

802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

Moreover, because "the controlling question" in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration "is currently authorized to handle controlled substances in the state," *Hooper*, 76 FR at 71,371 (quoting *Anne Lazar Thorn*, 62 FR 12,847, 12,848 (1997)), the Agency has long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy*, 72 FR 18,273, 18,274 (2007); *Wingfield Drugs*, 52 FR 27,070, 27,071 (1987). Thus, it is of no consequence that the action is being appealed. What is consequential is my finding that Respondent is no longer currently authorized to dispense controlled substances in Texas, the state in which he is registered.

Under the Texas Controlled Substances Act, a practitioner in Texas "may not prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision except for a valid medical purpose and in the course of medical practice." Tex. Health and Safety Code Ann. § 481.071 (West 2019). The Texas Controlled Substances Act defines "practitioner" in relevant part, as "a physician . . . licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state." *Id.* at § 481.002 (39)(A). Further, under the Texas Medical Practice Act, a person must hold a license to practice medicine in Texas. Tex. Occupations Code Ann. § 155.001 (West 2019) ("A

person may not practice medicine in this state unless the person holds a license issued under [the Medical Practice Act]."); *see also id.* at § 151.002 ("Physician" means a person licensed to practice medicine in this state."). Additionally, "[a] person commits an offense if the person practices medicine in [Texas] in violation of" the Act. *Id.* at § 165.152(a).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to practice medicine in Texas. I, therefore, find that Respondent is currently without authority to dispense controlled substance in Texas, the state in which he is registered with DEA, and I will order that Respondent's DEA registration be revoked.

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. AL1308370 issued to Lewis Leavitt III, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Lewis Leavitt III, M.D. to renew or modify this registration, as well as any other application of Lewis Leavitt III, M.D. for additional registration in Texas. This Order is effective December 21, 2020.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 17–09 and 17–10]

Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order

I. Procedural History

On October 5, 2016, a former Assistant Administrator for Diversion Control of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Suntree Pharmacy (hereinafter, Respondent Pharmacy) and Suntree Medical Equipment LLC (hereinafter, Respondent LLC) (hereinafter collectively, Respondents), of Melbourne, Florida. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC proposed the revocation of and denial of any pending application to modify or renew Respondents'

Certificates of Registration Nos. BS7384174 and FS2194289 "pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that [Respondents'] continued registrations are inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.*

Specifically, the OSC alleged that "over the course of the seventeen month period from October 2013 through March 2015, [Respondents'] pharmacists filled over 200 controlled substances prescriptions outside the usual course of pharmacy practice in violation of 21 CFR 1306.06, and in contravention of their 'corresponding responsibility' under 21 CFR 1306.04(a)." OSC, at 2. The OSC further alleged that Respondent Pharmacy's failure to exercise its corresponding responsibility was evidenced by its "repeatedly fill[ing] controlled substance prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags, and under circumstances indicating that the pharmacists were willfully blind or deliberately ignorant of the prescriptions' illegitimacy." *Id.* (citing *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 FR 28,667, 28,670 (2015)). The OSC listed seven red flags of diversion that Respondent Pharmacy allegedly did not resolve prior to filling prescriptions and listed twenty-two¹ patients whose prescriptions indicated red flags. *Id.* at 4, 5–9. Furthermore, the OSC alleged that Respondent Pharmacy was dispensing controlled substances to a physician who wrote prescriptions to himself in violation of Florida law and violated federal law in dispensing controlled substances to an office. *Id.* at 4 (citing Fla. Stat. § 458.331(1)(r) and 21 CFR 1306.04(b)).

The OSC alleged additional violations of Florida state law including: Title XLVI, Fla. Stat., Ch. 893.04(2)(a) (requiring a pharmacist filling a prescription to determine "in the exercise of her or his professional judgment, that the order is valid"); Fla. Bd. of Pharm. Rule 64B16–21.810(1) (requiring a pharmacist to review the patient record before filling a new or refilling a prescription for therapeutic appropriateness); Fla. Administrative Rule 64B16–27.800 (requiring the maintenance of retrievable records including "[p]harmacist comments relevant to the individual's drug therapy" and "any related information

¹ The OSC listed allegations related to three patients, R.A., A.B., and E.A., which the Government withdrew during the hearing "to save time." Tr. 689.

indicated by a licensed health care practitioner.”); *Id.* at 3.

The OSC notified Respondents of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 10–11 (citing 21 CFR 1301.43). The OSC also notified Respondents of the opportunity to submit a corrective action plan. *Id.* at 11 (citing 21 U.S.C. 824(c)(2)(C)).

On November 8, 2016, Respondents filed an appearance and a Motion for Extension of Time to File a Request for a Hearing, which the Administrative Law Judge (hereinafter, ALJ) granted in part on November 29, 2016. ALJX 2 (Extension Request), ALJX 5 (Order Granting in Part Extension).

Respondents filed a Request for Hearing on November 29, 2016. ALJX 6 (Request for Hearing). The matter was placed on the docket of the Office of Administrative Law Judges and assigned to ALJ Charles W. Dorman (hereinafter, the ALJ). On November 29, 2016, the ALJ established a schedule for the filing of prehearing statements. ALJX 7 (Order for Prehearing Statements). The Government filed its Prehearing Statement on December 20, 2016, and Respondent filed its Prehearing Statement on January 26, 2017.² ALJX 8 (hereinafter, Govt Prehearing) and ALJX 12 (hereinafter, Resp Prehearing). On January 31, 2017, the ALJ issued his Prehearing Ruling that, among other things, ordered that the two matters of Respondent LLC and Respondent Pharmacy would be heard in a consolidated hearing, to which both parties consented, and set out six stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements, which were filed by both the Respondent and the Government on March 8 and 20, 2017, respectively. ALJX 14 (Prehearing Ruling), at 1–5; ALJX 17 (hereinafter, Resp Supp Prehearing); ALJX 16 (hereinafter, Govt Supp Prehearing). During the prehearing proceedings, the Government filed a Motion *In Limine*, requesting that certain portions of the Respondents’ testimony and evidence be excluded at the hearing. See ALJX 21 (hereinafter, Govt Mot *In Limine*). In response to the Government’s Motion and Respondents’ response, the ALJ ruled that the proposed testimony of customer J.S.3 was irrelevant, because the issue is

² Respondent filed for an extension, which the ALJ granted in part over the Government’s objections. ALJX 9–11.

“legal, rather than factual, in nature.”³ ALJX 27, at 3 (Order Granting in part Govt Mot *In Limine*). The ALJ denied the Government’s request to exclude the testimony of several practitioners, the legitimacy of whose prescriptions was at issue in the case, but Respondents ultimately did not present testimony from these individuals. I have reviewed and agree with the procedural rulings of the ALJ with the exception of some of the bases for the findings in the Order Granting in part Govt Mot *In Limine* as explained *infra* Section III(A)(1)(c) and (d). The parties agreed to stipulations about the distances between patients and doctors and Respondent Pharmacy, the schedules and brand names of controlled substances, all of which are incorporated herein, RD, at 16–21.

The hearing in this matter spanned three days.⁴ The Government filed its Proposed Findings of Fact, Conclusions of Law and Argument on June 19, 2017. ALJX 35 (hereinafter, Govt Posthearing). Respondent filed its Closing Argument, Proposed Findings of Fact, and Conclusions of Law on June 19, 2017. ALJX 36 (hereinafter, Resp Posthearing). The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereinafter, RD) is dated August 15, 2017. Both the Government and the Respondents filed exceptions to the RD on September 5, 2017 (hereinafter, Govt Exceptions) and September 1, 2017 (hereinafter, Resp Exceptions) (respectively). ALJ Transmittal Letter, at 1. On September 18, 2017, the ALJ transmitted his RD, along with the certified record, to me. *Id.*

Having considered this matter in the entirety, I find that the record as a whole established by substantial evidence that Respondent Pharmacy committed acts that render its continued registration inconsistent with the public interest. Respondent Pharmacy filled hundreds of prescriptions without fulfilling its corresponding responsibility and acting outside of the usual course of professional practice in Florida, in violation of federal and state law. I conclude that revocation of Respondents’ registrations and denial of any pending application to renew or modify Respondents’ registrations are appropriate sanctions.

I issue this Decision and Order based on the entire record before me. 21 CFR

³ The ALJ also excluded the testimony of a pharmacy employee who was proposed by Respondent to testify about an audit report that had not been offered as evidence and another individual who had provided a report that was not relevant to the proceedings. ALJX 27, at 4.

⁴ Hearings were held in Daytona Beach, FL from April 24–26, 2017.

1301.43(e). I make the following findings of fact.

II. Findings of Fact

A. Respondents’ DEA Registrations

Respondents are registered with the DEA as retail pharmacies in schedules II through V under DEA Certificate of Registration Nos. FS2194289 and BS7384174 at the registered addresses of 7640 North Wickham Road, Suites 116 and 117, Melbourne, FL 32940. Government Exhibit (hereinafter, GX) 1.

B. The Government’s Case

The Government’s documentary evidence consists primarily of prescriptions and profile information for twenty-five patients. The Government called four witnesses: an expert, Dr. Tracey Gordon (hereinafter, Dr. Gordon), a DEA Diversion Investigator (hereinafter, the DI), an employee at Respondent LLC (hereinafter, M.P.), and Dr. Diahn Clark, Respondents’ Owner and Pharmacist in Charge (PIC) (hereinafter, Respondents’ Owner and PIC), whose testimony is summarized under the Respondents’ Case section.

1. Dr. Gordon

Dr. Gordon has a bachelor’s degree and a doctorate in pharmacy and is currently employed as a clinical hospice pharmacist. RD, at 7; Transcript (hereinafter, Tr.) at 22; GX 26 (Dr. Gordon’s resume). She holds a Florida pharmacy license and Florida consultant license and she also has twelve years of experience as a retail pharmacist, but she has not practiced as a retail pharmacist in a few years. Tr. 24. As a consultant pharmacist, Dr. Gordon inspects facilities like nursing homes and hospices to make sure that they are following Florida laws. *Id.* at 30. She is familiar with federal and Florida laws regarding dispensing controlled substances and was accepted as “an expert who is familiar with the practice of pharmacy in the State of Florida.” RD, at 7; Tr. 26, 31–32. The matters to which Dr. Gordon testified included a pharmacist’s corresponding responsibility in the State of Florida including the resolution of prescriptions presenting red flags, what constitutes a red flag, and her review and analysis of the prescriptions presented by the Government. Tr. 21–311. She reviewed a series of prescriptions, the Florida Prescription Drug Monitoring Program (hereinafter, E–FORCSE), documents, letters of medical necessity, medical records, computer printouts given to her by DEA from both the Agency and the Respondent “to determine if [Respondents were] exercising their

corresponding responsibility by practicing within the normal scope of pharmacy practice.” Tr. at 46–47. The ALJ found, and I agree, that Dr. Gordon’s testimony was “sufficiently objective, detailed, plausible, and internally consistent to be considered credible in this recommended decision.”⁵ RD, at 7.

