal case. The Government objected to the testimony by Mr. Parrado and argued that sur-rebuttal testimony was not permitted by the rules. *Id.* at 1027. This Tribunal sustained the government's objection, but permitted the Respondent to continue questioning Mr. Parrado to make his record for the Administrator's consideration should the Administrator find this Tribunal's evidentiary ruling in error. *Id.* at 1028–29.

This Tribunal instructed the parties to brief the issue as to the propriety of sur-rebuttal testimony. In their Posthearing Brief, the Government concedes that there is no express prohibition of sur-rebuttal testimony, however, the regulations provide that unduly repetitious testimony will not be admitted. Govt Posthearing Brief at 46–47; 21 CFR 1316.59(a). The Government argues that the Respondent did not identify what was being proffered and the additional testimony ''was doing nothing more than seeking to bolster [the Respondent's] case.'' Govt Posthearing Brief at 46.

Upon a review of the Government's brief and the transcript of the proceedings, I find that sustaining the Government's objection to sur-rebuttal testimony was ill-advised. Although there is no relevant regulation or rule authorizing sur-rebuttal, neither is there a regulation or rule authorizing rebuttal testimony.[43] However, the Attorney General's Manual on the APA finds in Presentation of Evidence, Section 7 (c) that ''[e]very party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.'' Accordingly, this Tribunal recommends that the Administrator find the subject ruling in error and fully consider Mr. Parrado's sur-rebuttal testimony as direct evidence, to the extent it does not exceed the scope of rebuttal evidence.[44]

On sur-rebuttal, in explaining the differences between the Government's and the Respondent's versions of the medical record exhibits, Mr. Parrado affirmed the propriety of updating pharmacy records as relevant information is learned. *Id.* at 1029–30. Mr. Parrado further affirmed the propriety of including Schedules 3–5 prescriptions within the pharmacy records to reflect the totality of the dispensing, and not just the Schedule 2 prescriptions.[*AA] *Id.* at 1033–34.

Mr. Parrado further opined that many of the medical conditions and diagnoses noted in Pharmacy 4 Less files, ''chronic pain, cancer, neoplasms, broken backs'' are conditions which cannot be treated by surgery, but rather by opioid therapy. *Id.* at 1029–31. The dosage and frequency of such opioid therapy is designed to permit the patient to operate at a normal level. *Id.* at 1032. As to Dr. Hamilton's expectation of the tapering down of opioid doses, Mr. Parrado noted tapering in chronic pain patients was often difficult and ineffective. *Id.* at 1036. Finally, Mr. Parrado offered that the Respondent issued a below average number of oxycodone tablets as compared to other Florida pharmacies during the relevant period. *Id.* at 1037–40. Mr. Parrado conceded there were no pharmacy records explaining that the long distances traveled by customers of the Respondent was due to pharmacies going out of business. *Id.* at 1041. Nor did Mr. Parrado observe records in this case suggesting patients could not afford extended release medications. *Id.* at 1041.

The Facts

Stipulations of Fact

The Government and the Respondent, through counsel, have agreed to thirteen stipulations, which I recommend be accepted as fact in these proceedings:

1. Pharmacy 4 Less, LLC, is registered with the DEA to handle controlled substances under Schedules II to V under DEA COR No. FP5459082. Its registered address is: 805 Douglas Avenue, Suite 159, Altamonte Springs, Florida 32714.

2. Pharmacy 4 Less's COR was issued on February 2, 2018.

3. Richard Sprys, R.Ph., C.Ph., is the owner and manager of Pharmacy 4 Less.

4. Amy Mincy, R.Ph., is a pharmacist at Pharmacy 4 Less.

5. On June 6, 2017, DEA conducted an audit of Pharmacy 4 Less.

6. Proposed Government's Exhibit 2 is a true and correct copy of the June 22, 2017 Administrative Subpoena served upon Pharmacy 4 Less.

7. Pharmacy 4 Less completed its compliance with the administrative subpoena on July 11, 2017.

8. DEA served Pharmacy 4 Less with an Order to Show Cause on July 5, 2018.

9. Pharmacy 4 Less submitted a Corrective Action Plan to John J. Martin, Assistant Administrator for the Diversion Control Division of DEA, on July 31, 2018.

10. Pharmacy 4 Less submitted a Request for Hearing to the Office of the Administrative Law Judges at DEA Headquarters on August 1, 2018.

11. On August 8, 2018, Mr. Martin denied Respondent's request to discontinue or defer administrative proceedings.

12. Ms. Amy Mincy signed the DEA Form 82, Notice of Inspection of Controlled Premises on behalf of Pharmacy 4 Less during the June 6, 2017 on-site inspection. Tr. 38.

13. RX 19, 21, 23, 25, 27, 29, 31, 33, 35, 37 were supplied to the DEA in response to the July 9, 2018 administrative subpoena. Tr. 812–13.

[*Z] The ALJ found that Mr. Parrado was not concerned by the sciatica code, as errors happen. I understand, and have edited this finding accordingly, Mr. Parrado's testimony to be that here the sciatica code was inherently reliable because it was handwritten rather than generated by a computer error, which he previously testified occurs frequently. Tr. 545.

[43] The Agency has permitted and considered surrebuttal evidence in the past. *Flavio D. Gentile,* M.D.; 55 FR 3113 (1990).

[44] Sur-rebuttal evidence is permitted to confront the opposing party's rebuttal evidence.

[*AA] Mr. Parrado testified that when considering the ''total profile'' of all prescriptions for these patients, ''the patients were getting all their medications there . . . . [that is] what you want. . . . You [do not] want him just buying controls from you because now you [do not] know what else is going on with that patient. . . . It essentially resolved that red flag'' meaning the person is not ''just trying to obtain narcotics from [the pharmacy].'' Tr. 1033–34.

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.

1. The Respondent currently holds active COR FP5459082. ALJ Ex. 1.

2. DI1 conducted an on-site inspection of Pharmacy 4 Less on June 6, 2017. Tr. 37.

3. Pharmacy 4 Less was randomly picked for regulatory inspection by the DEA. Tr. 37.

4. Ms. Amy Mincy signed the Notice of Inspection presented to her by DI1. Tr. 38–39; GX 30.

5. Ms. Mincy could not locate an initial inventory, and Mr. Richard Sprys confirmed via speakerphone with DI1 that Pharmacy 4 Less did not have an initial inventory. Tr. 39–40.

6. Ms. Mincy provided DI1 with a purported biennial inventory, but, *[according to DI1,] it did not indicate whether it had been completed either at the opening or closing of business. Tr. 41–42; GX 37.

7. When asked about the pharmacy's CSOS system, Ms. Mincy demonstrated to DI1 how the pharmacy ordered controlled substances on the system. Tr. 43–45.

8. DI1 contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters. Mr. Jewell ran a report which stated that Ms. Mincy received her own CSOS credentials in July 2018. Tr. 47–49; GX 29.

9. DI1 conducted an audit of Pharmacy 4 Less's records and inventories. Tr. 53–93, 919–26; GX 4, 31, 32. DI1 selected a starting date of January 1, 2017, due to discrepancies in the biennial inventory, the lack of an initial inventory, and Pharmacy 4 Less maintained handwritten Schedule 2 controlled substance logs. Tr. 56, 61.

10. DI1 and other personnel returned to Pharmacy 4 Less on June 21, 2017. Both Ms. Mincy and Mr. Sprys were present. Tr. 88–89.

11. DI1 asked Ms. Mincy and Mr. Sprys how they determined whether prescriptions were for a legitimate medical purpose. Both pharmacists responded they would check E–FORCSE and that they would verify prescriptions by contacting the patients' doctors. The DIs were provided with a red folder that contained screenshots from the pharmacy's computer system, Rx30. Tr. 89–92. The red folder contained screenshots from the Rx30 program. *Id.* at 96. The red folder also contained the pharmacists' notes on patients, referred to as ''due diligence files.'' *Id.* at 97.

12. On June 22, 2017, an administrative subpoena was issued to Pharmacy 4 Less, requesting hard copy prescriptions for all Schedules 2–5 controlled substance prescriptions from October 2015 through June 22, 2017, all controlled substance prescription data from Rx30, and all due diligence patient files. *Id.* at 93–94; GX 2. Pharmacy 4 Less complied by delivering a gray tote container that contained ''California'' folders filled with Schedule 2 hard copy prescriptions, a thumb drive containing all Rx30 data, and the red folder seen during the June 21 on-site inspection. *Id.* at 96. The Schedules 3–5 prescriptions were delivered to the DIs by Pharmacy 4 Less at an unidentified later date. *Id.* at 97.

Treatment of Patient A.E.

13. Pharmacy 4 Less dispensed hydromorphone 8 mg to Patient A.E. on 21 occasions between November 19, 2015, and June 1, 2017. GX 6.

14. On November 19, 2015, Pharmacy 4 Less dispensed Patient A.E. 84 tablets of hydromorphone 8 mg without determining whether Patient A.E. was opioid naïve. Tr. 183–86; GX 28, p. 6; GX 37, p. 11.

15. Between November 19, 2015, and June 1, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed hydromorphone 8 mg tablets to Patient A.E. at a price of approximately $5.95 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet. Tr. 195–99; 200–03; GX 28, pp. 6–7.

16. Between December 17, 2015, and June 1, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed hydromorphone to Patient A.E. without determining why hydromorphone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 192–95; 200–03; GX 28, p. 6.

Treatment of Patient A.R.

17. Pharmacy 4 Less dispensed oxycodone 15 mg to Patient A.R. on 17 occasions between March 17, 2016, and June 7, 2017; GX 8.

18. On March 17, 2016, Pharmacy 4 Less dispensed Patient A.R. 112 tablets of oxycodone 15 mg without determining whether Patient A.R. was opioid naïve. Tr. 205–07; GX 28, p. 12.

19. Between March 17, 2016, and June 7, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 15 mg tablets to Patient A.R. at a price of approximately $2.23 to $2.50 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 205–07, 212–14; GX 28, pp. 12–13.

20. Between May 11, 2016, and June 7, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed oxycodone 15 mg to Patient A.R. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 212–14, GX 28 p. 12.

21. Between March 17, 2016, and June 7, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 15 mg tablets to Patient A.R., even though Pharmacy 4 Less's records do not show that Pharmacy 4 Less ever addressed why Patient A.R. traveled southwest approximately 37 miles from his house in Daytona Beach, Florida to his doctor's office in Sanford, Florida; traveled approximately 15 miles further southwest to buy his controlled substances from Pharmacy 4 Less, and then returned approximately 45 miles northeast to his home in Daytona Beach, Florida. Tr. 207–14, 334–35, GX 28, p. 13.

Treatment of Patient A.V.

22. Pharmacy 4 Less dispensed buprenorphine and/or oxycodone to Patient A.V. on 14 occasions between April 12, 2016, and April 10, 2017. GX 10.

23. On March 17, 2016, Pharmacy 4 Less dispensed Patient A.V. 112 tablets of oxycodone 20 mg without determining whether Patient A.V. was opioid naïve. Tr. at 262, 267–68; GX 28, p. 8.

24. Between April 12, 2016, and February 13, 2017, on 8 separate occasions, Pharmacy 4 Less filled prescriptions for Patient A.V. for 112 tablets of oxycodone 20 mg, an opioid, within nine days of filling a prescription for 29–60 tablets of buprenorphine 8 mg, a controlled substance used to treat opioid addiction. Seven of the eight fills took place on the same day. Tr. at 261–76; GX 28, p. 8.

25. Between April 21, 2016, and April 10, 2017, Pharmacy 4 Less, on 12 separate occasions, dispensed oxycodone 20 mg tablets to Patient A.V. at a price of approximately $2.59 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $1.25 per tablet at the time. Tr. at 262–76; GX 28, pp. 8–9.

26. Between July 5, 2016, and April 10, 2017, Pharmacy 4 Less, on 10 separate occasions, dispensed oxycodone to Patient A.V. without determining why oxycodone was being

prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. at 268–76; GX 28, p. 8.

Treatment of Patient B.F.

27. Pharmacy 4 Less dispensed hydromorphone to Patient B.F. on 17 occasions between October 27, 2015, and May 15, 2017. GX 12.

28. On October 27, 2015, Pharmacy 4 Less dispensed Patient B.F. 64 tablets of hydromorphone 8 mg without determining whether Patient B.F. was opioid naïve. Tr. at 217–18; GX 28, p. 10; GX 38, p. 5.

29. Between November 24, 2015, and May 15, 2017, Pharmacy 4 Less, on 16 separate occasions, dispensed hydromorphone 8 mg tablets to Patient B.F. at a price of approximately $5.70 to $5.83 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet at the time. Tr. at 218–22; GX 28, p. 11.

30. Between December 30, 2015, and May 15, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed hydromorphone to Patient B.F. without determining why hydromorphone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 219–22; GX 28, p. 10.

Treatment of Patient B.N.

31. Pharmacy 4 Less dispensed either hydromorphone or oxycodone to Patient B.N. on 19 occasions between January 22, 2016, and June 2, 2017. GX 14.

32. On January 22, 2016, Pharmacy 4 Less dispensed to Patient B.N. 90 tablets of hydromorphone 8 mg without determining whether Patient B.F. was opioid naïve. Tr. 222–27; GX 28, p. 14.

33. Between January 22, 2016, and August 15, 2016, Pharmacy 4 Less, on nine separate occasions, dispensed hydromorphone 8 mg tablets to Patient B.N. at a price of approximately $5.95 to $6.45 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet at the time. Tr. 222–35; GX 28, p. 15.

34. Between September 9, 2016, and June 2, 2017, Pharmacy 4 Less, on ten separate occasions, dispensed oxycodone 30 mg tablets to Patient B.N. at a price of approximately $5.00 per tablet, even though other retail pharmacies were selling oxycodone 30 mg tablets at approximately $0.90 per tablet at the time; Tr. 232–35; GX 28, p. 15.

35. Between March 15, 2016, and June 2, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed hydromorphone and oxycodone to Patient B.N. without determining why hydromorphone and oxycodone were being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 222–35; GX 28, pp. 14–15.

Treatment of Patient K.E.D.

36. Pharmacy 4 Less dispensed oxycodone to Patient K.E.D. on 21 occasions between October 26, 2015, and June 7, 2017. GX 18.

37. On October 26, 2015, Pharmacy 4 Less dispensed to Patient K.E.D. 112 tablets of oxycodone 20.5 mg without determining whether Patient K.E.D. was opioid naïve. Tr. 241–44; GX 28, p. 16; GX 38, p. 7.

38. Between October 26, 2015, and June 7, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed oxycodone 20 mg tablets to Patient K.E.D. at a price of approximately $3.57 to $3.84 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $0.90 per tablet at the time. Tr. 241–47; GX 28, p. 17.

39. Between December 21, 2015, and June 7, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient K.E.D. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 244–47; GX 28, pp. 16–17.

Treatment of Patient K.Y.D.

40. Pharmacy 4 Less dispensed oxycodone to Patient K.Y.D. on 17 occasions between February 4, 2016, and June 12, 2017. GX 16.