2. The DI

The Government also presented the testimony of a DI who participated in the administrative investigation of the Respondents. Tr. 312–92. He testified to his training as a DEA DI and his experience in investigating over 100 pharmacies. He testified that Respondent Pharmacy was identified as “an extremely high purchaser of oxycodone, hydromorphone and methadone.” *Id.* at 316–17. He further testified as to the events that transpired pursuant to the two administrative inspections of Respondent Pharmacy. *Id.* at 318–19. The DI testified that DEA investigators traveled to Respondent Pharmacy to conduct an administrative inspection on September 13, 2013, during which time M.P. signed a DEA Form 82, Notice of Inspection, in which M.P. consented to the inspection of the premises. Tr. 317; GX 32 (DEA Form 82). The DI testified that, based on the report issued by the DEA inspectors at the time, Respondents’ Owner and PIC arrived at the pharmacy approximately ninety minutes afterwards. Tr. 318. During that inspection, the DI testified that the DEA inspectors expressed their intent to remove prescriptions from the pharmacy to make photocopies, but Respondents’ Owner and PIC told them that she would provide them with copies later, which M.P. delivered to DEA on September 23, 2013. Tr. 318, 323; GX 33 (DEA Form 12 signed by M.P. confirming delivery). The DI also testified that he served Respondents’ attorney D.M. with a subpoena in February of 2015 to obtain approximately a year and a half of prescriptions, but D.M. “questioned the validity of our ability to even issue a subpoena for records to him and stated, as far as he knew, there was no penalty for noncompliance, so he had privacy concerns, and he ended up not giving us the records.” Tr. 324–27. Thereafter, in April of 2015, DEA obtained and executed an Administrative Inspection Warrant, during which DEA investigators copied portions of

Respondent Pharmacy’s database that it used when filling prescriptions and provided Respondent Pharmacy with an exact copy. *Id.* at 323, 326–32; RD, at 8. The DEA investigators also removed, copied and returned paper medical records for patients. Tr. at 332–33. The DI additionally testified to his research into the ownership of Respondents and his observations of the Respondents’ location and business interactions. *Id.* at 323–60. The ALJ found, and I agree, that the DI’s testimony was “sufficiently objective, detailed, plausible, and internally consistent. Therefore, I merit it as credible” RD, at 8.

C. Respondents’ Case

1. Respondents’ Owner and PIC

Respondents’ Owner and PIC testified on behalf of Respondents. Tr. 529–767; 854–58. She testified that she held a degree in pharmacy and practiced until she went to law school, after which she practiced mostly in intellectual property law until she assumed sole ownership of the Respondents in or around 2009 or 2010. Tr. 530. She testified to her duties at the pharmacy, including supervising several part-time pharmacists who fill in while she is “doing other duties as the owner.” *Id.* at 533. She testified generally as to the policies and procedures of Respondent Pharmacy when she took over.

At that time, the only statute we identified initially was legitimate medical necessity. So my interpretation of that was to derive that from the physicians. So we created a policy where the patient would have to have a Brevard County license, a general policy. Of course, exceptions allowed, but the general policy was a Brevard County patient. If they saw a physician in an adjacent county, they would be required to obtain for me, directed to me individually at the pharmacy, not a group of medical records but a letter to me describing the legitimate medical necessity or the diagnosis that I could then glean the medical necessity from.

Id. at 536.

Respondents’ Owner and PIC additionally testified that Respondent Pharmacy had “broad policies that [Respondent Pharmacy’s pharmacists] better have a good reason for not following or be subject to counseling. But outside of those broad policies that are stated there or that were developed over time, they had their independent judgment” *Id.* at 676–77.

Respondents’ Owner and PIC testified that Respondent Pharmacy has a “policy and procedure handbook that employees do receive”; however, Respondents did not produce the

handbook in their defense.⁶ *Id.* at 710–11. She also stated that the policy is “updated regularly, but it’s generally just a day-to-day hands-on training. I’m there all the time.” Tr. 709. Respondents particularly focused on the employment of one of their employee B.S., whom Respondents’ Owner and PIC had hired as a part-time pharmacist in spite of knowing that “he had been suspended by the Board of Pharmacy for a period of time” and he had a prior criminal conviction, and whom she later fired. *Id.* at 553; RX G (employment file for B.S.).

Respondents’ Owner and PIC also testified as to her involvement with the resolution of red flags for her patients. As to the red flag regarding the distance her customers traveled, she testified that her wholesaler would allocate a certain amount of controlled substances to pharmacies and that “is why people drive farther than they normally would.” Tr. 766. She testified that she would look at the letters of medical necessity to help resolve the red flags regarding the distance traveled to obtain prescriptions, Tr. 701, “that would be one thing we would look at, in addition to a conversation with the patient.” Tr. 706.

The ALJ found, and I agree, Respondents’ Owner and PIC’s “testimony to be generally objective, detailed, and with some exceptions it was plausible, and internally consistent. Certain aspects of [Respondents’ Owner and PIC’s] testimony, however, detracted from her overall credibility. Those aspects included unnecessary contentiousness, exaggeration, and a lack of familiarity with the Pharmacy’s records.” RD, at 13. Specifically, the ALJ noted that she exaggerated her relationships with her customers, stating that she always had conversations with D.B. even though she had only filled prescriptions for him three times and similar exaggerations related to M.B., K.B.2, K.B.3 and A.G.

⁶ This Agency has applied, and I apply here, the “adverse inference rule.” As the D.C. Circuit explained, “Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.” *Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW) v. Nat’l Labor Relations Bd.*, 459 F.2d 1329, 1336 (DC Cir. 1972). The Court reiterated this rule in *Huthnance v. District of Columbia*, 722 F.3d 371, 378 (DC Cir. 2013). According to this legal principle, Respondents’ decision not to provide evidence within their control gives rise to an inference that any such evidence is unfavorable to Respondents. Therefore, I give little weight to instances where Respondents’ Owner and PIC testified that she relied solely on her policies to ensure that red flags were resolved, such as that cash is not a red flag, “because he would have been asked if he had insurance.” Tr. 719

⁵ Respondents argue that Dr. Gordon’s testimony was inconsistent and should not be afforded weight. As explained herein, I reject Respondents’ arguments regarding Dr. Gordon and I agree with the ALJ’s credibility assessment. Resp Posthearing, at 53–58.

He further noted that her testimony contained inconsistencies, such as that she stated the pharmacy had not filled any prescriptions after April 30, 2014, but the records showed that it had, and she stated that D.B.'s dosage had decreased when it had not. RD, at 14. The ALJ concluded, and I agree, that "to the extent, her testimony conflicts with other testimony, or exhibits, [] I find that the exhibits and the other testimony merit greater weight." RD, at 15.

2. Dr. Grant

Respondents presented testimony of an expert, Dr. Wayne Grant, who has been a pharmacist since 1990 and has a bachelor's degree and Doctorate in pharmacy. Tr. 425–527. Dr. Grant works in a "hospice and palliative care organization," where he has been employed for twelve years. *Id.* at 427. He also testified that he teaches a course online as an adjunct faculty at the University of Florida.⁷ Tr. 428. Dr. Grant also worked in an "in-house, closed pharmacy" for about fifteen years and a retail pharmacy for about five years. Tr. 431–32. Dr. Grant is licensed as a pharmacist in Ohio, and he has never worked in or been licensed as a pharmacist in Florida, although he has reviewed "mostly for comparative reasons," but not taken, some of the continuing education courses in Florida. Tr. 433, 437; RD, at 11. The Government objected to accepting Dr. Grant as an expert witness, because he lacked experience in the standard of practice in the state of Florida, but the ALJ accepted Dr. Grant as "an expert in the field of pharmacy." Tr. 237; 442.

The ALJ found, and I agree, that although generally Dr. Grant "appeared to be an honest and candid witness," his testimony merited "little weight" based on six reasons. RD, at 11. First, the ALJ reasoned that Dr. Grant was "deceptive even when answering questions about his qualifications." *Id.* Dr. Grant touted the benefits of working for the University of Florida as including continuing education, stating, "I get a lot of continuing education," but when asked whether he had taken Florida continuing education, he stated that he "had reviewed a number of those," but "mostly for comparative reasons." Tr. 433; RD, at 11. The ALJ further noted that "while professing to be an adjunct faculty member at the University of Florida, it turns out [Dr. Grant] does not teach, but only occasionally lectures."

⁷ The ALJ found, and I agree that Dr. Grant's faculty status at the University of Florida is not clear from his testimony. RD, at 10. Although he testified that he was an adjunct professor, he later testified that he only lectures in Florida once a year, for an "hour, hour and a half." Tr. 517–18.

RD, at 11 (citing Tr. 428, 516–17). Second, the ALJ noted that Dr. Grant's testimony that he did not know if he had been qualified in Florida was not credible, because when the ALJ asked him if he had ever testified in Florida, he stated that he had not. *Id.* (citing Tr. 438). Third, in describing "corresponding duty," Dr. Grant stated, "It looks at a standard in which pharmacy practice is when we're reviewing prescriptions that come into our care." Tr. 445. I agree with the ALJ's finding that Dr. Grant's "'expert' explanation of the phrase 'corresponding duty' is almost incomprehensible." RD, at 11. Fourth, Dr. Grant initially testified that he had reviewed the prescriptions at issue in the case and there did not seem to be any prescriptions on their face that appeared to be a violation of corresponding responsibility such that there needed to be "a conversation with the patient and the prescriber," but then, on cross examination, admitted in several instances that there should have been follow up. Tr. 445, 478–79, 508–11; RD, at 12. Fifth, the ALJ took issue with Dr. Grant's testimony that the term "cocktail" was not "a common term used in pharmacology." When asked if he knew what a cocktail was, Dr. Grant said "I'm familiar with what I think that terminology is" and then later answered the same question, "Other than a drink, I'm not really sure." Tr. 455–56. Then, Dr. Grant contradicted himself by explaining what a cocktail was, stating "[i]n more nefarious [sic] perhaps, they're looking at trying to lump benzos and opioids and a whole host of skeletal muscle relaxers in there too. But we don't teach about cocktails. We don't make cocktails." *Id.* at 456. I agree with the ALJ that not only was his testimony contradictory, but also, DEA "has long discussed drug cocktails." RD, at 12. Contrary to his own statements, that he had not heard of "drug cocktails" or that the term was not used in pharmacology, he later described them accurately and the federal agency that regulates controlled substance registrations uses the term regularly. Finally, the ALJ noted that Dr. Grant "even seemed unwilling to use the term red flag." RD, at 12. Dr. Grant testified that he was "familiar with the concept," but that he does not "teach anything about red flags" and that he had not heard the term in relation to opioids until about two or three years ago. Tr. 449, 518. The ALJ noted that Respondents' Owner and PIC had "no trouble using the term and understanding its meaning," and that DEA has used the term for many years. RD, at 12 (citing Tr. 587, 597–98, 610–

11, 617–18, 642, 650, 671–72, 676, 681, 688, 701, 727, 730).