41. On February 4, 2016, Pharmacy 4 Less dispensed to Patient K.Y.D. 84 tablets of oxycodone 30 mg without determining whether Patient K.Y.D. was opioid naïve. Tr. 237–38; GX 28, p. 20.

42. Between February 4, 2016, and June 12, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 30 mg tablets to Patient K.Y.D. at a price of approximately $3.45 per tablet, even though other retail pharmacies were selling oxycodone 30 mg at approximately $0.90 per tablet at the time. Tr. 237–41; GX 28, pp. 20–21.

43. Between March 31, 2016, and June 12, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed oxycodone to Patient K.Y.D. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 237–41; GX, p. 20.

Treatment of Patient R.R.

44. Pharmacy 4 Less dispensed oxycodone to Patient R.R. on 21 occasions between October 28, 2015, and May 30, 2017. GX 20.

45. On October 28, 2015, Pharmacy 4 Less dispensed to Patient R.R. 112 tablets of oxycodone 18 mg without determining whether Patient R.R. was opioid naïve. Tr. 247–50; GX 28, p. 18; GX 38, p. 8.

46. Between November 23, 2015, and May 30, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed oxycodone 15 mg tablets [*BB] to Patient R.R. at a price of approximately $2.28 to $2.41 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 247–50; GX 28, p. 19.

47. Between December 21, 2015, and May 30, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient R.R. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 248–50; GX 28, pp. 18–19.

Treatment of Patient R.V.

48. Pharmacy 4 Less dispensed oxycodone to Patient R.V. on 22 occasions between November 17, 2015, and June 19, 2017. GX 22.

49. On November 17, 2015, Pharmacy 4 Less dispensed to Patient R.V. 112 tablets of oxycodone 20 mg without determining whether Patient R.V. was opioid naïve. Tr. 251–53; GX 28, p. 22; GX 38, p. 7.

50. Between November 17, 2015, and June 19, 2017, Pharmacy 4 Less, on 21 separate occasions,[45] dispensed oxycodone 20 mg tablets [*CC] to Patient R.V. at a price of approximately $2.23 to $3.04 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $0.90 per tablet at the time. Tr. 251–55; GX 28, pp. 22–23.

51. Between January 11, 2016, and June 19, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed oxycodone to Patient R.V. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 252–55; GX 28, p. 22.

Treatment of Patient V.W.

52. Pharmacy 4 Less dispensed oxycodone to Patient V.W. on 21 occasions between November 30, 2015, and May 31, 2017. GX 24.

[*BB] Additionally, on October 28, 2015, Pharmacy 4 Less, dispensed oxycodone 18 mg tablets to Patient R.R. at a price of approximately $2.23.

[45] The Government is not alleging that the price charged on March 27, 2017 was unreasonable.

[*CC] Except for on April 22, 2017, when Oxycodone 15 mg was dispensed at a price of $2.23 per tablet. GX 22, p. 71.

53. On November 30, 2015, Pharmacy 4 Less dispensed to Patient V.W. 84 tablets of oxycodone 15 mg without determining whether Patient V.W. was opioid naïve. Tr. 256–57; GX 28, p. 24; GX 38, p. 9.

54. Between November 30, 2015, and May 31, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed oxycodone 15 mg tablets to Patient V.W. at a price of approximately $2.54 to $3.57 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 256–60; GX 28, pp. 24–25.

55. Between January 25, 2016, and May 31, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient V.W. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 258–60; GX 28, pp. 24.

Recordkeeping

56. Pharmacy 4 Less did not have an initial inventory readily available during DI1's on-site inspection. Tr. 39–40.

57. [According to DI1, the copy of Pharmacy 4 Less's biennial inventory that he viewed in-person during the inspection on June 6, 2017, did not notate whether the inventory was completed at the opening or closing of business. Tr. 41–42.] *DD

58. Pharmacy 4 Less's biennial inventory (apparently revised sometime after June 6, 2017) did not indicate whether it was conducted at the ''close'' or ''opening of business,'' instead listing the time that it was completed. *Compare* GX 37, p. 2 *with* RX 38, p. 1. *[Specifically, the content appeared on a blank document that Ms. Mincy described as a cover page with handwriting stating ''Biennial Inventory; Completed April 26, 2017; 8AM'' and with signatures by both pharmacists. *Id.* The cover page was included in a fax to DI1 from Respondent pharmacy on June 7, 2017.] *EE

59. Pharmacy 4 Less's records were inaccurate, and included shortages and overages. GX 4. Specifically, the shortages and overages are as follows

a. Oxycodone 15 mg: Shortage of 73 tablets
b. Oxycodone 20 mg: Shortage of 212 tablets
c. Oxycodone 30 mg: Shortage of 731 tablets
d. Hydromorphone 8 mg: Shortage of 149 tablets
e. Methadone 10 mg: Overage of 1,488 tablets
f. Suboxone 8 mg/2 mg: Overage of 224 tablets
g. Carisoprodol 350 mg: Shortage of 526 tablets

60. Pharmacy 4 Less's [invoices] *FF did not include the date the order was received for 84 invoices. Tr. 137–38; GX 26.

Analysis

Credibility Analysis of Fact Witnesses

Ability To Recall Events

DI1

Generally speaking, individuals experiencing an event out of the ordinary, such as an on-site inspection as occurred here, are likely to have a better memory of those events than the Government Diversion Investigator, who performs similar inspections on any number of clinics. It seems to me, all other factors being equal, it would be easier for a DI to forget or confuse events than the person inspected. However, in this matter, DI1 presented an overall clear description of events surrounding the June 6, 2017, and June 21, 2017 on-site inspections of Pharmacy 4 Less.

DI1 occasionally had difficulty recalling the specific individual who responded to his questions. *See, e.g.,* Tr. 90–91. This cuts slightly against his reliability. However, he was generally able to recall the key events as to what had occurred during the on-site inspections and the substance of the relevant conversations. His testimony is also generally corroborated by the documentary evidence.

Further, DI1 demonstrated a basic understanding of the relevant DEA regulations as provided in the Code of Federal Regulations in order to properly perform his duties.[46] He had some difficulty citing specific relevant provisions of the CFR when asked, which is quite understandable. However, part of DI1's testimony involved an issue contested by the Respondent regarding the necessity of the date of receipt on invoices maintained by the pharmacy, which this Tribunal finds necessary to separately analyze and discuss.[47] Tr. 136–39.

Based on a complete review of DI1's presentation of testimony, ability to recall events, and comparison with the other evidence, I find his testimony to be credible and should be afforded considerable weight.

Ms. Amy Mincy

Ms. Amy Mincy's credibility presents more of a challenge for this Tribunal to address. During the first portion of the hearing in Orlando, Florida, Ms. Mincy appeared on the stand for the entire duration of the third day of testimony. At the beginning of her testimony, Respondent's counsel attempted to cover Ms. Mincy's professional background and C.V. Ms. Mincy struggled greatly remembering details about pharmacies where she had previously worked, and other details about her own professional background. While the transcript does not fully capture Ms. Mincy's difficulties in discussing her background, there are indications within the transcript that demonstrate these issues.[48]

*DD Finding of fact modified for clarity.

*EE There is insufficient information in the record for me to conclusively determine whether or not the cover page was attached to the biennial inventory at the time of DEA's inspection. On the one hand, I fully credit DI1's testimony that the biennial inventory did not notate whether the inventory was ''completed at either the opening or closing of business.'' Tr. 41–42. However, I cannot tell whether DI was testifying that the specific words ''opening or closing of business'' did not appear on the biennial inventory (which I agree is true) or if he was testifying that the cover page at GX 37, p. 2 was not included on the biennial inventory that DI1 was handed on the date of the inspection. If DI1's testimony meant the latter, it was unclear, and unfortunately, the biennial inventory was not seized during the inspection. Instead, the biennial inventory was faxed to DI1 the following day and the cover page was included. Notably, Mr. Sprys was out of the country at the time of the inspection and subsequent fax. As Mr. Spry's signature appears on the biennial inventory cover page that was faxed, it does not seem implausible to conclude that the cover page existed prior to Mr. Sprys leaving the country and prior to the inspection. Therefore, I cannot find substantial evidence to support the Government's allegation that the biennial inventory lacked the notation regarding whether it was conducted at the opening or closing of business.

*FF Modified because he ALJ referred to these documents as ''222 Forms,'' but I find that they are more accurately described as ''invoices.''

[46] While this Tribunal heard testimony from DI1 about the regulations, it does not rely on DI1's understanding of the regulations in this Recommended Decision.

[47] *See infra* at section ''Date of Receipt on Invoices.''

[48] ''MR. INDEST: And since she's having a little bit of difficulty remembering some of these, I'd like the clerk to give her the hearing book and let her, if she needs to refer to the CV.

THE WITNESS: I'm good.

MR. INDEST: No, let's have it in front of you so we've got the dates right and everything, okay?'' Tr. 571.

''Q Okay, but where did you work next after that? Where did you work next? If you're having trouble remembering, if you need to refresh your recollection, please look at the CV because you're taking a long, long pause before you answer my questions. This might help speed things up.'' Tr. 572–73.

''Q Okay, and did you work as a pharmacy consultant after that?

A For some places, yes.

Q According to your CV, Ms. Mincy, listen, these are simple straightforward questions, and if you can't remember the answers.'' Tr. 573.

''MR. INDEST: Your Honor, I'd like the record to reflect I'm asking the questions and she's taking a long, long pause.'' Tr. 574.

Following the testimony of Ms. Mincy's background, Respondent's counsel moved on to the facts of this matter. Throughout her testimony, Ms. Mincy appeared to encounter great difficulty in remembering details of the June 6, 2017 on-site inspection. While Ms. Mincy appeared to remember some details, her presentation and delivery of those details appeared sometimes confused and disoriented. Throughout the direct examination, I noticed that Respondent's counsel had trouble eliciting answers from Ms. Mincy about the June 6, 2017 on-site inspection.[49] Further, Respondent's counsel made a number of statements on the record that demonstrated his difficulty in eliciting testimony from Ms. Mincy, leading to a number of objections by Government counsel for leading the witness.[50] While understandable that a lay witness may have some difficulties due to being nervous or anxious about her time on the witness stand, Ms. Mincy's inability to answer questions posed by her own attorney suggest issues with Ms. Mincy's ability to reliably recall events one would expect to be otherwise fairly memorable. Her presentation in Orlando clearly diminishes her reliability as a witness, especially as relates to her Orlando testimony.

During the second portion of the hearing in Arlington, Virginia, Ms. Mincy appeared to be more relaxed on the stand, which appeared to increase her ability to recall and to reliably convey her perception of the relevant events.

Overall, I find that the reliability of her testimony was significantly diminished by her inability to recall details about both her own personal history and those surrounding the events of the on-site inspections at Pharmacy 4 Less.[51]

The parties only presented one fact witness each as to the events surrounding the on-site inspections at Pharmacy 4 Less. It will therefore be necessary for me to compare and weigh the testimony of DI1 and Ms. Mincy regarding the factual circumstances surrounding the on-site inspections of Pharmacy 4 Less and the subsequent investigation.[52] Physical evidence is more corroborative of DI1's testimony than that of Ms. Mincy's. When their testimony is in conflict, I find that it is proper to give greater weight to the testimony of DI1 over that of Ms. Mincy.

Motivation to Color Testimony

DI1, as a public servant, typically has no personal stake in the outcome of the instant inspection or in the revocation of the Respondent's Registration. The instant investigation was initiated at random. I noted no animus on his part as to the Respondent, its owner, or employees. Although he may be viewed as being part of the prosecution team, I saw no indication from his testimony that any partiality interfered with his reliable testimony.

On the other hand, Ms. Mincy appeared to be very defensive of Pharmacy 4 Less and the pharmacy's practices. As one of the two pharmacists on staff at the pharmacy, the investigation directly implicates her practices and her employment at the pharmacy. I suspect that she would be more likely to color her testimony than would DI1.

Ms. Mincy made statements during her testimony that make her motivation to color her testimony more likely. When confronted about the testimony of DI1, recalling statements made by Ms. Mincy during the June 6, 2017 on-site inspection, Ms. Mincy seemed to personalize the conflict. Ms. Mincy claimed that DI1 would have been ''lying,'' or that ''he was confused.'' Tr. 823–25. Ms. Mincy said that DI1 ''was like a kid in a candy store.'' *Id.* at 824–25. She said that ''the longer he was there and the more he got access to, the wilder and crazier he got.'' *Id.* at 825. Ms. Mincy described her interactions with DI1 as ''tormenting'' and ''almost, like, harassment'' of the Respondent. *Id.* at 825–26. While Ms. Mincy may have been testifying as to how she felt during the surprise on-site inspection with DI1, this colorful language, along with her description and characterization of the inspection, makes her testimony suspect as a possible attempt to improperly discredit DI1's testimony and his characterization of the on-site inspection.[53] In combination with the previous discussion of Ms. Mincy's ability to recall events, I find that Ms. Mincy has more motivation to color her testimony than DI1.

Credibility Analysis of Expert Witnesses and Opinions

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. Thomas Hamilton, Pharm.D.

Dr. Hamilton testified as the Government's expert witness in this matter. Dr. Hamilton was offered and was qualified as an expert in the practice of pharmacy in Florida. Tr. 174. Dr. Hamilton has worked as a pharmacist for 18 years. *Id.* at 167–69. His experience includes time at a small pharmacy before moving to work full-time as a pharmacist for Publix, where he has served in a variety of roles, including as a Pharmacist, the Assistant Manager of the Pharmacy, and as the Pharmacy Supervisor. He has served as a ''fixer'' or temporary Pharmacy Manager in order to ''clean up'' pharmacies. *Id.* at 169. In his role as Pharmacy Supervisor, he was in charge of overseeing up to 60 pharmacies, and his duties included the hiring and firing of employees, and overseeing daily operations. *Id.* at 170. Additionally, Dr. Hamilton evaluated stand-alone, independent pharmacies for purchase

[49] ''ADMIN. LAW JUDGE DOWD: And I know you're having some difficulty with Ms. Mincy, but try not to lead, Mr. Indest.'' Tr. 588.

[50] ''MR. MANN: She needs to answer his questions and not listen to him repeat the answers to her.

MR. INDEST: Your Honor, she's having a very difficult time answering these questions.

ADMIN. LAW JUDGE DOWD: It is what it is. But I'm going to sustain the objection as to leading.

MR. INDEST: And, Your Honor, with that understanding, a witness that is hard to answer the questions should be given some, the counsel should be given some leeway to at least get the basic information.

ADMIN. LAW JUDGE DOWD: I think I've given you leeway, Mr. Indest.

MR. INDEST: Okay, thank you.

ADMIN. LAW JUDGE DOWD: We have to have the testimony come from the witness.

MR. INDEST: Okay, we'll try.'' Tr. 595–96.

[51] In its Posthearing Brief, the Government argues that Ms. Mincy's false testimony should not be credited. Govt Posthearing Brief at 33–36. The Government argues that she ''lied'' about checking E–FORCSE every time before she filled a prescription. I will not go to the extreme the Government suggests, especially in light of Ms. Mincy's demonstrated memory deficits. *[However, I do find that when comparing the testimony to GX 38, Ms. Mincy overstated her use of E–FORCSE and that her credibility on the subject is diminished. Remainder of footnote omitted for brevity.]