Based on the issues with the merits and credibility of Dr. Grant's testimony, the ALJ found, and I agree, that "where there is conflict between the testimony of Dr. Grant and the testimony of Dr. Gordon, I find that Dr. Gordon's testimony is more credible and is entitled to greater weight." RD, at 13. As such, I rely on Dr. Gordon's testimony to accurately describe a pharmacist's corresponding responsibility and the usual course of professional practice in the State of Florida.

3. D.M.

D.M. is an attorney who initially was representing Respondents, but who withdrew and became a fact witness prior to the start of the hearing. ALJX 28 (Motion to Withdraw); Tr. 799. He testified that he was retained by Respondent Pharmacy around 2008 to give advice on "compliance and keeping up with what the rules are, regulations, and policies and procedures." *Id.* at 801. As part of his advice, he stated that he researched and communicated red flags. *Id.* at 804–06. D.M. testified that he gave advice⁸ to Respondent Pharmacy in 2008 that it was generally legal for a doctor to self-prescribe,⁹ but that following the Florida Board of Pharmacy's statement to Respondent Pharmacy that it "wasn't allowed," he still thought it was legal, but recommended that Respondent Pharmacy "should not do that anymore." *Id.* at 809–10. He further testified regarding policies that he helped Respondent Pharmacy write in 2008 to not "fill for an out of county, out of the area customer" or "out of the county doctor" unless it was an established patient in which case they would "look at other factors." *Id.* at 807. D.M. also testified that in 2012 or 2013, he helped to write policies for schedule II controlled substances on letters of medical necessity. *Id.* at 821. However, D.M. also testified that he does not ensure or check compliance with the policies that he wrote. *Id.* at 825.

The ALJ found, and I agree that "D.M.'s testimony is consistent with other testimony of record. He testified in a candid and forthright manner and he was a credible witness." RD, at 15.

⁸ Although D.M. and Respondents' Owner and PIC claim this advice was given via email, neither could produce the emails. Tr. 829–30.

⁹ D.M. later clarified that the question in 2008 was not specific to controlled substances, but all prescription drugs. Tr. 823. He addressed controlled substances in his advice in 2015 after the Board of Pharmacy had told Respondent Pharmacy that the prescriptions could not be filled. *Id.* at 827.

D. Corresponding Responsibility and Course of Professional Practice in Florida

Dr. Gordon credibly testified that before filling a prescription “a pharmacist should assure that the medication is safe and exercise their corresponding responsibility to make sure the medication is for a legitimate medical purpose, to look at things like drug interactions, appropriateness of dose, what doctor is writing the prescription, how far the patients traveled,¹⁰ is it appropriate, is it safe for themselves and the community.” Tr. 33. She further testified that in exercising a pharmacist’s corresponding responsibility, “there’s not just one or two red flags you specifically look for.” *Id.* at 34. She testified that such red flags include, “the type of medication,” whether the dose is appropriate, combinations of controlled substances, whether the patient is in the local community, what type of doctor is prescribing, the distance from the doctor and the pharmacy.¹¹ *Id.* at 34–37. Dr. Gordon further testified about short-acting and immediate release medication, and specifically stated that “it does not make pharmacological sense to prescribe two short-acting opioids,” for example hydromorphone and oxycodone, “because they are doing the same thing,” and therefore such prescriptions are red flags. *Id.* at 36–39.¹² Additionally, Dr. Gordon testified

that pattern prescribing by a doctor who prescribes the same dosage and medication to all of his patients is a red flag, and there is also a red flag when those prescriptions are filled sequentially, one after the other. *Id.* at 39. Further, she testified that another red flag is a prescription cocktail, which she described as “the issuance of two or more prescriptions that do the same thing or enhance the effects of the other.” *Id.* She gave examples of prescription cocktails, such as “Soma, a benzodiazepine, like Ativan or Xanax, and an oxycodone or hydromorphone,” but that more recently she sees “just a Benzo with a opioid,” such as “Alprazolam or Xanax or Lorazepam or Ativan, plus hydromorphone or oxycodone, or both.” *Id.* at 40. Dr. Gordon testified that other red flags were when patients appeared to come from the same household and received similar medications, when patients are going to multiple doctors or pharmacies, and that prescriptions purchased with cash¹³ were a “big red flag.” *Id.* at 41–42. She stated that pharmacists can detect doctor shopping through “E-FORCSE,” which is a “computer program set up by the State of Florida that a pharmacy is supposed to report all of their controlled substances: the quantity, the medication, the doctor, and the pharmacy where it was filled, for every patron” and which started around 2010. *Id.* at 43.

Dr. Gordon testified that a pharmacist can resolve these red flags “by either talking to the patient and/or speaking to the physician” and in some cases “you may need to do both.” She further clearly testified that the resolution of the red flag “must be documented¹⁴ before you dispense the medication so

that you can let other pharmacists know what happened the time before” and that documentation must be “either on the prescription itself or in the computer system.”¹⁵ *Id.* at 44–45. When pressed by Respondents’ counsel regarding whether a pharmacy was required by statute to document the resolution of the red flag, Dr. Gordon stated that “it’s not an opinion. It’s the standard of practice” and further clarified “[t]he standard of practice, if there’s something questionable about a prescription, you document it after you speak with the patient or the doctor.” *Id.* at 215. Finally, Dr. Gordon testified that if it is impossible to resolve a red flag, such as a prescription written by a physician to himself or to a business or office, the standard of practice of pharmacy in Florida would require a pharmacist to “not dispense the medication.” *Id.* at 46.

Regarding red flags, Dr. Grant stated, “the only place that I’ve really seen this again is with the continuing education, which I have not completed, in regards to Florida, where they list in—this group lists and they put red flags, and they list a whole bunch of things down there as being red flags. And they suggest pharmacists should be looking at that. But it’s their process. It’s nothing I’m familiar with teaching.” Tr. 450. As explained above, I credit Dr. Gordon’s testimony over Dr. Grant’s.

Respondents’ Owner and PIC testified that she was aware that when a pharmacist spots a red flag for a prescription, that she must “resolve it, and if [she] cannot resolve it, not to fill it.” Tr. 566; RD, at 24. She testified that she trained her pharmacists to identify and resolve red flags. RD, at 24; Tr. 556–57. She also testified that she understands the concept of red flags and that she recognized that there are red flags in Respondent Pharmacy’s prescriptions. Tr. 796. Respondents’ Owner and PIC stated that, “I don’t believe we did as well with documentation. I do believe we did resolve red flags. Even then, I think we

¹⁰ Dr. Gordon testified that she had searched for local pain management doctors and Respondents’ Owner and PIC testified that there were not enough local practitioners in the area. Tr. 568. I agree with the ALJ, who determined that neither party submitted adequate support for their testimony and therefore gave the testimony of each little weight. RD, at 24 n.10.

¹¹ Respondents argued that Dr. Gordon was inconsistent regarding whether the red flag of distance was resolvable. Resp Posthearing, at 53 (citing Tr. 36, 110—however, the quoted material is on page 111). I disagree that this testimony was inconsistent. Dr. Gordon testified that in “this particular scenario” of the group of Dr. R.’s patients coming in together with prescriptions written on the same day and travelling a far distance, one after another in this case, the red flags were not resolvable. Tr. 111. She stated that there is room to clear red flags and gave an extreme example of all of the patients getting into the same car wreck and needing a short supply of something being a possible reason that a pharmacist could still fill the prescription, but she clearly testified that the scenario presented by Dr. R.’s patients coming in together did not present any facts that could have resolved the red flags. *Id.* Furthermore, these prescriptions contained multiple red flags, not solely the red flag regarding distance.

¹² Respondents argued that Dr. Gordon testified that it was a red flag to prescribe two short acting opioids and also to prescribe a long and a short acting opioid. Resp Posthearing, at 54 (citing Tr. 38, 83). I disagree with their characterization of Dr. Gordon’s testimony. Regarding the long and the short acting opioids, she testified that “it’s a red flag to see the dosage has changed or there is a different drug.” Tr. 84.

¹³ Respondents stated that Dr. Gordon was inconsistent on whether cash was a red flag, but I find that she credibly testified that “[i]t’s the combination of the red flags, the cash and the opioid, not just the point that they’re paying cash.” Tr. 295; Resp Posthearing, at 55. I agree with this statement and the ALJ’s finding that cash is a red flag in combination with the other red flags. RD, at 31 n.13.

¹⁴ Respondents suggested that Dr. Gordon “did not testify that the resolution of every red flag must be documented,” but that “she testified that a pharmacist is required to ‘document if you need more information to clear a red flag.’” Resp Posthearing, at 4 (citing Tr. 206). Respondents took Dr. Gordon’s quote out of context. During the hearing, Respondents’ counsel clarified the statement that he quoted in his brief, stating, “Okay. So document the resolution of red flags?” to which Dr. Gordon responded, “Yes. To show that—for each red flag, if there was a specific situation where you felt that the medication was for a legitimate medical purpose, that should be documented.” Tr. 206. I find that Dr. Gordon was very clear that the standard of practice and usual course of professional practice in Florida required a pharmacist to document the resolution of every red flag before dispensing.

¹⁵ Respondents argued that Dr. Gordon would require a pharmacist with multiple red flags “to write paragraphs of data regarding why the patient travelled to the next county, had back pain, was seeking a ‘highly abused medication,’ and had insurance but was not using it to fill the medication.” Resp Posthearing, at 58. There is no evidence or testimony in this case that what Dr. Gordon was proposing to be documented would be “paragraphs of data.” I reject this characterization of Dr. Gordon’s testimony. Respondents are trying to absolve themselves of responsibility to take any notes on their resolution of red flags by exaggerating the burden. The fact is that there was rarely any documentation as to the red flags in this case other than letters of medical necessity, so there is nothing on which to testify to or assess Respondent Pharmacy’s level of detail in resolving them.

could have done better at it.” *Id.* at 796. Finally, she stated that she received the letters of medical necessity, because she “knew that was an absolute requirement. That’s a statutory requirement. The others seemed to gradually evolve. And in my opinion, it was continued professional practice. So documentation of them was innate in my job even prior to the pain epidemic or the requirement of red flags.” *Id.* at 797.

I agree with the ALJ that Dr. Gordon’s testimony should be given the most weight on a pharmacy’s corresponding responsibility and the ordinary course of professional practice in Florida to resolve red flags and document the resolution on the prescription or in the patient record. RD, at 13.