[52] As to the lack of corroboration of portions of Ms. Mincy's testimony, the owner of Pharmacy 4 Less and the only other pharmacist at the pharmacy, Mr. Richard Sprys, had the ability to corroborate crucial details about the pharmacy Ms. Mincy's testimony about the pharmacy's operations, details regarding the June 6, 2017 phone call, and the June 21, 2017 on-site inspection. However, neither the Government nor the Respondent decided to call Mr. Sprys as a witness during the hearing. This Tribunal will not question either parties' trial strategy or determination of which witnesses to call, and notes that neither party has suggested any inference should be drawn regarding the failure to present evidence through Mr. Sprys. As such, we are without the benefit of Mr. Sprys testimony and are left only with the testimony evidence of DI1 and Ms. Mincy.

[53] In its Posthearing Brief, the Government asserts that Ms. Mincy's testimony should be discredited when it is contradicted by DI1. Govt Posthearing Brief at 37. While I cannot reach the Government's assertion that Ms. Mincy is ''lying,'' I have already found that greater weight will be given to DI1's testimony whenever there is conflict between DI1 and Ms. Mincy's testimony.

by Publix. This evaluation included review of the drug invoices, filled prescriptions and the nature of each pharmacy's overall business. *Id.* at 170–71. In order to spend more time with his young family, Dr. Hamilton decreased his responsibilities with the company, gave up his supervisory role, and now serves as a Pharmacy Manager of a single pharmacy. *Id.* at 286–87.

During the hearing in this matter, Dr. Hamilton reviewed a number of materials provided to him by the DEA, including prescriptions (front and back), related patient medical notes, and patient addresses. *Id.* at 177, 380–81. Additionally, Dr. Hamilton reviewed prescription pricing via GoodRX. *Id.* at 177–78. Dr. Hamilton also prepared an expert report in this matter based on the information and materials provided to him. GX 28.

In general, Dr. Hamilton provided detailed assessments of each of the 10 charged patients in this matter. He detailed his review of the prescriptions provided for each of the 10 charged patients and any ''red flags'' that he noticed through his review. His explanation that ''red flags'' can be resolved through a review of the prescription and some investigation, including speaking with the patient, reviewing medical history, or speaking with the prescriber, were all consistent with his ultimate opinions in this matter. His opinions in this matter were bolstered by his knowledge and experience in this field, as well as his knowledge of ''Florida regulation 64B'' and guidance provided by the National Board of Pharmacy Association, which provide the source of pharmacy standards of care in Florida. *Id.* at 180, 351–58.

On cross-examination, Dr. Hamilton's credibility was bolstered by his willingness to provide straightforward answers that were consistent with those opinions he had provided on direct examination. Dr. Hamilton conceded that he only reviewed the documents provided to him by the Government, but he was present throughout the hearing and was present to observe the testimony from the Respondent's witnesses. He indicated, when recalled during the Government's rebuttal case, that even after hearing the testimony and opinions from the Respondent's witnesses, his opinions in this matter had not changed. Tr. 1005. Further, Dr. Hamilton demonstrated objectivity. While Dr. Hamilton had differing opinions from Mr. Parrado in a variety of subjects, he was willing to concede areas in which he agreed with Mr. Parrado and did not appear to form opinions solely to favor the Government.

Overall, I find Dr. Hamilton's testimony and opinions in this matter to be credible and reliable.

Mr. Robert Parrado, BPharm., R.Ph.

Mr. Parrado testified as the Respondent's expert witness in this matter. Mr. Parrado was offered and qualified as a pharmacy expert. *Id.* at 431. Mr. Parrado has an extensive history in the pharmacy field. He appears to be approaching legend status in the field in Florida. He has been a licensed pharmacist in Florida since 1971. He was formerly licensed as a Consulting Pharmacist by the State of Florida until 1989. He has received numerous awards during his career. He is currently President and CEO of Parrado Pharmacy Consultants, Inc., which involves consulting with pharmacies, pharmacists, and with government agencies. *Id.* at 399–402; RX 5. He has previously worked at several pharmacies.

From 2001 to 2004, Mr. Parrado was a member of the Florida Board of Pharmacy. From 2003 to 2009, he was on the Board's Accreditation Council in Pharmacy Education. While on the Board, Mr. Parrado also served on the Rules Committee and the Legislative Affairs Committee. During 2004, Mr. Parrado was Chairman of the Florida Board of Pharmacy. Since 2001, Mr. Parrado has been a perpetual member of the National Association of Boards of Pharmacy. Mr. Parrado was a member of the National ''Rules Committee'' which developed ''model rules'' for consideration by individual states. *Id.* at 409. For 18 months, ending in 2001, Mr. Parrado was President-elect of the Florida Pharmacy Association. Later, Mr. Parrado served as Speaker of the House of Delegates for the Association.

Since 2014, Mr. Parrado has been guest lecturer on pharmacy law at the University of Florida College of Pharmacy. *Id.* at 410. As part of a recurring continuing education course, Mr. Parrado taught ''Resolving Red Flags, Allowing Patients to Legally Obtain Their Lawful Medical Prescriptions.'' *Id.* at 411. He has also presented to various professional organizations a course on ''Identifying Drug Diversion.'' *Id.* at 412. Mr. Parrado has testified as an expert witness previously, including an estimated eight or nine times as an expert called by DEA in these administrative proceedings. *Id.* at 414–16.

It is undisputed that Mr. Parrado has an extensive and impressive background in the pharmacy field. In particular, Mr. Parrado has a vast amount of experience in the practice of pharmacy within the state of Florida. His experience as a member of the Board of Pharmacy, including as a member of the Rules and Legislative Affairs Committees and as the Chairman of the Board, are highly instructive as to the Florida standard of care and those regulations governing Florida pharmacists. Mr. Parrado even noted that he was a co-author of Rule 64B16–27.831, which is the Florida state requirement that pharmacists question prescriptions that may not be valid and only fill the prescriptions if the pharmacist is able to validate the prescription. *Id.* at 420.

As it has been noted, Mr. Parrado has previously testified in similar DEA administrative proceedings. In *Superior Pharmacy I and II,* the Agency found that the ALJ in that matter properly qualified Mr. Parrado as an expert witness in that proceeding given his extensive experience in the pharmacy field. *See Superior Pharmacy I and II,* 81 FR 31,309, 31,322 n.16 (2016). Mr. Parrado was also previously certified as an expert in community pharmacy practice. *Hills Pharmacy, LLC,* 81 FR 49,815, 49,820 (2016). The Agency also gave credit to Mr. Parrado's expertise in *Edge Pharmacy,* 81 FR 72,092 (2016). As such, I further find that Mr. Parrado's background and expertise is more than sufficient to lend weight towards his testimony in this matter.

In this matter, Mr. Parrado provided generally reliable statements as to his review of the materials and his ultimate opinions. He testified that he had reviewed not only the Respondent's exhibits, but also was provided and reviewed the DEA's exhibits. Tr. 432. Mr. Parrado suggested that if he were in Dr. Hamilton's position, he would have asked the Government to provide more documentation.[54] As to ultimate opinions, while Dr. Hamilton generally provided specific answers to the questions posed by the parties, Mr.

[54] There was a question as to what requirement, if any, an expert witness has in requesting additional documents. Mr. Parrado indicated that it was his experience from *Superior Pharmacy I and II* that he should request more documents. Respondent's counsel argued that *Superior Pharmacy I and II* holds that if information to resolve red flags is not documented in materials provided to the expert, the additional documentation should be requested and provided to the expert if it exists. Tr. 444–45. The Government's objection to the question was sustained and the parties were invited to brief this issue in their Posthearing Brief. The Government argues in its Posthearing Brief that *Superior Pharmacy I and II* do not stand for the argument that the Respondent asserted. Govt Posthearing Brief at 42–43. Upon a review of *Superior Pharmacy I and II,* this Tribunal agrees with that assessment. It was not established that *Superior Pharmacy I and II* have created such an obligation on the part of an expert witness to request additional documentation.

Parrado would occasionally provide more summary or conclusory opinions to the questions posed to him. For example, Mr. Parrado gave the blanket conclusory opinion that based on the discussions between Mr. Parrado and Mr. Sprys and Ms. Mincy, of which there was no record or report, Mr. Parrado opined that in every instance of a red flag, they properly resolved the red flag prior to dispensing the subject controlled substance.

There were also a number of disagreements between Dr. Hamilton and Mr. Parrado in a number of areas, which will be discussed *infra.*

However, Mr. Parrado's testimony was diminished by his failure to include important details as to the bases of his opinions in this matter. First, Mr. Parrado failed to disclose that he interviewed Mr. Sprys and Ms. Mincy in forming his opinions in this matter. Tr. 497–500, 504–06. As bases for his opinions and having testified as an expert in a number of these proceedings, Ms. Parrado should be well aware of his obligations and the necessity to disclose the bases of his opinions, particularly if interviewing witnesses in this matter formed the bases of his opinions. My Order for Prehearing Statements specifically requires witnesses who rely on hearsay statements to identify those individuals in the prehearing statement. ALJ Ex. 3. Mr. Parrado's opinions were further diminished by the fact that Mr. Sprys did not testify, so he could not be subject to cross-examination on this issue. Therefore, Mr. Parrado's subject opinions are based on hearsay statements that were not subject to cross-examination. The Government was given an opportunity to cross examine Ms. Mincy. Additionally, Mr. Parrado testified that Ms. Mincy and Mr. Sprys confirmed to him that checking the E–FORCSE database was instrumental in their resolving certain red flags. As GX 38 reveals, Mr. Sprys and Ms. Mincy's access of the E–FORCSE was not as diligent as claimed. *See infra* section ''Opioid Tolerance High Starting Dosages.'' This suggests that Mr. Parrado's opinions in this regard are diminished by less than reliable claims made to him by Mr. Sprys and Ms. Mincy. Additionally, as there was little or no documentary support for Mr. Sprys and Ms. Mincy's claims to Mr. Parrado that they appropriately resolved each of the subject red flags, one would have to credit them with extraordinary memory, based on specific events over a few year period which the record does not establish.

Secondly, when cross-examined about his conclusions regarding the distance traveled by Patient A.R., Mr. Parrado was asked why he did not provide certain details about his opinions in his expert report. Tr. 540–41. When asked why he didn't put anything in his report about the pharmacist's relationship with Patient A.R., he stated ''I didn't see cause for that. My eloquence is not that great.'' These statements further diminish Mr. Parrado's bases for his opinions in this matter. Further, there was an inconsistency in Mr. Parrado's evaluation. In defending the Respondent's resolution of red flags, Mr. Parrado often relied on the PRM records maintained in the pharmacy file to justify the resolution. However, in instances where the PRM did not establish justification of the red flag, Mr. Parrado dismissed this fact and credited the Respondent's resolution by virtue of the mere effort of contacting the physician. This is contrary to the pharmacist's corresponding responsibility. The pharmacist must resolve red flags. An unsuccessful attempt to resolve red flags is insufficient.

However, overall, I do not find that Mr. Parrado was disingenuous or lacking candor in his testimony, even when he occasionally failed to answer questions in a direct manner or to provide notice of all facts and materials upon which he relied in making his opinions. I do find his testimony to be generally credible and reliable, to the extent the information upon which he relied was accurate.

As to both experts in this matter, I consider their opinions and the merits of each when weighing the factors and the law. Here, the experts had differing strengths. Mr. Parrado has a tremendous amount of experience in Florida Pharmacy law and practice, while Dr. Hamilton seems to have the edge regarding existing pharmacy practice and market forces. However, as with any battle of experts, it is the expert's justification, or explanation for his opinion, which is key. As developed in detail *infra,* generally Dr. Hamilton's justifications and explanations for his opinions appeared more consistent with existing market forces, the relevant law, and Agency precedent than those of Mr. Parrado.

*[Omitted for clarity.]

Conflicting Findings of Dr. Hamilton and Mr. Parrado

Florida Minimum Standard of Care

Dr. Hamilton provided testimony that he understood the Florida minimum standard of care to be guided by the Florida Administrative Code, specifically ''Regulation 64B'' and guidelines provided by the National Board of Pharmacy Association. Tr. 180–81. Specifically, Dr. Hamilton noted that the Florida standard of care included responsibilities not specifically included within the relevant Florida regulations. *Id.* at 1007–08. On the other hand, Mr. Parrado testified that he understood the minimum standard of care to be set strictly and exclusively by the [Florida] Pharmacy Act or the Florida Administrative Code. *Id.* at 456. Further, the experience that Mr. Parrado has in the creation and implementation of these standards give his testimony significant weight in determining the import and scope of Florida law.*GG

A careful review of Florida law and regulations guiding the practice of pharmacy within the State of Florida shows that the practice is generally guided by Chapter 465 of the Florida Pharmacy Act,[55] and Florida Administrative Code rule 64B16, which governs pharmacy practice. Based strictly on this review, Mr. Parrado's testimony as to the law and regulations governing the practice of pharmacy in Florida appears to be correct. While Dr. Hamilton may also be correct about the guidelines set by the National Board of Pharmacy Association that have guided the State of Florida in its implementation of laws and regulations setting the minimum standard of care, it cannot be ascertained from the literal text of relevant Florida regulations where the Association's guidelines have been given any legal force beyond those provided for in the statutes and regulations cited to by Mr. Parrado. *[However, I likewise find no support for the proposition that Florida law encompasses the entirety of the standard of care in the State of Florida. Here, Mr. Parrado testified that Florida pharmacists are required to take thirty hours of continuing education every two years, and that ''two of those hours have to be on the . . . opioid abuse and resolving red flags.'' Tr. 413. In this case, I find that Florida state law can be reasonably interpreted to support both Dr. Hamilton's and Mr. Parrado's testimony.]

Mr. Parrado's testimony would generally be credited as to the governing laws and regulations within the Florida Pharmacy Act and the Florida Administrative Code. *[And Dr. Hamilton's testimony would generally be credited as to the usual course of existing pharmacy practice.] However, individual scrutiny will be given to the sections of the Florida Administrative

*GG Sentence was relocated for clarity.

[55] Fla. Stat. § 465.001 *et seq.*

Code under which the Government has raised allegations against the Respondent for failing to meet the minimum standard of care.

Requirement To Document Resolution of Red Flags

Dr. Hamilton provided testimony that resolution of each ''red flag'' had to be documented somewhere in a patient's file to demonstrate that the ''red flag'' had been resolved. He noted that this would be required under the Florida standard of care and that ''[i]f [it is] not documented, there's no evidence that . . . it was resolved.'' *Id.* at 179–81. Dr. Hamilton conceded that although this requirement was not specifically written in the relevant Florida regulations, it was without question required in the context of the Florida regulations as part of the Florida standard of care. *Id.* at 1007–08.

Despite its obvious logic, Mr. Parrado disagreed with Dr. Hamilton's assertion that such documentation is required in Florida. Mr. Parrado conceded that documenting the resolution of ''red flags'' may represent ''best practice,'' including that he would also do it as a pharmacist, but that it is not required under Florida law or the standard of care. He provided that most pharmacists complete at least some kind of documentation to indicate resolution of ''red flags.'' He also stated that he had created a computer program called ''Red Flag Resolver'' to assist pharmacists in documenting the resolution of red flags in their own practice.

*[Omitted. Here both experts agree that documentation of red flag resolution is not explicitly required by Florida law. However, the regulations generally support the testimony of Dr. Hamilton regarding the importance of documentation in the usual course of professional practice in Florida. *See also Suntree Pharmacy and Suntree Medical Equipment, L.L.C.,* 85 FR 73,753, 73,772.*HH thnsp;56]

Therefore, under Florida regulations and findings of the Agency on this issue, I credit Dr. Hamilton's testimony that pharmacists are required under the Florida standard of care to document the resolution of ''red flags.''

Pricing of Prescriptions *II

Dr. Hamilton expressed concerns that *[the patients' willingness to pay cash for these] *JJ highly priced prescriptions was a ''red flag'' that should be addressed. Dr. Hamilton indicated that it does not make sense that a patient would continue to go to a pharmacy that is charging high prices when there are pharmacies that sell the same medications for much less. Tr. 194. For example, high prices were a red flag for Patient A.E. (paying up to $500 a month) because A.E. was paying up to $5.95 per pill *[in cash when he could have gotten the controlled substances elsewhere for 1.50 per pill]. Tr. 199; GX 28, pp. 6–7. He opined that patients do not want to pay more than they have to, and if the same prescription was offered at a lower price at a different pharmacy, the patient would have gone to that other pharmacy. Tr. 199. Dr. Hamilton also noted he has observed different pricing schemes for the same prescriptions for the same person, *[paying cash] for which he could not provide a rational explanation. *Id.* at 203–04.

Mr. Parrado disagreed with Dr. Hamilton's assertion that the prices on the prescriptions should be much lower than that charged by Pharmacy 4 Less. He opined that every pharmacy can determine their own prices, which may be more expensive when filling a controlled substance prescription based on the added work load (including checking E–FORCSE, better maintenance of records, and additional inventories). *Id.* at 449. He stated that pharmacy pricing can be very competitive. *Id.* at 450. The only explanations Mr. Parrado could give for a pharmacy charging different prices for the same medication was a potential higher cost from a different wholesaler, the use of discount coupons, or indigent pricing programs. *Id.* at 451–52. There was no evidence offered that these exceptional circumstances existed here.

As to Mr. Parrado's claim that opioids had become scarce, difficult to locate, and involved additional expense to the pharmacies, thus warranting higher prices, neither party introduced documentary evidence to support or to counter this claim. *Id.* at 451–52, 539. Mr. Parrado did not offer the actual reason the Respondent charged the prices they did, or whether the Respondent recognized their prices were significantly higher than other like-situated pharmacies. For example, we don't know if there was a pharmacy much closer to the patients' homes or doctor offices charging less, from any direct evidence. We are left with conflicting, sometimes anecdotal, evidence by Mr. Parrado and Dr. Hamilton.

Dr. Hamilton personally surveyed pharmacy prices in his area, near Fort Lauderdale, while Pharmacy 4 Less is located just north of Orlando. *Id.* at 178. Dr. Hamilton's formula to determine average prices by large and small pharmacies involved a survey of wholesale prices of opioids sold to pharmacies, generally increased by 20% for pharmacy mark up, does not rebut the justifying explanations given by Mr. Parrado. To be more accurate, the survey should have been limited to small pharmacies. However, Dr. Hamilton's reliance upon a GoodRx program to determine prices charged by pharmacies for opioids does provide objective support for his assertions that the prices charged by Pharmacy 4 Less for the various subject opioids were considerably in excess of what other pharmacies were charging. *Id.* at 177–78.

Based on a review of this record, I find that Dr. Hamilton provided a more reliable basis in support of his opinion of unusually high prices of opioids charged by Pharmacy 4 Less than the uncorroborated and more anecdotal and historical explanations given by Mr. Parrado. I do not discount the market forces cited by Mr. Parrado, although I reject the extent to which he opined they affected the prices charged by the Respondent.

Having found that Respondent's *[cash-paying patients at issue in this case were paying] unusually high prices for the subject opioids, triggering a red flag, the next inquiry is whether the Respondent resolved the red flag. There was no evidence introduced that the Respondent performed any inquiry or investigation as to why the subject patients were willing to pay such high *[cash] prices for the subject opioids. Dr. Hamilton's opinion that this red flag repeatedly went unresolved is fully supported by this record.

*HH In *Suntree,* the Respondent implied that the Government's expert's ''inability to draw a solid conclusion as to where the requirement to document the resolution of red flags is written somehow demonstrated that there is no such requirement in the standard of practice.'' *Id.* The Acting Administrator rejected that reasoning and found ''that Florida state law can be reasonably interpreted to support [the Government expert's] testimony, but that her testimony [was] independently credible that documentation of the resolution of red flags is a requirement of the practice of pharmacy in the State of Florida.'' *Id.* I find the same. Here, Dr. Hamilton clearly testified that the resolution of the ''red flag'' had to be documented in the file as part of the Florida Standard of Care, noting, ''[i]f it's not documented, there's no evidence that . . . it was resolved, or a phone call was made, or an answer was given.'' *Id.* at 179–80; *see also id.* at 306, 318, 337, 1006–11, 1016.

56 *[Omitted text where original footnote was included.]

*II I have made modifications as indicated throughout this section to more directly address the issue in this case—that the patients identified in the OSC were paying cash, and excessively high prices at that, for controlled substances which created a red flag.

*JJ *See infra* n. NN.

Long Distances Traveled by Patients

Both Dr. Hamilton and Mr. Parrado agreed that long distances traveled by patients to fill their prescriptions at Pharmacy 4 Less was a ''red flag'' that needed to be resolved before the prescription was filled. *Id.* at 209–10, 453. As to Patient A.R., Dr. Hamilton gave the opinion that there were multiple red flags. *Id.* at 209. He said that the distance from A.R.'s home to the physician was a red flag because A.R. had to explain the reason to be going to that physician. Further, the distance from the physician to the pharmacy is a red flag, because it was taking A.R. even further away from A.R.'s home, approximately 50 miles from his home. A.R. needed to explain why he was traveling so far to fill the subject prescriptions. *Id.* at 209–10. Dr. Hamilton first opined that this red flag was not resolvable, but later conceded that there may be circumstances in which it could be resolved, but that it would need to be notated in the pharmacy file. *Id.* at 210.

Mr. Parrado gave the opinion that while the long distance traveled would be a red flag, it was one that could be resolved. *Id.* at 453. He said that it only needed to be resolved once as long as the pharmacist knew the patient and knew why they are coming to the pharmacy. Further, he stated that it would not need to be re-resolved each time if the patient was ''coming from the same place, he's seeing the same doctors, coming to the same pharmacy.'' *Id.* at 453. When asked about this red flag on cross-examination, Mr. Parrado said that from his review, Patient A.R. appeared to have a relationship with a pharmacy that would fill his prescriptions when it was difficult to find places to fill prescriptions. *Id.* at 539. He observed that Pharmacy 4 Less had developed a relationship with A.R., was monitoring and checking up on him, and gave all other indications which would resolve that red flag, in his opinion. *Id.* at 539.

While there appears to be no dispute that long distances traveled can constitute a red flag, there is a dispute as to its resolution in this matter. Mr. Parrado claimed that in his review, he believed this red flag had been resolved. Mr. Parrado based his finding on A.R. having developed a relationship with the Respondent and the difficulty in locating pharmacies which carried opioids. Mr. Parrado's finding appears to rely significantly on a scarcity of pharmacies carrying opioids. Based on the existing record, such scarcity has not been directly established. That the Respondent pharmacy has developed a relationship with A.R. would certainly not justify the first few dispensing without resolving the distance traveled red flag. In the absence of any other evidence resolving this red flag, I credit Dr. Hamilton's testimony that even if the red flag is resolvable, it was not resolved in this case.

Opioid Tolerance and High Starting Dosages

I did not recognize significant disagreement between Dr. Hamilton and Mr. Parrado regarding the red flag evident at the initial dispensing of any significant strength of opioids. Dr. Hamilton testified that a high initial opioid prescription is a red flag that must be resolved. He asserted that if a starting dose is too high and a pharmacist fails to identify the patient as being opioid naïve to that dosage level, the prescription could potentially prove to be fatal. *Id.* at 188. While Mr. Parrado did not appear to disagree that this is a red flag that should be resolved, he differed in his assessment of the patients in this matter receiving high starting dosages such that they would fail to meet the minimum standard of care. For example, when asking about prescribing 84 pills of oxycodone 30 mg to a patient, Dr. Hamilton testified that it would have been too high of a starting dosage for some of the charged patients. On the other hand, Mr. Parrado observed that there is no upper limit on the quantity that can be prescribed to a patient or how many milligrams. He stated that each would depend on the patient and their individual tolerance level. *Id.* at 461–62. Their previous opioid medication levels would fairly suggest their level of tolerance. Essentially, Mr. Parrado took the position that initial subject opioid dispensing of a significant dosage represented a red flag, which was resolvable. I do not recognize significant conflict between the two experts in this regard.

The credibility of Ms. Mincy's testimony as relates to her investigating the opioid naiveté of the 10 subject patients deserves some analysis. Here, Ms. Mincy testified that she used E–FORCSE at the pharmacy to look at patients' histories and records before filling a prescription. *Id.* at 643. She indicated that she uses it daily and prior to every fill of a new prescription of her patients. *Id.* She even stated that E–FORCSE ''is the best system to resolve red flags, in [her] opinion.'' *Id.* at 645. She made multiple comments about the usefulness of the E–FORCSE system and how she uses it on a daily basis during her work in the pharmacy. Finally, she indicated that she uses it before she fills every controlled substance prescription. *Id.* at 645–46.

The Government introduced evidence of the E–FORCSE searches conducted by Pharmacy 4 Less between January 1, 2015, and June 6, 2017, for the 10 charged patients in this matter. GX 38. For six patients, A.E., B.F., K.E.D., R.R., R.V., and V.W., this exhibit shows that Pharmacy 4 Less conducted initial opioid fills for the six patients, but did not run a search on E–FORCSE on the corresponding date of the fill. For example, Patient A.E. first filled a prescription on November 19, 2015, but Pharmacy 4 Less did not check E–FORCSE for Patient A.E. until April 7, 2016. GX 38, p. 11. Apart from being able to run checks through E–FORCSE, Pharmacy 4 Less did not introduce any evidence that it otherwise completed or documented its resolution of any potential red flags for Patient A.E before doing an initial fill of the prescription. The evidence shows this to be true for Patients B.F., K.E.D., R.R., R.V., and V.W., as well. GX 38.

The E–FORCSE records introduced do substantiate that either Ms. Mincy or Mr. Sprys checked the E–FORCSE database for the initial opioid dispensing for the following subject patients: A.R. on March 16, 2016; A.V. on April 21, 2016; B.N. on January 22, 2016; and K.Y.D. on February 4, 2016. *See* GX 38; RX 21, p. 4, 23, p. 3, 27, p. 3, 31, p. 7. However, Ms. Mincy conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. Tr. 815–16. To the extent that Mr. Parrado credited Ms. Mincy's and Mr. Sprys' claims that they checked E–FORCSE to resolve opioid naïveté for the six patients noted above, this significantly diminishes Mr. Parrado's opinion.

The E–FORCSE records further belie Ms. Mincy's claim that she checked the E–FORCSE prior to filling each prescription. Tr. 645–46; GX 38. According to my math, of the 190 charged dispensed prescriptions within the subject record, the Respondent checked the E–FORCSE database 31 times, or 16.3% of the time. Ms. Mincy later testified that she checked E–FORCSE for each Schedule 2 prescription, and only recently began checking it for all controlled substance prescriptions. This significantly diminishes Ms. Mincy's reliability as a witness.

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious red flags of diversion, 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), and in violation of state law under the Florida Administrative Code and state requirements for the minimum standard of care.

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) (2010). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for her actions and demonstrate that she 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, 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).*KK

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 at 463 (noting, on remand, that despite the respondent's having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med. Shoppe–Jonesborough,* 73 FR at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. The Supreme Court has defined 'substantial evidence' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consolidated Edison Co. of New York* v. *National Labor Relations Board,* 305 U.S. 197, 229, 59 S.Ct. 206, 217 (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 Vill. Pharmacy* 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 that 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).

Red Flags of Diversion

The Government has alleged that Pharmacy 4 Less failed to resolve and document ''red flags'' of diversion outside the usual course of professional practice (21 CFR 1306.06) and the pharmacy's corresponding responsibility (21 CFR 1306.04(a)) and in violation of meeting the Florida minimum standard of care under Florida law.

High Starting Dosages

The Government has alleged that Pharmacy 4 Less routinely filled Schedule 2 controlled substances for patients with high starting dosages, including both the dosage being prescribed and the number of tablets being prescribed.

The Government presented evidence by Dr. Hamilton that the initial starting dosages for at least six of the charged patients (Patients A.E., B.F., K.E.D., R.R., R.V., and V.W.) were too high and potentially fatal to opioid naïve patients. Dr. Hamilton gave his opinion that the starting dosages for these charged patients were too high given the nature of the patients' medical records and other documents that he had reviewed. Mr. Parrado appeared to agree with Dr. Hamilton that it is necessary to determine whether a patient is opioid naïve and that it should be factored into the determination of what a proper starting dosage would be, but disagreed that the starting dosages were necessarily too high. Both experts agreed that in order to determine if a patient is opioid naïve, a pharmacist can check E–FORCSE, talk to the patient, consult with the prescribing doctor, or take other steps the pharmacist determines to be necessary.

Here, Ms. Mincy testified that she used E–FORCSE at the pharmacy to look at patients' histories and records before

*KK Text omitted for brevity.

filling a prescription. Tr. 643. She indicated that she uses it daily and prior to every fill of a new prescription of her patients. *Id.* She even stated that E–FORCSE ''is the best system to resolve red flags, in [her] opinion.'' *Id.* at 645. She made multiple comments about the usefulness of the E–FORCSE system and how she uses it on a daily basis during her work in the pharmacy. Finally, she indicated that she uses it before she fills every controlled substance prescription. *Id.* at 645–46.

The Government introduced evidence of the E–FORCSE searches conducted by Pharmacy 4 Less between January 1, 2015, and June 6, 2017, for the 10 charged patients in this matter. GX 38. For the six patients previously mentioned, this exhibit shows that Pharmacy 4 Less conducted initial opioid fills for the six patients, but did not run a search on E–FORCSE on the corresponding date of the fill. For example, Patient A.E. first filled a prescription on November 19, 2015, but Pharmacy 4 Less did not check E–FORCSE for Patient A.E. until April 7, 2016. GX 38, p. 11. Apart from being able to run checks through E–FORCSE, Pharmacy 4 Less did not introduce any evidence that it otherwise completed or documented its resolution of any potential red flags for Patient A.E before doing an initial fill of the prescription. The evidence shows this to be true for Patients A.E., B.F., K.E.D., R.R., R.V., and V.W. GX 38.

Therefore, the Government has met its burden of proof as to this allegation as to these six patients.