E. Allegation That Respondent Pharmacy Filled Prescriptions Written by a Practitioner to Himself in Violation of Florida Law

The OSC alleged that Respondent Pharmacy dispensed controlled substances to a physician that were prescribed to himself in violation of Florida Statute Section 458.331(1)(r). The relevant Florida law states that it is grounds for disciplinary action or denial of a license to “dispens[e] . . . any medicinal drug appearing on any schedule set forth in chapter 893 by the physician to himself or herself, except one prescribed, dispensed or administered to the physician by another practitioner” Fla. Stat. § 458.331(1)(r).

1. Patient J.S.3

The Government alleged that between March 2014 and December 2014, Respondent Pharmacy violated its corresponding responsibility and Florida law when it dispensed six prescriptions for controlled substances to a doctor, J.S.3, who was prescribing controlled substances to himself in violation of Florida law. OSC, at 4; RD, at 27. It further alleged violations of Respondent Pharmacy’s corresponding responsibility for filling twelve additional prescriptions written by J.S.3 to himself from June 2012 to June 2013. Govt Prehearing, at 8. The Government’s evidence demonstrates that Respondent Pharmacy filled prescriptions written by J.S.3 to himself for various controlled substances to include: Percocet, Ambien and testosterone. GX 2, at 1–34.

Dr. Gordon testified that the prescription to J.S.3 for Ambien filled on June 12, 2012, contained a red flag¹⁶

because “the name of the patient is the same as the name of the physician” and that “it’s against the law for a physician to write a controlled substance for himself.” Tr. 49–50; GX 2, at 1, 2. She additionally testified that a prescription for oxycodone/Tylenol with the brand name Percocet filled on July 13, 2012, and all of the other prescriptions filled by Respondent Pharmacy for J.S.3 presented red flags and were in violation of Florida law for the same reason.¹⁷ Tr. 51–61; GX 2, at 1–34. Dr. Gordon testified that the fact that “the patient is the physician” is a red flag and that the red flags were unresolved. Tr. 59–60. In response to the Government’s question regarding whether a pharmacist applying “the minimal acceptable standard of practice of pharmacy” in Florida should have filled these prescriptions, Dr. Gordon stated that “[a] pharmacist should not have filled any prescription written by a physician that wrote it for himself, a controlled substance.” *Id.* at 62.

Respondents’ Owner and PIC testified that she had sought advice from her attorney, D.M. about whether it was lawful for a doctor to self-prescribe and D.M. had told her it was lawful in an

represented that the issue with J.S.3’s prescriptions was only an issue as a matter of law, that a pharmacist cannot fill a physician’s prescription as a matter of law.” Tr. 60. The OSC clearly stated that the J.S.3 prescriptions raised red flags, but Respondents’ counsel alleged that there was discussion of this issue in pretrial conferences related to Respondents’ request to provide testimony of J.S.3. *Id.* at 61. This issue became confused when Respondent proposed the testimony of J.S.3, which the ALJ excluded on the basis that “the ultimate issue with regard[] to this allegation is legal, rather than factual, in nature.” ALJX 27 (Order Granting In Part the Government’s Motion *In Limine*), at 3. The Government’s attorney at the hearing stated that “the red flag seems to be a matter of law, and I’m simply asking the expert whether there’s any indication whether the pharmacist was able to justify in its mind the dispensing of these prescriptions.” Tr. 61. The ALJ sustained the Respondents’ objection; however, he overruled the objection related to Dr. Gordon’s opinion regarding whether filling the prescriptions was within the standard of practice. *Id.* Despite this argument at the hearing, I find that Dr. Gordon appropriately testified that the physician’s prescription to himself was a red flag. I do not find that the ALJ erred in excluding the testimony of J.S.3 as irrelevant. The testimony of J.S.3 as described by the Respondent could not have added any additional facts that would alter the finding herein. However, I disagree that the issue here was solely about whether these prescriptions violated Florida law, as explained further herein. I further discuss this issue in Section III(A)(1)(c).

¹⁷Dr. Gordon also identified other red flags with these prescriptions, such as that the prescriptions lacked a DEA number, the prescriptions were paid for by cash, the physician called in the prescription with no hard copy in violation of Florida law; however, these red flags were not identified in the OSC or the Government’s Prehearing statements, so I am not basing my decision on these red flags. Tr. 52–59.

email.¹⁸ Tr. 571, 777, 809; RD, at 28. She further testified that she had received this advice “early on in my ownership of the business,” which “might even have been prior to my ownership of the business. 2008, 2009.” *Id.* at 777. She stated that she did not revisit his advice after that time and that she “probably should have, but [she] did not.” *Id.* D.M. testified that he researched and gave advice to Respondents’ Owner and PIC “in 2008, generally” regarding “could a doctor self-prescribe.” Tr. 809. D.M. concluded that it was permissible and when asked what advice he communicated to Respondent Pharmacy, he stated, “At that point in time, we were not using the words red flag. The word was scrutiny. And that it should pass the sniff test, but it wasn’t prohibited and it was permissible but required scrutiny.” *Id.* at 810. Respondents’ Owner and PIC testified that the Board of Pharmacy visited in 2015¹⁹ and told Respondents’ Owner and PIC that “it was not lawful” to fill a prescription that a doctor had written for himself, after which D.M. confirmed his original legal advice, but recommended that Respondent Pharmacy stop filling these prescriptions, and Respondent Pharmacy did not fill any further prescriptions. Tr. 573, 763, 777, 809. The last prescription filled for J.S.3 was on January 14, 2015. GX 2, at 33–34; Tr. 762; RX H, at 2–3; RD, at 28.

Based on the evidence in the record, I find that from 2012–2015, Respondent filled numerous prescriptions from prescriber J.S.3 to himself without resolving the red flag that he was self-

¹⁸The Respondent did not submit the email as evidence.

¹⁹It is noted that Respondents’ version of the Patient profile for J.S.3 included in the E.O.M. or “end of month” statement a typed note that stated “cannot write personal scripts. DC” and the date the record was printed is covered by a photocopied sticky note. RX H, at 1; Tr. 698. The Government noted that the copy in the Government’s evidence that was seized on April 7, 2015, and contains a print date of “April 7, 2015” does not include the same language in the E.O.M. statement. Tr. 699; GX 2, at 35. Nevertheless, Respondents’ PIC and Owner stated that she made that sticky note in January of 2015 and offered no explanation for why the Government’s evidence did not include the typed note in the database. Tr. 699–700. Respondents argued in their Posthearing Brief that there were no prescriptions filled for J.S.3 after January 14, 2015. Resp Posthearing, at 9 n.1. This argument does not explain why the documents in the Government’s possession that were printed three months after the last prescription to J.S.3 did not contain the same typed E.O.M. note. The ALJ found, and I agree, that Respondents’ PIC and Owner did not testify credibly that the document in RX H was the same record that was available to the Government on the date of seizure in April 7, 2015, because the sticky note obscures the date that the document was printed. RD, at 28 n.11. This appears to me to be a falsification of records and further undermines my ability to trust Respondents’ Owner and PIC.

¹⁶Respondents’ counsel objected to Dr. Gordon’s testimony that the J.S.3 prescriptions were unresolved red flags, stating that “the Government

prescribing in violation of state law. See *infra* Section III(A)(1)(c).

F. Allegation That Respondent Pharmacy Filled Prescriptions Written for "Office Use" in Violation of 21 CFR 1306.04(b)

The OSC alleged that Respondent "dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions which indicated that the ultimate user was an 'office' in violation of 21 CFR 1306.04(b)." OSC, at 4. The Government submitted evidence of prescriptions and fill stickers, which demonstrated that between September 23, 2014, and January 28, 2015, Respondent Pharmacy filled prescriptions for office use to Dr. I's office on 8 occasions and to Dr. A's office once. GX 3; RD, at 29.²⁰ The Government's expert witness Dr. Gordon testified that "written for office use" means that "the pharmacy filled prescriptions for controlled substances not for an individual but for a facility." Tr. 64. She testified that the prescriptions "for office use" were not purchases by a medical office, but the evidence demonstrated that they were prescriptions because they were "assigned a prescription number," and had the office name in the place of a "patient's name," and further the pharmacy generated "fill stickers." *Id.* at 65. She stated that "according to the standards set by Florida, a controlled substance should be issued to an individual patient, not an office to be distributed through unknown patients," and therefore, she testified that the prescriptions dispensed for office use were dispensed outside the usual course of professional practice. *Id.* at 64, 66. Upon prompting by Respondents' counsel, Dr. Gordon further testified that "if there were an invoice and the prescription was issued to a practitioner," it would have resolved the issue, but clarified that it was not within the acceptable standard of practice to order controlled substances from a pharmacy to be distributed to a dispensing practitioner and then report it to E-FORCSE. *Id.* at 278–79; 288–89.

Respondents' Owner and PIC testified that when she "had an interest to wholesale some compounding," she asked her counsel (D.M.) about whether she could fill prescriptions for an office and that "he said it was lawful between 3 and 5 percent" of her total

²⁰ Respondents' Owner and PIC and the RD mentioned thirteen prescriptions to Dr. I's office, but the Government's evidence appeared to contain only eight and one to Dr. A's office and sixteen fill stickers. GX 3; Tr. 577; RD, at 29. The prescription for Dr. A. was filled by the Respondent Pharmacy to [A's] Office on the fill sticker. GX 3, at 4.

inventory.²¹ *Id.* at 583. She also admitted that she did not ask D.M. specifically about dispensing in the context of the prescriptions to Dr. I's office and that she had not specifically shown him or asked him about using blank prescriptions and fill stickers. *Id.* at 696–97, 777. She testified that she had accessed the accreditations for Dr. I. and found that Dr. I. was a dispensing practitioner.²² *Id.* at 578. However, she testified that after the Board of Pharmacy visited in 2015 and told her that wholesaling was not allowed, Respondent Pharmacy stopped dispensing to practitioners and her counsel changed his advice. *Id.* at 584.

I find that Respondent Pharmacy filled prescriptions for Dr. A.'s office and for Dr. I.'s office for office use. See *infra* Section III(A)(1)(b) for further discussion.

G. Allegation That Respondent Pharmacy Failed To Exercise Its Corresponding Responsibility When it Dispensed Controlled Substances Pursuant to Prescriptions Not Issued in the Usual Course of Professional Practice or for a Legitimate Medical Purpose

The OSC alleged that Respondent Pharmacy failed to exercise its corresponding responsibility under 21 CFR 1306.04 as evidenced by its having dispensed controlled substances without resolving "red flags of diversion" that were present, including prescriptions: For highly abused narcotics; written to individuals travelling long distances; from groups of individuals who travelled long distances, from the same doctor, presented at the same time; for multiple drugs designed to treat the same condition in the same manner; constituting obvious early refills; and, for "costly narcotic medications, which the customer repeatedly purchased with cash." OSC, at 4.