As to the remaining four subject patients, the E–FORCSE records introduced reflect that either she or Mr. Sprys checked the E–FORCSE database for the first charged prescriptions for the following subject patients:[*LL] A.R. on March 16, 2016; A.V. on April 21, 2016; B.N. on January 22, 2016; and K.Y.D. on February 4, 2016. *See* GX 38; RX 21, p. 4, RX 23, p. 3, RX 27, p. 3, RX 31, p. 7. Ms. Mincy conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. Tr. 815–16. *[Consistent with Dr. Hamilton's testimony, I find that Respondent acted outside of the usual course of professional practice and in violation of its corresponding responsibility when it failed to resolve and/or to document resolution of the opioid naïveté red flag as to each of the ten patients at issue in this case.][*MM]

[Cash Paid and] Excessive Pricing [*NN]

The Government has alleged that Pharmacy 4 Less routinely filled controlled substance prescriptions *[for patients who were paying cash at] extremely high prices.

As previously discussed, I credit Dr. Hamilton's opinion that Pharmacy 4 Less charged unusually high prices. Using his calculations in relation to large and small pharmacies, and his findings as to average prices charged in the surrounding area, Dr. Hamilton determined that there is generally only a slight difference between large and small pharmacies prices, with the difference generally amounting to a few dollars per prescription. *Id.* at 194–98. However, the Government's evidence suggests that Pharmacy 4 Less was charging prices much higher than that expected by a pharmacy within the surrounding area, whether it be a small independent pharmacy or a large retail pharmacy. *[Most concerning, the patients at issue in this case were paying for these over-priced controlled substances with cash which created a red flag. When Dr. Hamilton was asked at the hearing what he meant by the red flag he labeled ''paid cash, extremely high prices'' in his report, *see* GX 28, at 6, Dr. Hamilton explained that absent diversion, ''[t]here is no reason for a . . . patient to continue to go to a pharmacy that has'' ''extremely high prices when there [are] pharmacies that would sell it for much less.'' *Id.* at 194.]

While the Respondent put on evidence by Mr. Parrado as to the excessive pricing, I note that Mr. Parrado did not reveal the actual reasons the Respondent charged such prices, nor reveal similar prices by pharmacies closer to the subject patients' homes or physicians. *[Mr. Parrado further testified that some pharmacies only take cash, they ''do not take insurance . . . it's hard to get on some of these insurance networks,[*OO] then [you are] subject to their audits.'' Tr. 450.] I have found that his opinions on this allegation were more anecdotal and historical, and did not provide a sufficient basis to completely refute Dr. Hamilton's more objective and timely analysis.

Therefore, I find that the Government has met its burden of proof as to this allegation. The record establishes that the Respondent's *[patients at issue in this case paid cash at] prices that were noticeably higher than market forces would explain and sufficient to create a red flag. However, the record does not support a finding that the Respondent prices were exorbitant to the extent those transactions represented ''knowing'' diversion by the Respondent.

I do not find that solely on the basis of the high prices charged by the Respondent that Pharmacy 4 Less knowingly issued the prescriptions without a legitimate medical purpose. In their Posthearing Brief, the Government argues that ''[w]here a pharmacy is consistently charging exorbitant prices, DEA 'may properly draw the inference that the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others.' *Jones Total Health Care Pharmacy, LLC,* 81 FR 79,188, 79,199–200 (2016).'' Govt Posthearing Brief at 39–40. The Government argues that, while there may be some variance in pricing, which the Administrator in *Jones Total Health Care* acknowledged, ''exceeding the average retail price by more than 200% at times is not what one would expect to find at a legitimate pharmacy.'' Govt Posthearing Brief at 31. As noted in *Jones Total Health Care,* the view that prices charged by a

[*LL] In its exceptions, the Government argued that merely running a name through E–FORCSE was insufficient to resolve the opioid naïve red flag, and that the pharmacist needed to affirmatively review the report, determine that the report addressed the red flag, and document the resolution. Govt Exceptions, at 9–10. I agree with the Government's position, but do not find that the ALJ erred. The ALJ considered the E–FORCSE records along with Ms. Mincy's testimony that she was using E–FORSCE to resolve the red flag in exactly the manner the Government said was required. There are credibility issues with Ms. Mincy's testimony, but ultimately, the ALJ in a different section of the RD found that Respondent Pharmacy's failure to document resolution of this red flag demonstrated a violation of its corresponding responsibility. *Infra* section ''Failure to Document Resolution of Red Flags.'' I have modified this section of the RD to clarify that the ALJ found that the Respondent Pharmacy's failure to document resolution of this red flag demonstrated a violation of Respondent Pharmacy's corresponding responsibility and was outside the usual course of pharmacy practice.

[*MM] This replaces the ALJ's original finding that the Government failed to carry its burden that the opioid naïveté red flag went unresolved for four of the ten patients.

[NN] Throughout the testimony in this case and in its Posthearing Brief, the Government emphasized the excessively high prices charged by the pharmacy. However, the Government's expert also opined that the customer's cash payment at excessively high prices created red flags that were not resolved prior to dispensing. *See also* OSC, at 3–7; Govt Supp. Prehearing, at 7–15 GX 28, at 5–6; Tr. 194–98. I have made modifications throughout this section as noted in brackets to account for the ''cash payment'' portion of the issue.

[*OO] In its exceptions, Respondent asserted that ''[i]t takes almost 2 years for a new pharmacy to be accepted by all insurance companies.'' Respondent's Exceptions, at ¶ 3. Though this specific factual assertion lacks evidence in the record, I find it is in line with Mr. Parrado's anecdotal testimony which was properly considered by the ALJ in reaching his decision.

pharmacy in excess of average prices can support an inference that the pharmacy knew the prescriptions were not being issued for a legitimate medical purpose. *Jones Total Health Care,* 81 FR at 79,200 (citing *United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996); *United States* v. *Cooper,* 868 F.2d 1505, 1512 (6th Cir. 1989); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979)).

Here, no direct evidence was offered by either party regarding the prices actually charged by alternate pharmacies near the patients' homes or physician's offices. *[Absent additional and more specific evidence,][*PP] I find that an inference based solely on the higher prices charged herein *[omitted] that Pharmacy 4 Less knowingly filled the prescriptions without a legitimate medical purpose, would not be warranted. *[Still, as I found above, the record establishes that the Respondent's patients at issue in this case paid cash at prices sufficiently high to create red flags, which were not resolved. And there is sufficient evidence to support a finding that the pharmacists who filled those prescriptions without documenting resolution of those red flags violated their corresponding responsibility due to their willful blindness to the prescriptions' potential illegitimacy. *See Suntree,* 85 FR at 73,770.]

Long-Term Fill for Immediate Release Pain Medication

The Government has alleged that Pharmacy 4 Less routinely filled controlled substance prescriptions for immediate release pain medication over long periods of time.

Dr. Hamilton testified that a patient receiving short-acting medications over a long period of time is a red flag that must be resolved before the prescription is filled. He stated that immediate-release medication should not be taken over long periods of time, with the medication being ''immediate-release for a reason.'' Tr. 193. He further testified that if it is prescribed over a long period of time, there needs to be documentation from the physician about the patient as to why a long-acting medication failed or other circumstance that would demonstrate why a short-acting medication was being prescribed over a long-period of time. *Id.* at 194.

The Respondent did not present evidence to directly counter the Government's evidence. Mr. Parrado agreed that this was a red flag that needed to be resolved. He only generally asserted that the physician determines what medication the patient will be on, that many insurance companies will not pay for extended release medication, and the charged patients may have had insurances that did not cover them. *Id.* at 447. However, he did counter that oxycodone can be used for extended periods of time, based upon academic literature, and that there was no set duration of time which oxycodone should stop being used. *Id.* at 447. He did concede that as a pharmacist, he questioned whether a short acting versus a long acting prescription was properly prescribed. *Id.* at 447–48. Without evidentiary corroboration,[*QQ] Mr. Parrado's testimony in this regard is little more than speculation. It does not meaningfully counter Dr. Hamilton's subject opinion.

Therefore, I find that the Government has met its burden of proof as to this allegation. *[Specifically, I find that Respondent pharmacy acted outside of the usual course of professional practice and in contravention of its corresponding responsibility when it failed to resolve and/or document resolution of the red flag arising from long-term use of immediate-release pain medications.]

Long Distance Traveled by Patient A.R.

The Government has alleged that Pharmacy 4 Less filled prescriptions for Patient A.R., who traveled long distances (fifty miles from his home) to fill his prescriptions.

Both Dr. Hamilton and Mr. Parrado agreed that long distances traveled by patients to fill their prescriptions at Pharmacy 4 Less was a ''red flag'' that needed to be resolved before the prescription was filled. *Id.* at 209–10, 453. As previously discussed, while there appears to be no dispute that long distances traveled can constitute a red flag, Dr. Hamilton and Mr. Parrado did disagree about the potential for resolution of the red flag in this matter as to Patient A.R. However, Mr. Parrado again gave general opinions on this matter as to why Patient A.R. may have been traveling such long distances to fill his prescriptions at Pharmacy 4 Less. Without proper documentation to show if Pharmacy 4 Less even attempted to resolve such a red flag, Mr. Parrado's assertions remain speculative and cannot be definitively shown.[57] Further, I find that the distances traveled by Patient A.R. were long enough that Dr. Hamilton's opinion is to be credited that this is a red flag that needed resolution, which Pharmacy 4 Less has failed to do.

Therefore, I find that the Government has met its burden of proof as to this allegation. *[Specifically, I find that Respondent pharmacy acted outside of the usual course of professional practice and in contravention of its corresponding responsibility when it failed to resolve and/or to document resolution of the red flag arising from the long distance A.R. traveled to fill his prescription.]

Drug Combination Prescriptions

The Government has alleged that Pharmacy 4 Less filled prescriptions for drug combinations that needed to be questioned. In particular, the Government has alleged that Pharmacy 4 Less improperly filled prescriptions for Patient A.V. that combined buprenorphine along with oxycodone.

Dr. Hamilton testified that buprenorphine issued with oxycodone presents a red flag that needs to be resolved. *Id.* at 263–76. He explained that buprenorphine is a medication used for opiate withdrawal, and issuing it along with oxycodone, an opioid, would present a red flag because the opioid would no longer be of any use. *Id.* at 263. He testified that when these combinations are used, it would be expected to see that the patient, would *[within a few days to a few weeks, *Id.* at 974] be weaned off of the opioid and it would be substituted with the buprenorphine. *Id* at 263. Dr. Hamilton indicated that he did not see any evidence that Pharmacy 4 Less had resolved this red flag before issuing the prescriptions to Patient A.V. *Id.* at 266. When confronted with the Respondent sponsored PRM file, which included references to tapering the patient off of opioids, Dr. Hamilton opined that such cryptic reference was insufficient to resolve the red flag or be sufficient documentation within the pharmacy record. *Id.* at 972. *[Specifically, Dr. Hamilton testified that ''the note says that the . . . physician is tapering the patient off of medications that [he is] addicted to, but [there is] a continuation of the oxycodone fill in the same amounts, same quantity, same timeframe. It continues over the course of the whole year.'' *Id.* It is clear from

[*PP] Original text modified for clarity and brevity.

[*QQ] In its Exceptions, Respondent asserted that ''[p]atients are on immediate release because the price of long term is 3 to 5 times as much and their insurance does not pay for it. Almost all patients had forms that we filled out and signed for reimbursement from their insurance companies.'' Resp Exceptions, at ¶ 2. This factual assertion, again without evidence in the record to support it, fails to qualify as the evidentiary corroboration needed to establish Dr. Parrado's testimony as anything other than speculation.

[57] Mr. Parrado testified that all of the red flags were resolved to his satisfaction by his speaking with Ms. Mincy and Mr. Sprys, as their explanations resolved all of the charged red flags. Without more specificity, I cannot attribute significant probative value to this blanket opinion.

Dr. Hamilton's testimony that the drug combination red flag arises twice in this case: first, when the buprenorphine and oxycodone are prescribed together; and again, when the drug combination continues over time without tapering.]

Mr. Parrado agreed with Dr. Hamilton that this drug combination is a red flag ''that [he] would have wanted to look into very carefully.'' *Id.* at 463. However, Mr. Parrado indicated that he believed the red flag had been resolved because he found that Pharmacy 4 Less had contacted Patient A.V.'s doctor, in which the doctor explained that he was trying to get A.V. off of the oxycodone by intermittently using buprenorphine. *Id.* at 463–64. When I asked where Mr. Parrado had seen this red flag resolved in the records he reviewed, he stated that he had seen it in the patient's record maintenance folder. *Id.* at 464; RX 22, 23.

Upon a review of the evidence, I find that Patient A.V.'s patient record maintenance file maintained by Pharmacy 4 Less does give some indication that Pharmacy 4 Less contacted A.V.'s doctor. In the Patient Memo, it states ''PATIENT DC'D 4/17/17 CONTINUED DETOX WITH COM. DRUGS FOR HIS SPECIFIC LEVEL OF ADDICTION TAPERING PER DR. W SEIFERT—MD CONSULTED AND RESULTED IN CONTINUED THERAPY.'' RX 22, p. 1.[*RR] However, what cannot be ascertained is when this information was entered into the system.

It is clear from at least the face of the prescriptions that Pharmacy 4 Less did not provide additional documentation beyond what is shown in the patient record maintenance file. With the impossibility of determining when this information was entered, it cannot be definitively ascertained whether Pharmacy 4 Less resolved the *[initial] red flag at the time the prescriptions were issued or whether this information was inserted at a later time. *[However, even if the Respondent Pharmacy did resolve the initial red flag arising from the drug combination, there is no evidence in the record that the red flag arising from the continual prescribing of the drug combination without proper tapering was resolved.

Therefore, I find that the Government has met its burden of proof as to this allegation by establishing that Respondent Pharmacy failed to resolve the red flag of arising from the long-term use of this drug combination without tapering.][*SS]

Failure To Document Resolution of Red Flags

I have presented my findings as to each of the five allegations set out by the Government as to Pharmacy 4 Less's failure to resolve red flags. The Government has argued that not only has Pharmacy 4 Less failed to resolve these red flags, but their failure to document resolution of red flags warrants an inference that the red flag was never resolved.

As I have already discussed, *[Omitted. I credit Dr. Hamilton's testimony that pharmacists are required under the course of professional practice in Florida to document the resolution of ''red flags.'']*[TT] As such, I make my recommendation that the Administrator find Pharmacy 4 Less was required to document the resolution of red flags, and that it failed to do so.

During the hearing, Mr. Parrado provided testimony about the Florida laws and regulations that underpin the standard of care for Florida pharmacists. As one of the individuals involved with the drafting of Florida regulations in question, he gave insightful comments about the creation and basis for the rules. However, as I noted during the hearing, Mr. Parrado's comments were instructive, but not dispositive. Tr. 468. I am foremost guided by the text of the law and regulations,[*UU] *[and by the Government's expert testimony regarding the standard of care in the State of Florida.]

Based upon the evidence provided, I find that Pharmacy 4 Less has failed to document or show other evidence that demonstrates resolution of the red flags [58] as alleged by the Government in the previous five allegations, excluding the *[allegation related to the initial red flag arising from] Patient A.V.'s prescribed drug combination.[*VV]

Recordkeeping Violations

Initial Inventory

The Government has charged that Pharmacy 4 Less did not have an initial inventory in violation of 21 CFR 1304.11(b). Section 1304.11(b) provides that ''[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the . . . distribution, or dispensing of controlled substances. . . .''