1. Red Flags Associated With Patients of Dr. R.

The OSC alleged that between February 12, 2014, and May 3, 2014, Respondent Pharmacy "dispensed narcotic medications to groups of customers who resided in close proximity to [Respondent Pharmacy], but who obtained their prescriptions from a physician located in Miami, Florida, more than 170 miles from their

homes." OSC, at 4. The Government alleged that the distance between the prescribing practitioner and his patients constituted red flags and Respondent Pharmacy did not adequately resolve the red flags prior to dispensing prescriptions. *Id.* Furthermore, the Government alleged that Dr. R.'s prescriptions presented additional red flags that were unresolved by the pharmacy.

The Government's evidence includes a letter from Dr. R., dated May 22, 2014, which explains that Dr. R. moved his practice from Broward County to Miami, but his Broward County patients had decided to continue under his care. GX 29, at 1. The letter provided high level details about his office protocols to ensure against diversion. *Id.* The ALJ noted that the letter did not provide any names of Dr. R.'s patients. RD, at 30. Respondents' Owner and PIC stated that the letter "was issued after [Respondents' Owner and PIC] decided to no longer accept [Dr. R.'s] prescriptions." Resp Posthearing, at 11 (citing RX H, at 61). Dr. Gordon opined that the letter did not resolve any of the red flags for patients "because it still doesn't explain why they're going to be driving further, putting the patients at risk." Tr. 193. She testified that although the fact that Dr. R. discusses his practice's controls²³ could help a pharmacist evaluate the red flags, "[i]t still doesn't justify them traveling three hours." *Id.* at 272. Further, Dr. Gordon testified that nothing in the pharmacy records confirmed Dr. R.'s practice controls were actually implemented and there were no written statements from the patients as to why they chose to travel to see Dr. R., and there was no documentation of any pharmacists' discussion with Dr. R. necessitating the letter in Respondent Pharmacy's records. Tr. 270, 286–87; RD, at 72.

Respondents' Owner and PIC testified that she had spoken on the phone to Dr. R. and "found him legitimate." Tr. 555. However, she stated that she had made a policy not to fill Dr. R.'s prescriptions, around the time that she received a letter from him on May 22, 2014, and she counseled B.S.²⁴ for filling those prescriptions "because we don't want the scrutiny of it." *Id.* at 560, 770; 557; RX H, at 62. However, she stated that despite that policy, there were two

²³ Dr. Gordon also testified that there was no information in Respondent Pharmacy's files that demonstrated that any of the controls mentioned in the letter had been implemented, except for a urine screen, but "[i]t was not monthly" as Dr. R.'s letter had claimed. Tr. 286.

²⁴ Respondents' Owner and PIC testified that B.S. was later terminated for other reasons in 2016. Tr. 564.

²¹ Respondents' Owner and PIC stated that she received this legal advice in writing, but Respondent offered no evidence of the advice. Tr. 695–696; RD, at 29.

²² It is noted that Respondents' Owner and PIC did not offer a similar justification for the prescription to Dr. A's Office.

instances where Respondents' Owner and PIC had decided to fill Dr. R.'s prescriptions as an exception to that policy. Tr. 771; 560. One was on April 7, 2014 to J.S.2. *Id.* at 773; GX 6, at 7.

a. Pattern of Filled Prescriptions for Dr. R.'s²⁵ Patients

The Government presented evidence that not only did Dr. R.'s patients travel long distances to receive their medication, but also they often filled the prescriptions on the same date and "at the same time, one after another." RD, at 71. On February 12, 2014, Patients J.S.1, A.J., and S.P. presented prescriptions for oxycodone and hydromorphone from Dr. R. GX 6, at 1–2; GX 5, at 3–4; GX 4, at 3–4; RD, at 70. Dr. Gordon testified that the pattern of filling in groups is a red flag, because "that's a group of patients going to see the same doctor, getting the same type of medication, same class of medication, and going to the pharmacy on the same day to get their prescriptions filled." Tr. 106. Similarly, on March 11, 2014, Patients D.G. and J.S.1 presented prescriptions from Dr. R. for oxycodone and their prescription numbers indicate that "[r]ight after one another they were filled." Tr. 107; GX 9, at 5–6; GX 6, at 3–4. On March 15, 2014, Respondent Pharmacy filled prescriptions for hydromorphone from Dr. R., for Patients E.H., S.P., and A.J. with sequential fill numbers. GX 8, at 1–2; GX 4, at 5–6; GX 5, at 5–6. On April 11, 2014, Respondent Pharmacy filled prescriptions for S.P., A.J. and E.H. for hydromorphone. GX 4, at 1–2; GX 5, at 7–8; GX 8, at 3–4. Finally, on May 3, 2014, Respondent Pharmacy filled prescriptions for J.S.1 and D.G. for oxycodone and hydromorphone with sequential fill numbers. GX, 6, at 11–12; GX 9, at 9–10.

Dr. Gordon further explained that under normal pharmacy procedures, these Schedule II controlled substances must be locked up and "the lock and key belongs to the pharmacist," and therefore, the pharmacist would have been aware of the pattern of group filling. Tr. 109–10. She opined that the red flags for these prescriptions were not resolvable and that she would not have filled them, because "it's an effort to take—to get that drug and take it out. And then one right after it is for the same thing." *Id.* at 110–11.

b. S.P.

On February 2, 2014, March 11, 2014, and April 11, 2014, Respondent

²⁵ All of the patients in this section are patients of Dr. R., but some of the patients also received prescriptions from other doctors, which also presented red flags as described herein.

Pharmacy filled prescriptions for hydromorphone for S.P. GX 4, at 4, 2, 6. Dr. Gordon testified that the first red flag in the initial prescription was that the prescription for hydromorphone was "written for the highest strength the drug is available." Tr. 67. Further, the prescription was "from a doctor who is about three hours away from where the patient resides." ²⁶ *Id.* Finally, the fill stickers indicate that the patient paid with cash. *Id.* at 68; GX 4, at 2, 4, 6. The prescription dated February 2, 2014, includes a note on the prescription stating that it was "verified by Nicole." GX 4, at 3. Dr. Gordon explained that "when a technician calls the doctor's office to verify the validity of the prescription itself, that the prescription was written and issued by the physician." Tr. 68. S.P.'s file also contains a form letter with handwritten blanks filled in from Dr. R. faxed on February 12, 2014, that states that Dr. R. "examined and prescribed narcotic medications" to S.P. GX 4, at 8. Dr. Gordon opined that the letter provides the "reasoning for issuing this prescription," but does not resolve any of the red flags discussed and stated, "[i]t makes it worse because it's providing a diagnosis that we see a lot with prescriptions that are associated with diversion of chronic pain syndrome or some kind of back reason, and would also make me wonder how a patient could sit in a car for three hours one way to go to a doctor" Tr. 70. She concluded that the prescriptions dispensed to S.P. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. Tr. at 70.

c. A.J.

From January 21, 2014, to April 11, 2014, Respondent Pharmacy filled prescriptions from Dr. R. for customer A.J. GX 5, at 1–8. A.J.'s address on the prescriptions is Palm Bay, Florida and the distance from Dr. R.'s office in Miami is 176 miles. GX 5, at 3, 5, 7; RD, at 31 (citing Stipulation 8). From December 5, 2014, to March 27, 2015, Respondent Pharmacy filled eight prescriptions for A.J. from another doctor, Dr. D. GX 5, at 9–28. Dr. D.'s office in Orlando, Florida was 74 miles from A.J.'s address. RD, at 32 (citing Stipulation 9). Dr. Gordon testified that the prescriptions from Dr. R. raised numerous flags, including: the type of medication; the fact that it was the

²⁶ The Parties stipulated that the distance from S.P.'s home in Malabar, Florida to Dr. R. in Miami is 170 miles. RD, at 31 (citing Stipulation (hereinafter, Stip.) 7).

highest strength dosage available (hydromorphone eight milligrams); "the distance traveled by the patient to go see the doctor and that the patient was paying cash." Tr. 77. Dr. Gordon also testified that it was a red flag that the prescriptions from Dr. D. included a prescription for morphine in addition to the hydromorphone at the highest dosage, both of which treat the same condition. *Id.* at 80, 84; *e.g.*, GX 5, at 9, 11. She further testified that the prescriptions from Dr. D. raised red flags because of the type of medications, the fact that A.J. was paying cash and the fact that the "codes that are on here are all back pain or chronic pain syndrome," which are "commonly seen on diverted medications." ²⁷ *Id.*

A.J.'s profile contains an entry that states, "Dr. D. called personally about patient & will send letter over next week." GX 5, at 29. There is no letter from Dr. D. in the file and the Respondents' Owner and PIC testified that it was "generally" the policy to note the receipt of a letter in the system.²⁸ Tr. 735–36. The file also contains a form letter faxed on January 23, 2014,²⁹ from Dr. R. with the patient's name, diagnosis and last MRI filled in by hand. GX 5, at 30; RX H, at 59. Dr. Gordon testified that neither the notation regarding Dr. D., nor the letter from Dr. R. resolved the red flags associated with A.J.'s prescriptions, because there was no documentation explaining the long distances that A.J. traveled to see these doctors. Tr. 85–86; *see* GX 5, at 29, 30; RX H, at 59. She concluded that the prescriptions dispensed to A.J. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. Tr. at 86.

d. D.G.

From January 14, 2014, to May 3, 2014, Respondent Pharmacy filled prescriptions for customer D.G. written

²⁷ Respondents argue that Dr. Gordon "seems to have an overall bias against patients with back pain." Resp Posthearing, at 54. I disagree. She testified that it had been her "experience" that people who commonly abuse medications present with prescriptions related to back pain. Tr. 220. It is noted that there are numerous red flags on the prescriptions where Dr. Gordon flagged back pain as an additional red flag.

²⁸ However, there was a letter from Dr. R. for patient A.J. and no corresponding notation regarding its receipt in A.J.'s profile. GX 5, at 29, 30; RD, at 32.