The Government provided the testimony of DI1 that on June 6, 2017, during the on-site inspection, DI1 asked Ms. Mincy if Pharmacy 4 Less had an initial inventory. Tr. 39. When asked, Ms. Mincy could not locate the initial inventory and did not know where it was, and contacted Mr. Sprys to ask about the initial inventory. *Id.* at 39–40. This was done in the presence of DI1 and DI2. Tr. 39. DI1 explained to Mr. Sprys what an initial inventory was and asked if Pharmacy 4 Less had one, to which Mr. Sprys stated that he did not. Tr. 40. *[Omitted for brevity.]

The Respondent did not put on any evidence to confront this allegation,[*WW] although the Respondent, during cross-examination of DI1, questioned whether DI1 spoke to Mr. Sprys over the telephone regarding the initial inventory. Tr. 154.

As noted, the Government has the burden of proof in these proceedings to prove the charges alleged in the OSC and those later raised in the prehearing statements. The Government must meet its burden by a preponderance of the evidence for its burden to be satisfied as to each allegation. Here, the Government produced the testimony of DI1 that Ms. Mincy did not know where the initial inventory was, and that Mr. Sprys indicated that the pharmacy did

[*RR] The Government argued in its exceptions that the ALJ improperly relied on RX 22 because the exhibit was admitted only conditionally and the condition for its admission was ultimately not met. While I understand the Government's argument regarding reliance on the exhibit in this way, the ALJ did not rely on RX 22 standing alone, rather he relied on it as support for Mr. Parrado's opinion which was that the Respondent Pharmacy had contacted the patient's physician and resolved the initial red flag. Ultimately, in light of the preponderance of the evidence, RX 22 is of little importance to the finding on this red flag.

[*SS] I have omitted the ALJ's original finding in Respondent's favor based on his uncertainty over whether or not the Respondent had resolved the initial drug combination red flag as may have been documented in RX 22. The ALJ did not evaluate the red flags that arose as a result of the continued filling of the drug combination prescriptions without signs of proper tapering, and having so evaluated them, I have reached a different result.

[*TT] *See also supra* ''Requirement to Document Resolution of Red Flags.''

[*UU] Omitted for clarity.

[58] Further, the Government offered evidence that DI and the rest of his team did ask Ms. Mincy if they documented their resolution of red flags and where they did so. DI was provided documents by the Respondent at DI's request upon which records were identified that failed to indicate the resolution of red flags. *[This footnote was relocated for preservation after the original text to which it referenced was omitted].

[*VV] Omitted, for brevity, the inference that Respondent Pharmacy's failure to document resolution of the red flags supported a finding that the red flags were in fact not resolved. Here, there is ample evidence of red flags that were unresolved and/or undocumented.

[*WW] In its exceptions, Respondent claimed that it opened in 2015 with ''zero narcotics'' and that ''[t]his report was shown to DEA agents on initial inspection in 2015.'' Resp Exceptions, at ¶ 7. This assertion is not supported by the evidentiary record. Moreover, the reference to ''this report'' is ambiguous and may or may not refer to an initial inventory, but even if an initial inventory was taken, there is no assertion that Respondent had an initial inventory during the 2017 inspection. This exception is simply without merit.

not have one. This evidence went essentially uncontested.

The Agency has previously found that ''testimony alone provides substantial evidence'' to support a finding that a registrant failed to properly prepare records. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR 79,188, 79,191 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018). The Agency rejected the respondent's argument that because the DEA bears the burden of proof, it must provide independent evidence towards such allegations. *Id.*

As previously discussed, I find that DI1's testimony in these proceedings was credible and indicated trustworthiness. The Government has submitted testimonial proof sufficient to satisfy its burden, that the Respondent did not have an initial inventory. Further, while the Respondent has no burden to disprove the Government's allegation, it would not benefit the Respondent to withhold such a document if such document existed. Based on DI1's testimony and the lack of physical evidence presented by either party, I find that the Government has met its burden to show that the Respondent has failed to keep an initial inventory as required under § 1304.11(b).

Biennial Inventory

The Government has charged that Pharmacy 4 Less failed to indicate whether the biennial inventory was taken at the opening or closing of business as required by 21 CFR 1304.11(a). Section 1304.11(a) provides, in part, that ''[t]he inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.''

The Government presented testimony from DI1 that the biennial inventory was provided to him by Ms. Mincy during the June 6, 2017 on-site inspection. DI1 testified that the biennial inventory given to him did not meet the requirements as set in the DEA regulations. Tr. 41. One failing that DI1 noted was that, by Ms. Mincy's statements, the biennial inventory was not completed during a single day, but over the course of several days. Tr. 41. Another defect was that there was no notation on the biennial inventory as to whether it was completed at the opening or closing of business. *Id.* at 41–42. DI1 was unsure about the accuracy of the biennial inventory due to these issues, which caused him not to use it as part of his audit of the pharmacy's inventory. *Id.* at 56, 61, 66, 154–56.

The Respondent presented testimony from Ms. Mincy that DI1 had asked to see the biennial inventory, which she produced and gave him a copy. *Id.* at 605. She indicated that the biennial inventory was located in a binder in the locked medication room along with the perpetual inventory. *Id.* at 607, 622–23. Ms. Mincy testified that on June 6, 2017, she gave DI1 the biennial inventory at the pharmacy. *Id.* at 773–74. She indicated that he had left it at the pharmacy after the inspection, and that he called back looking for it because he had forgotten to take it with him. *Id.* at 774.

The Respondent then introduced a copy of the biennial inventory. RX 38. The exhibit included a cover sheet that noted that the biennial inventory was completed on April 26, 2017, at 8:00 a.m., and was completed by Ms. Mincy and Mr. Sprys. Tr. 617–18, 767–68; RX 38, p. 1. The following page was the actual first page of the printed out biennial inventory. Tr. 619, 767; RX 38, p. 2. The remaining pages are all part of the biennial inventory, and the printout indicates a date of April 26, 2017. Tr. 620–22; RX 38, pp. 2–16. The exhibit contains handwriting that indicates that the biennial inventory was completed on April 26, 2017, at 8:00 a.m. and was signed by Mr. Sprys and Ms. Mincy. Tr. 767–69; RX 38, pp. 1, 2, 8.

Ms. Mincy testified that the biennial inventory had been completed at 8:00 a.m. because it must be completed in the morning before business or at the end of the day at the close of business to avoid discrepancies in the pharmacy's counts. Tr. 620. She further testified that she and Mr. Sprys had signed and dated the biennial inventory to validate that the information was true and correct, and that she had completed it during that date and time. *Id.* at 624–25. She indicated that it took her approximately three hours to complete the biennial inventory, so she would have arrived at the pharmacy at approximately 5:00 a.m. *Id.* at 628. She testified that she personally prepared both reports contained within the biennial inventory, and personally entered all of the information herself on the date listed on the form. *Id.* at 772. As for the date indicated at the top of each page, Ms. Mincy stated that it reflects the date on which the report was run. *Id.* at 772–73; RX 38, pp. 2–7, 9–16.

The Government conducted a voir dire of Ms. Mincy as to RX 38. Tr. 774. She testified that RX 38 was a true and correct copy of what she had given DI1 on June 6, 2017, and that there had not been any alterations made to the document after she gave it to him. *Id.* at 774–75. She claimed that no one had written on the document to include the handwriting at the top of RX 38, p. 2 after she had given it to DI1 or after it had been faxed to him. *Id.* at 775. She testified that the biennial inventory had later been faxed to DI1 by Bill Sprys. *Id.* at 776–77. The Government showed Ms. Mincy another version of a copy of the biennial inventory that did not contain the handwriting written on RX 38. *Id.* at 778–81. The Government's copy was admitted as GX 37. Ms. Mincy indicated that there must be two versions of the inventory, one labeled complete and one that was not labeled. *Id.* at 780.

The Government later conducted cross-examination of Ms. Mincy about the biennial inventory. *Id.* at 817. She admitted that while the biennial inventory did not indicate that it was conducted at the close of business, she asserted that it was completed before the opening of business at 8:00 a.m. *Id.* at 817. When asked on cross-examination, she changed her earlier testimony to say that she completed the biennial inventory from 6:00 a.m. to 8:00 a.m. on April 26, 2017, an hour later than she had previously indicated. *Id.* at 822.

Ms. Mincy was also confronted with statements DI1 testified she had said during the inspection. When asked if she had said during the on-site inspection that she had completed the inventory over the course of several days, she claimed that DI1 was confused. *Id.* at 823–24. When asked if she had said that she would have to shut down the pharmacy to do the biennial inventory, she said that DI1 misunderstood. *Id.* at 825.

Based on both parties' assertions, DI1 left the biennial inventory at the pharmacy after the on-site inspection. At that point, DI1 did not have a copy of the biennial inventory. I noted during the course of the hearing that DI1 had testified Ms. Mincy had provided a document that was represented as a biennial inventory, but that it didn't qualify because there was no indication that the document was prepared on a single occasion, so he left it at the pharmacy because he would not use it as part of his audit. Tr. 155.*XX

At the outset, I note the immediate differences between GX 37 and RX 38 as highlighted by the Government. Both GX 37, p. 7, and RX 38, p. 2, present similarly printed material, but RX 38 contains handwritten material at the top of the page that purports to show that the biennial inventory was completed on ''4/26/17'' at ''8AM'' and is contains signatures purported to be Ms. Mincy

*XX Paragraph relocated for clarity.

and Mr. Sprys. The Government represents that GX 37 is the biennial inventory that was faxed to DI1 from Bill Sprys at Pharmacy 4 Less on the day following the June 6, 2017 on-site inspection. While it cannot be ascertained when exactly the handwritten material was included on RX 38, p.2, I find it inescapable that the handwritten notes were added after the inventory was faxed to the government. This is further supported by the assertion from Ms. Mincy that she did not appear to know where the handwritten notes came from.*YY Tr. 786–88. In sum, the handwriting on RX 38 demonstrates that it is more likely that DI1 was provided a clean copy by the Respondent through the fax on June 7, 2017, and the handwriting on RX 38 was written at a later time.[59] *ZZ I credit DI1's testimony as to the statements made during the June 6, 2017 on-site inspection, as well as the lack of indication on the biennial inventory when the inventory had taken place.

*[I agree with the ALJ's credibility finding regarding the handwriting on GX 37, p. 7 and RX 38, p.2. However, I also note that both the copy of the biennial inventory faxed to the Government, GX 37, p. 2, and the copy maintained by Respondent, RX 38, p. 1, contained what Ms. Mincy described as a ''cover page'' which stated ''Biennial Inventory, completed 4/26/17, 8am'' and was signed by both Ms. Mincy and Mr. Spry. Tr. 617–18. While the cover sheet contained the same information written in GX 37, p. 7 and RX 38, p. 2, there is simply insufficient information in the record for me to determine whether or not this ''cover page'' was attached to the Biennial Inventory at the time of inspection. Accordingly, I cannot say that there is enough evidence to support a violation of 1304.11(a). As my finding differs from the ALJ's in this regard, the remainder of the ALJ's discussion on this topic is omitted. Even without this violation, there is more than enough evidence on the record to indicate that Respondent pharmacy's registration is inconsistent with the public interest.

Therefore, I find that the Government has not established by sufficient evidence that Respondent's biennial inventory failed to comply with the requirements of 21 CFR 1304.11(a) as alleged.]

Ms. Mincy's Access to CSOS

The Government has charged that during DEA's review of Pharmacy 4 Less's CSOS, Ms. Mincy admitted to using Mr. Spry's CSOS credentials to order controlled substances in violation of 21 CFR 1311.30(a), (c). Section 1311.30(a) provides that ''[o]nly the certificate holder may access or use his or her digital certificate and private key.'' Section 1311.30(c) provides that ''[a] certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.''

The Government presented credible testimony from DI1 that he asked Ms. Mincy how Pharmacy 4 Less documents and records their ordering of controlled substances and validation of a prescription's legitimacy. Tr. 43.[60] DI1 testified that he observed Ms. Mincy proceeded to a laptop in the pharmacy to log into the CSOS system. *Id.* at 45. DI1 asked Ms. Mincy if she had her own CSOS credentials (which DI1 asserted is required for anyone accessing the CSOS system and cannot be shared with anyone else). *Id.* at 46. DI1 testified that Ms. Mincy stated she did not have her own credentials and did not have a power of attorney for anyone else's credentials. *Id.* Ms. Mincy stated to DI1 that she was using Mr. Richard Sprys credentials to log onto CSOS. *Id.* The Government put on further evidence that DI1 later contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters, to determine which personnel at Pharmacy 4 Less had access to the CSOS system. *Id.* at 47–48. Mr. Jewell ran a report and the report stated that Ms. Mincy only received her own CSOS credentials in July 2018, after the on-site inspection. *Id.* at 48–49; GX 29.[61]

The Respondent presented testimony from Ms. Mincy that she was asked by DI1 to look at the pharmacy's CSOS system. *Id.* at 612–13. The pharmacy uses the CSOS system sourced through AmerisourceBergen. *Id.* at 612. Ms. Mincy testified that she showed DI1 the steps to order, but could not order because she did not have CSOS credentials at the time of the inspection. *Id.* at 613, 839–40, 867. *[During her testimony, Ms. Mincy went into some detail explaining how the system worked; *AAA she testified that she logged into AmerisourceBergen and demonstrated how controlled substances could be added to an order without the CSOS credentials. *Id.* at 840, 867. She explained that upon completion of the order, Schedule III–V medications are submitted to AmerisourceBergen, but that Schedule II controlled substances are not submitted without taking extra steps to verify the CSOC certificate. *Id.* at 867.] When showing the program to DI1, Ms. Mincy stated she did not put in any credentials *[to complete the process of ordering Schedule II controlled substances], because she did not have any at the time. *Id.* at 615, 867–68. Ms. Mincy stated she then heard DI1 say that she had been ordering with Mr. Spry's credentials, which she followed up by telling him that was not correct. Tr. 615.

It is extremely difficult to reconcile the testimony and evidence presented by the parties regarding this allegation. On one hand, the Government presented testimony of DI1 indicating that he observed Ms. Mincy log onto the CSOS system, and that Ms. Mincy stated during the on-site inspection that she had ordered controlled substances using Mr. Sprys' credentials. On the other hand, the Respondent presented testimony of Ms. Mincy that [she logged in to the AmerisourceBergen system, not CSOS,] that she never [said she was using Mr. Sprys' credentials,] and that she told DI1 that his assertion was not correct. Both versions cannot be correct. Based on the previous analysis of the witnesses' credibility, DI1's version is [generally] more credible, considering Ms. Mincy's memory issues and motivation to color her testimony. *[However, Ms. Mincy testified in much greater detail than DI regarding the system and the steps she took to demonstrate it to DI, and this testimony was not addressed by DI when he later took the stand as a rebuttal witness. The Agency is clear that CSOS is the ''only method for ordering Schedule I and II controlled substances electronically,'' and can be used for other Schedules, but there is no information on the record about at what point during the purchasing process the credentials are necessary. *https://www.deaecom.gov/*

*YY Furthermore, I do not find credible Ms. Mincy's assertion that there were two or three versions of the inventory, one labeled complete and others that were not labeled. *[Content was moved for clarity.]

[59] In their Posthearing Brief, the Government asserts that Ms. Mincy has intentionally backdated documents, including RX 38. Govt Posthearing Brief, at 36. As discussed, I cannot determine exactly who added the additional handwriting included on RX 38 or when it was added, and cannot accept the Government's assertion that it was, in fact, Ms. Mincy who backdated it after it had been delivered to the Government.

*ZZ The preceding sentence and the following sentence were relocated for clarity.

[60] DI1 asserted during his testimony that when a pharmacy orders and receives controlled substances on-site, they are required to notate that they received them with the date and the initials of the person that received them. Tr. 44.

[61] *See supra* n.15.

*AAA Respondent, in its exceptions, made additional factual assertions regarding Mr. Sprys' ability to access CSOS and order controlled substances, which are not only missing from the evidentiary record but are entirely irrelevant to the issue at hand and have no impact on my decision in this case. Resp Exceptions, at ¶ 10.

qanda.html.[*BBB] Further had Ms. Mincy actually purchased controlled substances using the CSOS account during the inspection, I find it confusing that the Government did not include evidence related to such purchase.

Despite the credibility issues present in this case,[*CCC] the Government's evidence lacked basic information regarding the CSOS system and what the DI actually observed (as opposed to what he heard Ms. Mincy say) that led to his conclusion that Ms. Mincy had used Mr. Sprys' credentials to log into the CSOS system. Without that information it is difficult to determine the weight of the evidence, and as the Government has the burden of proof, I simply cannot find substantial evidence to support violations of § 1311.30 (a) & (c).]

Electronically Linked Record of Quantity and Date Received

The Government has charged that Pharmacy 4 Less's receiving records showed that Pharmacy 4 Less failed to create an electronically linked record of a quantity and date received for its controlled substances in violation of 21 CFR 1305.22(g). Section 1305.22(g) provides that ''[w]hen a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.''

After a thorough review of the evidence and testimony presented by the parties, I have found a lack of any evidence presented towards this charge by the Government. While the DI1 extensively testified about the Government's charge of a lack of a date of receipt on the pharmacy's invoices, the Government did not probe into the allegation that Pharmacy 4 Less failed to create electronically linked records under § 1305.22(g). While DI1 indicated that Pharmacy 4 Less did not have PDF copies of the CSOS records, he did testify that the CSOS is online and can be a totally electronic record. Tr. 44–45. However, there was no evidence that Pharmacy 4 Less had failed to create an electronically linked record of any shipments of controlled substances.

However, the Respondent, while brief, presented some evidence of their compliance with § 1305.22(g). The Respondent presented testimony by Ms. Mincy towards two inspections at Pharmacy 4 Less by the Florida Department of Health Investigative Services. Tr. 658–81; RX 14, 15. One inspection report, dated February 28, 2017, before the DEA's on-site inspection, indicated that the investigator from the Florida Department of Health had found that Pharmacy 4 Less was compliant with the requirement that ''DEA 222 forms properly completed or records of receipt of CSOS orders electronically completed, archived and retrievable.'' Tr. 661; RX 15, p. 2. This requirement then directly cites to 21 CFR 1305.22(g). RX 15, p. 2. The second inspection report, dated September 5, 2017, after the DEA's on-site inspection, indicated that the investigator from the Florida Department of Health again found that Pharmacy 4 Less was compliant with the requirement under § 1305.22(g). RX 14, p. 2.

While the Respondent's evidence will ultimately go towards the analysis of Factor Two under the public interest factors, it is also relevant to rebut the Government's charge under § 1305.22(g). While the DIs may have had some indication that Pharmacy 4 Less was not in compliance with the requirements under § 1305.22(g), the record is void of any testimony or evidence to support such a charge. Further, the Respondent has offered evidence, at least from the viewpoint of an inspector with the Florida Department of Health, that Pharmacy 4 Less was in compliance with the requirements under § 1305.22(g) before and after the DEA's on-site inspection. Therefore, I find that the Government has not met their burden of proof as to this allegation.

Date of Receipt on Invoices

The Government has charged that Pharmacy 4 Less possessed 85 invoices without the date of receipt recorded in violation of 21 CFR 1304.22(c). Section 1304.22(c) provides, in part, that ''[e]ach person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.''

I note at the outset that a review of the Government's charge in the OSC and in their Prehearing Statements presents a problem. Upon a careful review of the language of § 1304.22(c), it becomes apparent to me that this section has no requirement that the pharmacy must indicate a date of receipt of controlled substances. Section 1304.22(c) relates to ''Records for dispensers and researchers'' and requires certain records be maintained, both those provided in § 1304.22(c) and those required under § 1304.22(a)(2)(i), (ii), (iv), (vii), and (ix). None of these subsections indicate any requirement to maintain a date of receipt.

I find that the Government's subject allegation does not cite to a regulation which proscribes the conduct alleged. Substituting a different regulation post-hearing would create daunting notice and due process issues. To allow the Government to do so would create an improper burden-shifting beyond those recognized by the APA and the fundamental tenets of notice and due process. *See Farmacia Yani,* 80 FR 29,053, 29,059–60 (2015). One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). Because the Government apparently did not allege in the Order to Show Cause or in its Prehearing Statements the applicable citation to the law on which it bases its allegation, before proceeding to address whether the evidence supports the Government's factual contention, it is necessary determine whether the Government otherwise provided adequate notice of its intent to litigate the issue. *See* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.''). ''The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the

[*BBB] ''What is a CSOS Certificate? A CSOS Certificate is a digital identity issued by the DEA's CSOS Certification Authority (CSOS CA) that allows for electronic ordering for Schedule I and II (as well as III–V) controlled substances. A CSOS Certificate is the digital equivalent of the identification information contained on a DEA Form-222. CSOS Certificates are issued to *individuals* and are required for electronic ordering of Schedule I and II controlled substances.''

[*CCC] The Recommended Decision stated that ''it is more believable than not, from this record, that Ms. Mincy was given access to Mr. Sprys' digital certificate and private key. Despite her contractor status, she ran the pharmacy Monday through Thursday. She used Mr. Sprys' credentials to log onto the CSOS system in the presence of DI1, before she had her own credentials.'' Although I agree with the ALJ's credibility findings generally, I believe that the Government could have easily produced evidence to support this claim, and I decline to find a violation.

complaint and fashioning an explanation that refutes the charge of unlawful behavior.'' *Pergament United Sales,* 920 F.2d at 135 (citation omitted). While the issue of whether an allegation ''has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique,'' *id.* at 136, ''the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement'' that a respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.,* 144 F.3d at 688 (quoting *NLRB* v. *Quality C.A.T.V., Inc.,* 824 F.2d 542, 547 (7th Cir. 1987) (citation omitted)).

From the outset, the Government has consistently cited to § 1304.22(c) as the basis of this charge for Pharmacy 4 Less failing to record the date of receipt on 85 invoices. However, as discussed, § 1304.22(c) does not contain any such requirement. In this proceeding, it is not the responsibility of the Respondent, this Tribunal, or the Administrator to substitute a different regulation than charged to fit the evidence the Government has presented.[62] The Government has been given multiple opportunities to amend its pleadings, but it has not done so.

[Moreover, the record does not support a finding that the issue was litigated by consent.] To further confuse the matter, the Respondent conducted voir dire of DI1 as to GX 26. The Respondent questioned whether the federal regulations require that invoices had to be signed and dated by the person receiving the controlled substances shipment. Tr. 141. DI1 stated that while he could not accurately quote the regulations off the top of his head, he had a general understanding that the regulations required these things. *Id.* at 140–41. The Respondent then argued that if the Government were offering GX 26 to prove a violation of § 1305, the exhibit should not be admitted because § 1305 only requires a signature and date by the receiver for Schedule 2 controlled substances.[63] *Id.* at 142. The Government responded that it offered the entire exhibit into evidence for all controlled substances, but stated that it may have cited an improper section and would limit their ability to prove that charge. *Id.* at 142–43. The Respondent argued that the Government cited to § 1305.22 throughout the Order to Show Cause, the Government's Prehearing Statement, and the Government's Supplemental Prehearing Statement, and that they had been given notice of their citation mistake by the Tribunal during the prehearing conference. *Id.* at 143. The Government said that it may have intended to limit itself to strictly Schedule 1 and 2 controlled substances, but that it could not cite that at that moment. Tr. 144. [Here, although Respondent pharmacy clearly believed that the § 1304.22 citation in the OSC was incorrect, they proceeded with the litigation believing that the Government had intended to cite § 1305.22(g).*DDD 64 21 CFR 1305.22 deals strictly with electronic (as opposed to paper) orders for Schedules I and II controlled substances (as opposed to Scheduled III–V), so it also does not provide a legal basis for the allegation that Respondent violated the law by failing to record a receipt date on its paper invoices. I suspect the Government intended to charge Respondent with a violation of § 1304.21,*EEE but I will not consider it based on lack of notice.]

While the Government has presented a sufficient amount of evidence towards their allegation that Pharmacy 4 Less possessed invoices without the date of receipt (as the Government claims the cited regulation requires), the Respondent has consistently objected to the Government's legal basis for its allegation [and there has been no notice of a proper legal basis.] Therefore, I find that the Government cannot sustain their burden in their allegation under § 1304.22(c) as charged. [Therefore, it is not necessary to review the evidence and testimony in support of this allegation, and I have omitted it accordingly.]

Inaccurate Inventory

The Government has charged that Pharmacy 4 Less maintained an inaccurate inventory *FFF in violation of 21 CFR 1304.22(c). Section 1304.22(c) again provides, in part, that ''[e]ach person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section.[*GGG] In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.''

The Government included this new charge, after the issuance of the Order to Show Cause, in its Prehearing Statement. The Government's Supplemental Prehearing Statement states that ''DI1 will testify that he conducted an audit of Pharmacy 4 Less's inventory, and found that it was inaccurate, a violation of 21 CFR 1304.22(c). The way that the audit was performed depended on the controlled substance involved. For Schedule II Controlled Substances, Pharmacy 4 Less maintained a handwritten perpetual inventory which was used to audit the controlled substances with a start date

[62] ''[I]t is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding.'' *Top RX Pharmacy,* 78 FR 26,069, 26070 n.7 (2013) (quoting *Gregg & Son Distribs.,* 74 FR 17,517–18 n.1 (2009)); *James William Eisenberg, M.D.,* 77 FR 45,663, 45,674 n.47 (2012).

[63] Upon review of the OSC and the Government's Prehearing Statements, I believe that the Respondent misstated § 1305 as the basis for this charge and questioned DI1 on the basis of a regulation not charged. The Government charged a failure to indicate a date of receipt under § 1304.22.

*DDD [This text was relocated for clarity.] When I later asked about § 1305.22, DI1 was provided a copy of the Code of Federal Regulations to determine if it was the section that requires a person receiving a shipment of controlled substances must initial and date. Tr. 163. While looking at the regulations, DI1 indicated that it was not § 1305.22. Tr. 163–64. He stated that § 1305.22 refers to the procedure for filling electronic orders, which refers to CSOS. Tr. 164–65. After looking through the regulations, he indicated that he didn't know the actual regulation, but that § 1305.22 was not what he was talking about. Tr. 165.

[64] The following morning on the second day of the hearing, before the start of testimony, I inquired with the Government as to whether they still intended to include all scheduled controlled substances or limit the evidence to only those invoices including Schedules 1 and 2 controlled substances. The Government indicated that they wanted to proceed with all scheduled controlled substances. The Respondent objected and again raised his argument that § 1305 only provides requirements for Schedules 1 and 2 controlled substances. However, upon a review of the hearing transcripts, I have found that these conversations were not recorded and transcribed. This recitation of the discussion is from my memory, but should be provided in the context of the analysis as to any ultimate due process concerns.

*EEE At one point, DI identified and read 21 CFR 1304.21(d) into the record, but agreed that section did not require the recording of the date of receipt (and he did not identify 1304.21(a) which does require pharmacies to keep records regarding the date of receipt of controlled substances). Tr. 164. Ultimately DI's testimony was that he did not know which regulation required pharmacies to document the date controlled substances were received. Tr. 165.

*FFF The Government's reference to an ''inaccurate inventory'' in this section does not seem to refer to any specific inventory document such as the initial inventory, biennial inventory, or even the perpetual inventory. Rather, the Government seems to be using the phrase generally to state that the Pharmacy's records and the quantity of controlled substances on hand at the pharmacy did not align.

*GGG These required records include, amongst other things, the name, quantity, and strength of controlled substances and the number of units that are acquired to inventory or distributed or disposed. *Id.*

of January 1, 2017. For other controlled substances, the start of business was used. Among other inaccuracies, DI1's audit found that Pharmacy 4 Less had a shortfall of 731 tablets of oxycodone 30 mg, a shortfall of 526 tablets of carisoprodol 350 mg, and a surplus of 1,488 tablets of methadone HCL 10 mg. DI1 will authenticate his computation chart. DI1 will also authenticate the handwritten oxycodone and methadone perpetual inventories that were used to conduct the oxycodone and methadone audits.'' Government's Supplemental Prehearing Statement, at 4–5.

During the Prehearing Conference, I inquired with the Government as to the addition of this new allegation and whether they intended this to act as a new charge. The Government said that it did intend it as a new charge. The Respondent objected and argued that it should not be required to answer to charges not listed in the Order to Show Cause. I informed the Respondent as to the Agency's liberal notice requirements and provided them with the opportunity to address any new allegations in a Supplemental Prehearing Statement provided the Government amended or added to its new allegation. I find the Government provided sufficient notice to satisfy due process as to this supplemental charge.

In the Respondent's Amended Supplemental Prehearing Statement, the Respondent not only offered a proposed stipulation that their inventory was correct, but also indicated that Ms. Mincy's proposed testimony would include testimony that Pharmacy 4 Less's inventory was accurate. As it will be discussed, Respondent both cross-examined DI1 on his audit of Pharmacy 4 Less's inventory, as well as provided testimony from Ms. Mincy about the pharmacy's inventory.

The Government presented evidence from DI1 about the audit he conducted of Pharmacy 4 Less's perpetual inventories in order to find if their inventories were accurate. As previously noted, DI1 did not use either an initial inventory or biennial inventory as the starting point for the audit.[*HHH] DI1 created a computation chart of the controlled substances in order to conduct an audit of the pharmacy's inventories. GX 4.

DI1 indicated January 1, 2017, as the starting point for the audit. Tr. 55. This date was selected because it was the date in which the pharmacy had used in its handwritten Schedule 2 controlled substance inventories. Tr. 56; GX 31, 32. These include the perpetual inventory form for Methadone 10 mg tablets (GX 31) and Oxycodone 30 mg tablets (GX 32). *Id.* at 57. He testified that he used the pharmacy's inventories and made sure that the inventories received or filled prior to January 1, 2017 were correct to use as a starting point. *Id.* at 61–62. Then he would take records from the pharmacy for the period of the audit and correlate those with invoices and any other records showing when the pharmacy had received additional controlled substances. *Id.* at 62. Once those numbers were verified, DI1 then looked at what the pharmacy had on hand according to their records, took all the received controlled substances within that timeframe, and then added those numbers together to find a total accountable number. *Id.* at 63.