²⁹ It is noted that this letter was faxed on January 23, 2014, but the first prescription for A.J. was filled on January 21, 2014; therefore, even had this letter resolved some of the red flags for future prescriptions, which I find it did not, it was not received in time to resolve the red flags for the first prescription. *See* GX 5, at 2.

by Dr. R. GX 9, 1–10. D.G.’s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R.’s office in Miami is 175 miles. GX 9, at 2, 4, 6, 8; RD, at 33 (citing Stipulation 13). D.G.’s customer file also includes a prescription, dispensed on October 15, 2014, written by another doctor, Dr. B., in Winter Garden, Florida, which is 76 miles from D.G.’s address. GX 9, at 11; RD, at 33 (citing Stipulation 17). Dr. Gordon testified that these prescriptions raised multiple red flags including: “the type of medication, which is an opioid, the strength³⁰ of the medication, the distance traveled from the patient’s home to the doctor, and cash.” Tr. 94–95. Further, she testified that the prescriptions from Dr. B. had the same red flags and that the patient was traveling an hour away, which would still trigger a red flag. Tr. 97. The Government’s evidence includes a form letter from Dr. R. stating that the date of visit was February 11, 2014,³¹ and a diagnosis of lower back pain. GX 9, at 14. Dr. Gordon testified that nothing in the file,³² including the letter, resolves the red flags, because it does not explain why he is traveling such a distance, particularly considering that he allegedly had lower back pain. Tr. 98. She concluded that the prescriptions dispensed to D.G. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 98.

e. E.H.

From March 15, 2014, to May 9, 2014, Respondent Pharmacy filled prescriptions for customer E.H. written by Dr. R. GX 8, 1–6. E.H.’s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R.’s office in Miami is 175 miles. *Id.* at 2, 4, 6; RD, at 34 (citing Stipulation 20). E.H.’s customer file also includes prescriptions filled July 23, 2014, to April 1, 2015, written by various doctors at a pain management clinic in Orlando, Florida, which is 74 miles from E.H.’s address. GX 8, at 7–24; RD, at 34 (citing Stipulation 21). Dr. Gordon testified that

³⁰ Dr. Gordon further explained that the strength is a concern “because it’s the highest dose the drug is available in in an immediate-release form.” Tr. 94.

³¹ It is noted that although the letter was undated, it had to have been sent after the last visit identified in the letter as February 11, 2014, which was after Respondent Pharmacy’s first fill on January 17, 2014, for this patient. GX 9, at 2.

³² The patient profile for D.G. includes a note in the memo section that states “3/17/2015 must have new letter of med necessity for any further fills.” GX 9, at 13. However, that note was dated long after the last prescription in the record for D.G. of October 15, 2014. *Id.* at 12.

these prescriptions raised multiple red flags including: “the type of medication, the strength of the medication, the distance traveled, and cash.” Tr. 100. Further, she testified that the prescriptions from the practice in Orlando had the same red flags and that the patient was still traveling a distance.³³ *Id.* at 102. The Government’s evidence includes a form letter with the patient, diagnosis and last MRI filled in from Dr. R. faxed on March 14, 2014. GX 8, at 26. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 105. She concluded that the prescriptions dispensed to E.H. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

f. J.S.1 and J.S.2

From February 12, 2014, to May 5, 2014, Respondent Pharmacy filled prescriptions for customers J.S.1 and J.S.2 written by Dr. R. GX 6, at 1–14. According to the prescriptions, J.S.1 and J.S.2 live at the same address in Palm Bay, Florida. RD, at 34 (citing Tr. 585); compare GX 6, at 1–2, with GX 6, at 5–6. The distance from the residence of J.S.1 and J.S.2 to Dr. R.’s office in Miami is 174 miles. GX 6; RD, at 35 (citing Stipulation 10). They lived 22 miles from Respondent Pharmacy. RD, at 35 (citing Stipulation 12). Dr. Gordon testified that the prescriptions to J.S.1 and J.S.2 raised the same red flags as the other patients including, “the type of medication, the strength is the highest strength of the medication, the distance traveled, and cash.” Tr. 87, 113. The Government’s evidence includes a form letter for J.S.2 with the patient, diagnosis and last MRI filled in from Dr. R. faxed on March 10, 2014. GX 6, at 16. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 113. No such letter is in the file for J.S.1. *See generally* GX 6. She concluded that the prescriptions dispensed to J.S.2³⁴ were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 113–114. Dr. Gordon further testified that the fact that J.S.1 and J.S.2 reside at the same address

³³ One of the prescriptions includes a Rockledge address for the Orlando practice, which Dr. Gordon testified is still far away from E.H.’s home. Tr. 103–04.

³⁴ Dr. Gordon’s testimony did not include a specific conclusion regarding corresponding responsibility for J.S.1 separate and apart from J.S.2; however, I find that the record is clear that the red flags for both of these patients were the same and therefore I draw the same conclusion for J.S.1 that I do for J.S.2.

raises an additional red flag, “because that shows that they’re a group. They both live at the same address, they’re getting the same type of chronically sought after narcotic from the same doctor, both traveling an hour or three hours south one way to get their medication, both have a similar diagnosis of back pain.” *Id.* at 114.

Respondents’ Owner and PIC stated that the majority of the prescriptions Respondent Pharmacy filled for J.S.1 and J.S.2 were filled by B.S, but that she had filled some of J.S.2’s prescriptions. *Id.* at 586. She recalled having a conversation with J.S.2 about the distance driven and that it was “short-term” and “[h]e did tell me the diagnosis. I don’t recall about the time.” *Id.* at 588. She also testified that she had encouraged J.S.2 to find a local pain physician and he had found one in Orlando, which she considered to be local despite being 50 miles away, because “there weren’t the availability of a lot of pain management doctors, period, but there were even less that had openings.” Tr. 593–94.

g. C.C.

From December 28, 2013, to May 5, 2014, Respondent Pharmacy filled prescriptions for customer C.C. written by Dr. R. GX 11, at 1–12. C.C.’s address on the prescriptions is in Melbourne, Florida and the distance from Dr. R.’s office in Miami is 176 miles. GX 11; RD, at 36 (citing Stipulation 28). C.C.’s customer file also includes prescriptions filled from August 18, 2014, to March 30, 2015, written from a practice in Rockledge, Florida. GX 11, at 13–44; RD, at 36. Dr. Gordon testified that the prescriptions from Dr. R. to C.C. raised the same red flags as the other patients.³⁵ Tr. 123. Dr. Gordon also testified that even though the doctor in Rockledge was local to C.C., the prescriptions still raised red flags because the prescriptions were “still the short-acting opioid at the highest dose, the chronic back pain, and cash.” *Id.* at 125; GX 11, 13–44. The Government’s evidence includes a form letter for C.C. from Dr. R. with the patient name diagnosis and last MRI filled in by hand, which although undated, appeared to be received April 7, 2014, according to the notes in the Respondent Pharmacy’s files. GX 11, at 45–46. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags for the prescriptions for C.C. Tr.

³⁵ The Government noted that the fill sticker on one of the prescriptions gives an address in Boynton Beach for Dr. R., but Dr. Gordon said that although “it probably shaves off maybe an hour and a half drive,” it still raises the same red flags. Tr. 123–24.

126–127. She concluded that the prescriptions dispensed to C.C. from Dr. R.³⁶ were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

h. P.P.

From January 31, 2014, to April 10, 2014, Respondent Pharmacy filled prescriptions for customer P.P. written by Dr. R. GX 12, at 1–6. P.P.'s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R.'s office in Miami is 173 miles. GX 12; RD, at 36 (citing Stipulation 30). Dr. Gordon testified that the prescriptions from Dr. R. to P.P. raised the same red flags as the other patients for the strength, type of medication, “a highly sought after opioid,” and the distance traveled. Tr. 128. She further stated that P.P. charged his insurance for some of the prescriptions, but paid cash for the prescription filled on February 18, 2014, which indicates a red flag when patients are “maybe trying to hide something from the pharmacist. They get it filled somewhere else and bill their insurance.” *Id.* at 128. The Government's evidence includes a form letter for P.P. from Dr. R. with the patient name, diagnosis and last MRI filled in by hand, which was faxed on January 23, 2014. GX 12, at 8; RX H, at 264. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags for the prescriptions for P.P. Tr. 129–130. She concluded that the prescriptions dispensed to P.P. prescribed by Dr. R. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

Although the letter of necessity from Dr. R. was included in the Government's evidence, there was no corresponding note of receipt in his patient file and there was no note that Respondent Pharmacy would not take out of county prescriptions.³⁷ GX 12, at 7.

³⁶ Although Dr. Gordon testified that the prescriptions from the physician in Rockledge raised red flags, she limited her opinion that Respondent had not fulfilled its corresponding responsibility or acted within the usual course of professional practice to the prescriptions to C.C. by Dr. R. I am limiting my findings to Dr. R.'s prescriptions, because most of the other prescriptions included a red flag of distance and Dr. Gordon did not explain how or whether the absence of that red flag in this instance might affect the pharmacist's corresponding responsibility and professional practice.

³⁷ The ALJ noted, and I agree, that the Respondents' Owner and PIC testified that even though there was no notation, a pharmacist filling a prescription for P.P. could check the paper file for the letter of necessity; however, without a notation, a pharmacist would not know that the letter existed

Respondents' Owner and PIC stated that no prescriptions were filled for patient P.P. after May 14, 2014, but the ALJ found, and I agree, that Respondents' own exhibits demonstrate that not to be the case. Tr. 633; RD, at 37; RX H, at 265 (showing that the last prescription filled for P.P. by Respondent Pharmacy was on September 22, 2016). Respondents' Owner and PIC also testified that the prescriptions for P.P. were filled by Pharmacist B.S.,³⁸ a former employee of Respondent Pharmacy. Tr. 632–33.

i. K.P.

From February 4, 2014, to April 8, 2014, Respondent Pharmacy filled prescriptions for customer K.P. written by Dr. R. GX 13, 11–16. Additionally, from April 22, 2013, to August 24, 2013, Respondent Pharmacy filled prescriptions for K.P. from a prescriber in Fort Lauderdale, Florida.³⁹ K.P.'s address on the prescriptions varies;⁴⁰ however, K.P.'s address on all of the fill stickers from Respondent Pharmacy indicates that he was located in Fort Lauderdale, Florida. GX 13, at 2, 4, 6, 8, 10, 12, 14, 16. The distance between K.P.'s address and Respondent Pharmacy is 164 miles. RD, at 38 (citing Stipulation 32). Dr. Gordon testified that these prescriptions raised numerous red flags including: “the type of medication, the highly sought out opioid, the strength of the medication, the distance to the pharmacy [. . .] and that the patient was paying cash.” Tr. 132. The Government's evidence includes a form letter with the patient name, diagnosis and last MRI filled in from Dr. R. faxed on January 31, 2014. GX 13, at 18; RX H, at 273. There was no documentation of the letter in the notes section of the patient profile in Respondent Pharmacy's system, but there was an undated note stating not to fill any more “out of county physicians.” GX 13, at 17; RD, at 38. There was no letter of necessity or other notes regarding the prescriber in Fort Lauderdale. *See*

to know to check the paper file. RD, at 37 n.17 (citing Tr. 748–49)

³⁸ Although B.S. may have filled the prescriptions in the Government's evidence, it is noted that Respondents' evidence demonstrates that B.S. was terminated for potential diversion on April 23, 2016; therefore, a different pharmacist must have filled P.P.'s prescriptions following B.S.'s termination. RX G, at 51; Tr. 564.