DI1 then determined how many controlled substances Pharmacy 4 Less actually had on site during the June 6, 2017 on-site inspection. *Id.* This was done by hand counting the tablets located on hand in the pharmacy at the time of the inspection. *Id.* He also determined the number of sales for each controlled substance during the audit period by looking at documentation provided to him by Ms. Mincy. *Id.* at 63–64. DI1 then added up the total number of the inventory that had been counted in the store on June 6 and the sales that had been accounted for by the records to determine the total amount of tablets accounted for. *Id.* at 65. DI1 then compared the ''total accountable for'' number and the ''total accounted for'' number to determine if there was a shortfall or surplus, indicated as the ''total difference.'' *Id.* The same process was completed for Schedules 3 through 5 controlled substances, but the starting number at the beginning of business was zero because the pharmacy had no controlled substances on hand when they started as a pharmacy. *Id.* at 66.

As previously noted, the Respondent conducted a cross-examination as to the computation chart revealing some formatting errors. This Tribunal allowed the Government to substitute a more legible copy of it. Tr. 919–26. A check of the mathematics done within GX 4 demonstrate that the mathematics have been done correctly and demonstrate discrepancies between the pharmacy's records as used by DI1 and the amount that DI1 accounted for during his count at the pharmacy during his on-site inspection.

The Respondent presented testimony from Ms. Mincy about the pharmacy's inventories. Ms. Mincy confirmed that DI1 had asked to see the pharmacy's biennial and perpetual inventories,[*III] along with DI1 and DI2 conducting a pill count during the June 6, 2017 on-site inspection.[*JJJ]

Based on the testimony and evidence presented by the parties, I find the audit conducted by DI1 to be consistent with his portrayal of events during the June 6, 2017 on-site inspection and that it credibly shows discrepancies between the records maintained by the pharmacy and the actual count of tablets as determined by DI1. For example, DI1's calculations determined that Pharmacy 4 Less has 1,488 more tablets of Methadone HCL 10 mg on hand than was provided for in their records. This large of a disparity between the amount counted and the records show that it cannot be the result of miscounting the tablets on hand at the pharmacy during the on-site inspection.

While Ms. Mincy may have testified to her role at the pharmacy in maintaining the supplies and inventories, I find, in light of my previous reliability analysis of Ms. Mincy, that her explanations regarding inventory procedure and practice do not overcome the Government's evidence showing the pharmacy inventories were inaccurate. The failure of the pharmacy to maintain an initial inventory and failure to maintain an accurate biennial inventory, along with the great potential for error that a handwritten perpetual inventory provides, also lend weight to the Government's allegation that Pharmacy 4 Less maintained inaccurate inventories.

*[The Government has demonstrated that Respondent's on-hand inventory had overages and shortages when compared to Respondent's records at the time of the inspection. The Agency has found that such overages and shortages create a risk for diversion. It is clear that

[*HHH] Respondent argued during the hearing that there is no requirement to maintain a perpetual inventory and that the perpetual inventory was thus an improper document upon which to base the audit. Tr. 18, 58, 630–31, 925. I agree that Respondent was not required to create a perpetual inventory. However, what matters here is that Respondent could not account for a significant number of controlled substances by adequate documentation. *See Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy,* 76 FR 51,415, 51,416 (2011). These significant variances were present both where the perpetual inventory was used in the audit and where it was not. Notably, Respondent Pharmacy made no attempt to rebut the government's *prima facie* case demonstrating inaccurate recordkeeping aside from bald assertions that its on-hand inventory was accurate.

[*III] Ms. Mincy testified that the perpetual inventory was a handwritten document. Tr. 631. As for its purpose, she stated ''[e]very time we fill a prescription we like to note it so that we can keep up with our inventory on hand, to make sure that we are keeping enough drugs in stock like for the next day, you know, we [do not] want to run out.'' *Id.*

[*JJJ] Omitted information regarding the biennial inventory for brevity and inserted information regarding the perpetual inventory.

there were unexplained discrepancies between Respondent's records and the amount of inventory on hand. Such discrepancies provide substantial evidence that Respondent has violated 21 CFR 1304.22(c). See *e.g., Ester Mark, M.D.,* 56 FR 16,760, 16,774 (2021); *Wayne Pharmacy,* 85 FR 63,579, 63,582 (2020).]

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

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a). At the outset, I find that the Government has demonstrated and met its burden of proof in support of revocation through its case that the Respondent has failed to resolve red flags of diversion and document the resolution of red flags of diversion. Further, the Government has additionally demonstrated, that Pharmacy 4 Less has violated certain recordkeeping requirements of the Code of Federal Regulations. Inasmuch as the Government has established by a preponderance of the evidence that the Respondent *[acted outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida, and] violated federal laws relating to controlled substances on numerous occasions,*KKK it has met its *prima facie* burden of proving that the requirements for a sanction pursuant to 21 U.S.C. 824(a) are satisfied.

Public Interest Determination: The Standard

Pursuant to 21 U.S.C. 823(f) (2006 & Supp. III 2010), the Administrator[65] may revoke a DEA Certificate of Registration if persuaded that the maintaining such registration would be 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 ''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 2 and 4: Experience in Dispensing, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of the Respondent's COR based primarily on conduct most aptly considered under Public Interest Factors 2 and 4.[66] *LLL[67] [68] [69]

*[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.*MMM *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).]

Here, Pharmacy 4 Less provided evidence of its compliance with state and federal law through the introduction of two Florida Department of Health Inspection reports.[70] RX 14, 15. One of the reports, dated February 28, 2017, occurred before the June 6, 2017 on-site inspection by the DEA. RX 15. The report appears to show that Pharmacy 4 Less was in compliance with all applicable portions of the state inspector's report, which not only cites to Florida administrative regulations, but also to federal regulations. While the thoroughness and thus full significance of the Florida state inspections cannot be gleaned from the inspection reports, and the Florida inspector cannot be held to determine compliance with federal regulations in the same manner as DEA DIs, it is sufficient evidence to show that the Florida inspector not only determined at least some sufficient maintenance of required standards under federal regulations, but particularly with Florida administrative regulations under Florida state law. This gives indication that Pharmacy 4 Less was in compliance with, at a minimum,

*KKK Omitted text for clarity.

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

[66] 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 1). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor 3).

*LLL For brevity and keeping with recent cases, I have removed the legal standard used originally by the ALJ throughout this section to analyze Factors 2 and 4 and have replaced it with this text.

[67] *[Omitted text where footnote was included.]

[68] *[Omitted text where footnote was included.]

[69] *[Omitted text where footnote was included.]

*MMM As it is not relevant, I have removed the ALJ's analysis regarding the history of Pharmacy 4 Less and its impact on the local community which, according to the ALJ, was based on very little evidence in the record.

[70] *[Omitted text where footnote was included.]

applicable Florida state law (based on the requirements by the State of Florida Department of Health Investigative Services) before the DEA's on-site inspection.

Further, Pharmacy 4 Less also introduced a second state report dated September 5, 2017, which occurred after the DEA's on-site inspection. RX 14. The report has a few discrepancies when compared to RX 15. The second report does not appear to be completely filled out, particularly at the end of the second page. Further, it does not have a signature page as that provided for in RX 15. However, when comparing both documents, it is clear that RX 14 was completed by a computer or some sort of electronic device, while RX 15 was completed by hand. This second report also demonstrates, in the same manner as RX 15, that the Florida inspector not only found Pharmacy 4 Less to be compliant with some federal regulations, but particularly with sections of Florida administrative regulations.

Both of these reports weigh in favor of Pharmacy 4 Less as evidence of their compliance with federal and state law, as determined by inspectors from the Florida Department of Health Investigative Services. [However, the reports are not dispositive of the issues in this case, in particular the resolution of red flags, and the specific allegations in this case must still be addressed.]

Standard of Care as to Charged Violations *NNN

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

An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28667, 28670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341 (citing *Med. Shoppe—Jonesborough,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50397, 50407–08 (2007); *EZRX, L.L.C.,* 69 FR 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61613, 61617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64921, 64924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR 36910, 36911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by filling prescriptions ''in the face of [numerous] red flags for which there [was] no evidence that they were ever resolved.'' Govt Prehearing, at 8, and 9–14. Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10898, *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 49816, 49836–39

*NNN The added text in this section clarifies the analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

(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 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62316, 62317–22 (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 66149, 66163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Here, the Government established the presence of red flags on the prescriptions that Respondent Pharmacy filled.]

Further, under Florida law, [which is supportive of the applicable standard of care in Florida,] a pharmacist is required to conduct a prospective drug use review before filling or refilling any prescription for controlled substances. Fla. Admin. Code r. 64B16–27.810. Florida also requires that pharmacists question prescriptions that may not be valid and only fill the prescriptions if the pharmacist is able to validate the prescription. Fla. Admin. Code r. 64B16–27.831.[*OOO]

This leads me to the conclusion that Pharmacy 4 Less [*PPP] has operated outside the usual course of professional practice (in violation of 21 CFR 1306.06) and in violation of its corresponding responsibility (in violation of 21 CFR 1306.04(a)). Further, as the Florida laws and regulations provide for the standards of practice for pharmacists and pharmacies, including requiring certain standards of review and documentation, I find that the charged regulations bear a substantial relationship to the CSA's purposes of drug abuse and diversion. As such, I find that Pharmacy 4 Less has failed to meet the standard of care as provided for under Florida law and regulations [and as I have found above].

In light of the record as to this factor, I find that the favorable evidence introduced through the Respondent is overwhelmed by the evidence introduced through the Government that the Respondent has failed to comply with federal *[omitted] law [and has violated its corresponding responsibility]. Therefore, I find [factors 2 and 4] significantly favor revoking the Respondent's registration.

Due Process Right of the Respondent

*[Omitted.] The Government asserts in its Posthearing Brief that Pharmacy 4 Less has been ''disingenuous'' during the course of this matter and should be penalized for its decision to file a motion to suppress, and to withhold subpoenaed records from the Government when it asserted HIPAA privacy issues and was preparing to contest the DEA's administrative subpoena in United States District Court. Govt Posthearing, at 44. *[Omitted. The ALJ found] that the Respondent's decision to contest the DEA's administrative subpoena should not be held against the Respondent as either an adverse inference or as an independent violation. [I decline to make any findings regarding the Government's argument and have omitted the analysis accordingly.]

Acceptance of Responsibility

The Government's *prima facie* burden having been met, the Respondent must present sufficient mitigating evidence to assure the Administrator that he 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).[*QQQ] This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay,* 664 F.3d at 822. As, past performance is the best predictor of future performance, DEA has repeatedly held that where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for his actions and demonstrate that he 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,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination). So too, in making the public interest determination, ''this Agency places great weight on an [applicant'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.

While an applicant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10,083, 10,094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,504 (2007). 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. *Ruben,* 78 FR at 38,364.] [*RRR]

The Respondent argued during the hearing that it had accepted responsibility by virtue of its submission of a corrective action plan (which the DEA rejected), modification of its behavior, a reduction in the number of patients they see and for whom it fills prescriptions, as well as the implementation of a number of other remedial changes. Tr. 30. However, no one from Pharmacy for Less has admitted any wrongdoing regarding the vast majority of infractions I found.

I find that Ms. Mincy, the only fact witness for the Respondent, did not accept responsibility for either her actions or on behalf of Pharmacy 4 Less. Additionally, I find that Ms. Mincy was sometimes a less than reliable witness. Although correcting violative 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). As such, I find that Pharmacy 4 Less has failed to unequivocally accept any responsibility in this matter.[71]

[*OOO] Omitted, for brevity, text regarding the legal standard requiring a nexus between the state law that has been violated and the CSA's purpose of preventing drug abuse and diversion. I find that, here, Florida law was used to support determination of the standard of care, but that the Government did not allege independent violations of state law.

[*PPP] Omitted finding of a violation of Florida law.

[*QQQ] This sentence was relocated and replaced existing text for clarity and brevity.

[*RRR] Inserted text for completeness.

[71] During this proceeding, this Tribunal conditionally admitted RX 18–37 as potentially

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). Here, Pharmacy 4 Less has failed to establish that it can be entrusted with maintaining its registration.[*SSS]

[The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondents submitted to determine whether or not they have presented ''sufficient mitigating evidence to assure the Administrator that [they] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Regarding all of these matters, there is nothing in the record establishing that Respondent Pharmacy has accepted responsibility for its actions.] The Respondent's only fact witness, Ms. Mincy, conveyed that she was resentful at the Agency's intervention at the pharmacy. She seemed to maintain a confrontational attitude with DI1, suggesting he was harassing the Respondent and that he was lying during testimony. [The closest Respondent came to accepting responsibility was in its Exceptions, in which Respondent ''admit[ted] that [it was] filling too many c2 [Schedule II] prescriptions in the past.'' Resp Exceptions, at ¶ 5. Even if this admission were part of the evidentiary record, the entirety of the record lacks the unequivocal acceptance of responsibility necessary to establish Respondent' trustworthiness with a registration.

The egregiousness of Respondent Pharmacy's conduct and the interests of specific and general deterrence support a sanction of revocation. RD, at 99. Respondent Pharmacy filled many prescriptions over multiple years for these patients without resolving numerous red flags. There is nothing in the record that lends support to the proposition that Respondent Pharmacy's future behavior will deviate in any positive respect from its past behavior. Due to the fact that Respondent Pharmacy has accepted no responsibility nor offered any remedial measures,[*TTT] it has given me no reassurance that I can entrust it with a registration and no evidence that it will not repeat its egregious behavior.

Regarding general deterrence, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *David A. Ruben,* 78 FR at 38,385. Based on the number and egregiousness of the established violations in this case, a sanction less than revocation would send a message to the regulated community that compliance with the law is not a condition precedent to maintaining registration.

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

As such, I find from the course of these proceedings that Pharmacy 4 Less has lost a significant amount of trust and has failed to prove to the Agency that it can be entrusted to maintain its COR in lawful fashion.

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. Further, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it to maintain its COR.

Therefore, I recommend the Respondent's DEA COR FP5459082 should be *revoked* and any pending applications for renewal or modification of such registration be *denied*.

Signed: May 22, 2019.

Mark M. Dowd,

U.S. Administrative Law Judge.

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related to remedial measures taken by the Respondent. *See* Tr. 702; 1047. As I find that the Respondent has failed to accept any responsibility, I find that RX 18–37 should not be considered by the Administrator towards remedial measures taken by the Respondent. *See Ajay S. Ahuja,* 84 FR 5479, 5498 n.33 (2019) (''[A] registrant does not accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR 62,316, 62,346 (2012). Further, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016)'').

[*SSS] For brevity and keeping with recent cases, I have modified the legal standard used originally by the ALJ regarding loss of trust and have replaced it with this text.

[*TTT] I have already addressed that Respondent Pharmacy presented factual assertions related to remedial measures for the first time in Respondent's Exceptions, but most of those facts are not supported by the record and were not under oath or subject to cross examination.