³⁹ One of the fill stickers for the Fort Lauderdale prescriber indicates a Miami address, but I find this to be irrelevant because the red flag for K.P. related to location is the distance he lived from the pharmacy. *See* GX 13, at 10; Tr. 133.

⁴⁰ A few of the prescriptions show addresses in Sunrise Florida, which is west of Fort Lauderdale. RD, at 38 n.18. Additionally, one of the prescriptions indicates that K.P. lives in Palm Bay, which Dr. Gordon testified “creates more of a red flag. Where does he live?” GX 13, at 11; Tr. 134–35.

generally GX 13; RD, at 38. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 135–136. She concluded that the prescriptions dispensed to K.P. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 136.

Based on all of the record evidence, and the testimony of Dr. Gordon, which I credit, I find that the prescriptions issued by Dr. R. and other doctors for Dr. R.'s patients as detailed herein, raised red flags, including that customers arrived in groups, purchased prescriptions with cash, traveled long distances and because the prescriptions were for highly sought after controlled substances at highest strengths. I further find that the letters of medical necessity provided by Dr. R. did not resolve the multiple red flags on his prescriptions and that, even if these red flags were resolvable, there was no credible evidence in the record that Respondent Pharmacy resolved them before it filled the prescriptions. I conclude that the pharmacists filling the prescriptions did not fulfill their corresponding responsibility and the prescriptions were not dispensed in the usual course of professional practice.

2. Other Prescriptions Presenting Red Flags

a. J.C.

From approximately October 11, 2013, to January 16, 2015, Respondent Pharmacy filled prescriptions for customer J.C. written by a prescriber in Fort Lauderdale, Florida. GX 10. Most of the prescriptions record only a street address for the patient without a city, but a few prescriptions list the city as Palm Bay, Florida.⁴¹ *Compare, e.g.,* GX 10, at 1 with GX 10, at 71–82; RD, at 39. The address on all of the fill stickers states that J.C. lives in Indialantic, Florida, which is 158 miles from the prescriber's office in Fort Lauderdale. *See, e.g.,* GX 10, at 2; RD, at 39 (citing Stipulation 22). There is nothing in the record evidence that resolves the discrepancy between the addresses on the prescriptions and the address on the fill stickers. RD, at 39. The first five prescriptions in the Government's exhibit were all issued on January 3, 2014, and are all for varying strengths and amounts of the same controlled substance, Roxicodone, including two prescriptions for 10 milligrams and two prescriptions for 20 milligrams and one prescription for 5 milligrams. Tr. 115,

⁴¹ Dr. Gordon testified that even if the patient had lived in Palm Bay, it would be a 2 to 2.5 hour trip to Fort Lauderdale. Tr. 116.

835; GX 10, at 1–10; RD, at 39. Dr. Gordon testified that the five prescriptions for Roxicodone “just screams red flags.” Tr. 117. “Furthermore, the instructions for taking these five prescriptions for the same controlled substance suggested that J.C. could have been taking all of these medications at the same time.” RD, at 39 (citing Tr. 834–35). On the same date, January 3, 2014, in addition to the five prescriptions for the Roxicodone, Respondent Pharmacy also filled a sixth prescription for J.C. for the highest available dosage of diazepam, or Valium, which “would now constitute a drug cocktail.” Tr. 117; GX 10, at 175–76.

Furthermore, the ALJ found, and I agree, that Respondent Pharmacy additionally filled this same drug cocktail of oxycodone and diazepam for J.C. on January 28, 2014 (Tr. 118–19; GX 10, at 11–20, 177–78); July 19, 2014 (GX 10, at 95–96, 193–194); September 3, 2014 (GX 10, at 111–14,⁴² 191–92); September 23, 2014 (GX 10, at 119–26, 193–94); December 22, 2014 (GX 10, at 141–44, 197–98); and January 16, 2015⁴³ (GX 10, at 145–48, 199–200).

Further, Respondent Pharmacy filled prescriptions for J.C. that constituted early refills. Tr. 121. For example, the ALJ found, and I agree, that Respondent Pharmacy filled multiple prescriptions for J.C. on January 28, 2014 (Tr. 121, GX 10, at 11–19) and then again filled prescriptions on February 11, 2014, and February 26, 2014. GX 10, at 19–20, 21–26, 27–30. Dr. Gordon said this raised red flags because “[t]he patient already got like a ton of oxycodone, and this is just like twelve days later he just got a whole nother [sic] batch.” Tr. 122. She further testified that nothing in the patient records⁴⁴ is written to resolve the red flags for J.C.’s prescriptions. *Id.*

⁴² It was not alleged by the Government and is therefore not being considered, but is noted that the Government’s exhibit also demonstrates that J.C. filled prescriptions written on September 2, 2014 at Respondent Pharmacy on September 3, 2014, and September 5, 2014, and September 10, 2014. GX 10, at 114, 116, 118.

⁴³ The prescriptions for oxycodone and Diazepam were all prescribed on January 16, 2015, but Respondent Pharmacy dispensed them on January 16, 2015, January 19, 2015, and January 28, 2015. GX 10, at 145–152; 199–200. The evidence shows that Respondent Pharmacy dispensed prescriptions for oxycodone and diazepam, which constituted a drug cocktail, on January 19, 2015. *Id.* at 148, 200.

⁴⁴ The Patient profile includes a note that says that someone spoke with the prescriber and verified medical necessity on October 2, 2012. The notes also include a note on March 30, 2015, after several years of filling prescriptions, that the address on RX must match address on the driver’s license and that there could be “no more credit.” GX 10, at 201.

Respondents’ Owner and PIC testified⁴⁵ that if J.C. paid cash for a prescription, the fill sticker stated “cash” and if he used insurance it would read “advance.” Tr. 615. J.C. paid cash for his prescriptions 10 times. RD, at 40 (citing Tr. 613); *see e.g.*, GX 10, at 146. Respondents’ Owner and PIC further testified that she knows J.C. and he was a customer for 10 years. Tr. 596, 740. She further testified that she had had a conversation with the prescribing doctor⁴⁶ “about the therapy because it is different, so I particularly wanted to know about the use of several different strengths of oxycodone.” *Id.* at 597. In speaking with the doctor, Respondents’ Owner and PIC testified that “[J.C.] was on a very tightly tailored pain management treatment plan where as his pain fluctuated, he would use a different dose to use the minimal amount to relieve the pain.” *Id.* at 610. Later, she changed the rationale for the multiple prescriptions, stating, “those were split scripts⁴⁷ so that if the patient either didn’t have the funds or if it wasn’t available because of shortages . . . so that he could get a partial here and there.” Tr. 855.

Dr. Gordon testified that there were no instructions with these prescriptions about how to take them. *Id.* at 832–34. In order to address the prescriptions under the standard of practice, she said that a pharmacist would need to call to find out why the patient needs all of the prescriptions, “and is the patient supposed to take one at a time or can they take all four at the same time.” *Id.* at 835, 837. She concluded that the prescriptions dispensed to J.C. were not dispensed within the usual course of

⁴⁵ Respondents’ Owner and PIC also testified that she believed that the Government had not included all evidence from the patient memo in their exhibits, because she “knew this patient well.” Tr. 612. Respondent did not offer additional evidence and the print out in her exhibits on J.C. contains the same information in the patient memo as the Government’s print out. *Compare* RX H, at 145 with GX 10, at 201.

⁴⁶ Respondents’ Owner and PIC testified that this doctor had a good reputation in the community. At first, Dr. Gordon testified that it is not within the standard of practice to rely on a physician’s reputation to fill a prescription, but later amended her statement to allow that reputation “will come into play.” Tr. 832, 838. I do not find this information particularly relevant, because there is nothing in the record documenting Respondents’ Owner and PIC’s belief that the physician’s reputation resolved the multitude of red flags that these prescriptions presented.

⁴⁷ Some of the prescriptions did include a note indicating “split script;” however, I find Dr. Gordon more credible that this could not resolve the red flag of the need for all of the prescriptions or the instructions on how to take them. *See e.g.*, GX 10, at 161. Additionally, on March 20, 2015, Respondent Pharmacy filled all of the prescriptions that appeared to be duplicative on the same day, which undermines the notion that they were split scripts. *Id.* at 159–64.

professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 120

b. M.B.

From October 3, 2013, to March 13, 2015, Respondent filled prescriptions for patient M.B., whose address on the prescriptions and fill stickers was listed in Palm Bay, Florida. GX 14, at 1–88. Dr. Gordon testified that these prescriptions raised multiple red flags. For example, the prescriptions filled for hydromorphone and lorazepam on December 30, 2013, constituted a drug cocktail. Tr. 137. Dr. Gordon noted many instances of drug cocktails dispensed to M.B., including Ativan and hydromorphone, MS Contin, or extended-release morphine. Tr. 138. The ALJ noted that beginning in December 2014, Respondent Pharmacy was filling two prescriptions for hydromorphone for M.B. at the same time it filled prescriptions for lorazepam for him. RD, at 41; GX 14, at 65–88. Dr. Gordon testified that a further red flag was the location of the physician in Sanford, which is about an hour away from M.B.’s residence in Palm Bay. *Id.* at 138. The records for patient M.B. demonstrate that M.B. paid for his prescriptions “cash for some things and insurance for others.” Tr. 138; *compare* GX 14, at 10, with *id.* at 12.

The Government’s Exhibit included a letter dated May 6, 2013, with a corresponding note in the patient profile from M.B.’s prescriber. GX 14, at 89–92. The letter included a diagnostic code and list of medications, but “provide[d] no information about why M.B. was making a 170 mile round trip to see” the prescriber. RD, at 41; GX 14, at 90–92. Dr. Gordon testified that nothing in the file, including the letter, resolved the red flags. Tr. 138–39. She concluded that the prescriptions dispensed to M.B. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 139–40.

Respondents’ Owner and PIC testified that she spoke to M.B.’s prescriber and “had a general conversation, not patient specific.” Tr. 640. She testified that “63 out of 91 [of M.B.’s] prescriptions” were paid by insurance, and that M.B.’s payment with cash “raised a red flag that was resolved,” because “the insurance, if they won’t pay for it, then we give them the option to pay cash.”⁴⁸ *Id.* at 642. Respondents’ Owner

⁴⁸ I note that M.B.’s patient records demonstrate that he paid cash for most of his prescriptions for hydromorphone and the other prescriptions with

and PIC testified that M.B. had “presented with a prescription from a different physician,” and that she had “faxed Dr. [C]’s office to see the reason for his discharge” and found out “that he had been discharged for cause,” so she refused to fill further prescriptions for M.B. Tr. 643 (citing RX H, at 274 (found at 283)).

c. C.A.

From December 17, 2013, to February 10, 2014, Respondent Pharmacy filled prescriptions for patient C.A., whose address on the fill stickers was listed as Sebastian, Florida,⁴⁹ which was 86 miles from the prescriber in Orlando. GX 15, at 1–7; RD, at 41 (citing Stipulation 35). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the distance traveled and that all of the prescriptions were paid for in cash. Tr. 141; GX 15, at 2, 4, 6. “Two of the three prescriptions that contain these red flags were filled by [Respondents’ Owner and PIC].” RD, at 42 (citing Tr. 142; GX 15, at 1–2, 5–6). The patient’s profile notes “must have letter of med nec for March 2014 fill Dr. Kuhn.” GX 15, at 7. The exhibits included an undated letter. GX 15, at 8. From the date of the note, it appears that this letter must have arrived around the time of the March 2014 fill and after the three prescriptions in the exhibit. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 143. She concluded that the prescriptions dispensed to C.A. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

d. D.B.

From December 17, 2013, to March 26, 2015, Respondent Pharmacy filled prescriptions for patient D.B. GX 7, at 1–60. D.B.’s address on the fill stickers is in Port St. Lucie, Florida, which is 76 miles from Respondent Pharmacy; however, D.B.’s address on the prescriptions is in Jupiter, Florida. GX

insurance, which would support Respondents’ Owner and PIC’s testimony regarding the resolution of the red flag; however, he used insurance to pay for “hydromorphone 8 MG tablet” on March 13, 2015 (GX 14, at 86) and Respondents offered no explanation to resolve this discrepancy. More importantly, Respondents provided no documentation of the alleged resolution of this red flag or any other of the red flags for patient M.B.

⁴⁹ As the ALJ noted, the address listed for C.A. on the prescriptions had the same street address as the fill stickers, but listed the city as Barefoot Bay, Florida instead of Sebastian, Florida. *Compare* GX 15, at 1, *with id.* at 2. The distance between these two cities is negligible and despite the Government trying to raise the difference as a red flag at the hearing, it does not appear to be relevant. Tr. 141.

7, at 1–60; RD, at 42 (citing Stipulation 27). The doctor’s office in Jupiter, Florida is 111 miles from Respondent Pharmacy. RD, at 42 (citing Stipulation 26).

Dr. Gordon testified that these prescriptions raised multiple red flags, including the type and strength of the medication, the distance traveled to the pharmacy and that many of the prescriptions were paid for with cash. Tr. 144. Additionally, many of the prescriptions filled were for drug cocktails. *Id.* at 144–47. For example, Respondent Pharmacy filled a drug cocktail of: Oxycodone and the highest dose of Xanax (filled by Respondents’ Owner and PIC six days after the oxycodone prescription) in December 2013. GX 7, at 1–3; Tr. 145–46; RD, at 42. Respondents’ Owner and PIC filled a prescription for oxycodone, Percocet and Xanax, which included two immediate release opioids, on July 1, 2014. Tr. 148; GX 7, at 21–26. Respondent Pharmacy filled prescriptions for Percocet, Xanax and Ambien on February 21, 2015. Tr. 146–47; GX 7, at 51–56. Additionally, on October 24, 2014, Respondent Pharmacy filled two identical prescriptions for the highest dosage of oxycodone. Tr. 147; GX 7, at 35–38.

Further, the record demonstrates early fills, which constitute red flags. For example, on June 19, 2014, Respondent Pharmacy filled a prescription for a 30 day supply of Percocet and 30 day supply of oxycodone, and Respondents’ Owner and PIC re-filled both for a 30 day supply on July 1, 2014, despite that 30 days had not passed. Tr. 726–27; GX 7, at 19, 20, 21–14. Respondents’ Owner and PIC admitted that it was an early fill “as to counting the days.” Tr. 727. She further responded “yes” to the question as to whether the early fill constituted a red flag and admitted that nothing in the patient profile or on the prescription resolved the red flag. Tr. 727.⁵⁰

The patient memo box on D.B.’s patient profile includes a note from March 30, 2015, that “address on RX must match driver’s license.” GX 7, at 61; Tr. 733. Further, Respondents’ Owner and PIC testified that she had resolved the red flag that he was traveling so far, because “he had a

⁵⁰ Respondents’ Owner and PIC argued that the fact that the patient “consistently saw the same doctor who wrote subsequent scripts which seemed to legitimize” the prescriptions, because “that would suggest that a conversation was had about how much was used and why he was writing it yet again.” Tr. 729. I reject the notion that a red flag that demonstrates that a prescription may be illegitimate is resolved because the practitioner who issued the initial potentially illegitimate prescription, issued another potentially illegitimate prescription.

residence in Satellite Beach that he intended to move back to” and Respondents provided a copy of what appears to be a scanned prescription, dated March 24, 2015, with a handwritten note in Respondents’ Owner and PIC’s handwriting, stating, “Moving back to Sat Bch July.” Tr. 619; RX H, at 192. However, the ALJ found, and I agree, that “the pharmacy had been filling D.B.’s prescriptions since December of 2013, yet all of the prescription addresses indicated that D.B. lived in Jupiter, Florida, while the fill stickers indicated he lived in Port St. Lucie.” RD, at 43.

Dr. Gordon testified that nothing in the Government’s evidence resolved the red flags on the prescriptions. Tr. 147–49. She concluded that the prescriptions dispensed to D.B. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 149.

e. J.D.

From October 18, 2013, to April 3, 2015, Respondent Pharmacy filled prescriptions for patient J.D. whose address on the prescriptions and most of the fill stickers⁵¹ was listed as Cocoa Beach, Florida, which was 75 miles from the prescriber in Sanford, Florida. GX 16, at 1–72; RD, at 43 (citing Stipulation 36). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the Xanax and hydromorphone were at high dosages, the distance traveled, paying for prescriptions with cash, and drug cocktails of hydromorphone and Xanax. Tr. 152–54; RD, at 43. The ALJ found, and I agree, that the Government’s evidence demonstrates that Respondent Pharmacy filled prescriptions for both hydromorphone, at its highest dosage, and Xanax on 16 different dates. RD, at 43–44 (citing GX 16, at 7–70). Furthermore, the ALJ found, and I agree, that Respondent Pharmacy provided J.D. with early refills on March 21, 2014, May 16, 2014, October 3, 2014, November 21, 2014, and January 9, 2015. RD, at 44 (citing GX 16, at 11–26, 39–62).

The patient’s profile notes a May 14, 2013, letter of medical necessity from Dr. C., seven months after Respondent Pharmacy began filling J.D.’s prescriptions. GX 16, at 73. The letter provides a list of medications, a diagnosis code and the initial date of

⁵¹ The first two prescriptions list an address of Titusville, Florida on the fill stickers and not the prescriptions, but the rest of the prescriptions list Cocoa Beach on both. GX, 16, at 1–4.

treatment, but no explanation for the distance traveled, strength of the medication or the combination of medications. GX 16, at 74–75. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 154.⁵²

f. K.B.3

From December 27, 2013, to January 23, 2015, Respondent Pharmacy filled prescriptions for patient K.B.3, whose address on the prescriptions and fill stickers was listed as Palm Bay, Florida, which was 88 miles from the prescriber, Dr. S., in Sanford, Florida. GX 17, at 1–27; RD, at 44 (citing Stipulation 37). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the hydromorphone was prescribed at its highest strength, the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 155–56; RD, at 44. The ALJ additionally noted that Respondents' Owner and PIC "filled prescriptions for K.B.3 for the maximum available dosage of hydromorphone on June 25, 2014, and July 22, 2014." RD, at 44 (citing GX 17, at 29–35). Respondents' Owner and PIC testified that she did not see any red flags related to the distance traveled or any other red flags related to K.B.3's prescriptions and that she "interacted with him regularly." Tr. 660.

The patient's profile notes that on September 24, 2014, Respondent Pharmacy received a letter of medical necessity from Dr. S. GX 17, at 28. The Government's Exhibits include three different letters dated September 24, 2014, January 30, 2013, and September 2, 2013, explaining that K.B.3 had been under various doctors' care for back pain,⁵³ but they "don't address why the patient's paying cash, they don't address why the patient's going such a long distance to obtain these sought after opioids, desirable opioids." Tr. 157; GX 17, at 29–34. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 156–157. She concluded that the prescriptions dispensed to K.B.3 were not dispensed within the usual course of professional practice and the

⁵² Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for J.D.; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

⁵³ It is noted that one of the records contains a physical exam that notes that the patient's back is normal and does not identify any pain. GX 17, at 33.

pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 157.

g. K.B.2

From October 21, 2013, to March 26, 2015, Respondent Pharmacy filled prescriptions for patient K.B.2, whose address on the prescriptions and fill stickers was listed as Melbourne, Florida, which was 67 miles from the prescriber in Orlando, Florida. GX 18, at 1–98; RD, at 45 (citing Stipulation 38). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the diazepam and hydromorphone were prescribed at its highest strength, the distance traveled to the prescriber, paying for prescriptions with cash. Tr. 158–64; RD, at 45. Dr. Gordon also testified that Respondent Pharmacy filled drug cocktails for K.B.2 consisting of diazepam, hydromorphone and morphine sulfate.⁵⁴ Tr. 159–61. The ALJ concluded that Respondent Pharmacy filled this drug cocktail for K.B.2 13 times between January 13, 2014, and March 26, 2014. RD, at 45 (citing GX 18, at 11–98). He further noted that "[a]lthough K.B.2 would normally receive his prescriptions for these three controlled substances on the same day, he would frequently present the prescriptions to the Pharmacy within a two or three day time frame." RD, at 45 (citing *e.g.*, GX 18, at 11–16, 17–22, 27–32, 33–38, 39–44, 45–50, 77–82, 93–98). Respondents' Owner and PIC also filled prescriptions for morphine sulfate and diazepam on June 10, 2014. RD, at 45 (citing GX 18, at 41–44).

The patient's profile notes that on April 15, 2013,⁵⁵ Respondent Pharmacy received a letter of medical necessity from Dr. P. GX 18, at 99. The letter describes K.B.2's chronic pain and spine injuries and provides an MRI performed on July 30, 2012. *Id.* at 101. Dr. Gordon testified that nothing in the file, including the letter and MRI, resolves the red flags. Tr. 164–166. She stated, "It's the distance. Why is somebody taking a long-acting opioid, immediate-

⁵⁴ The ALJ noted, and I agree, that although the Government did not allege the drug cocktails in the OSC for K.B.2, they were noticed in the prehearing statement. RD, at 45 n.23; Govt Prehearing, at 16.

⁵⁵ The letter predates by several months any of the prescriptions in the Government's records; however, Respondent submitted evidence that it had been filling similar prescriptions for K.B.2 since November 2011. GX 18, at 100; GX 18, at 1; RX H, at 324.

release acting opioid, and Valium driving so far?"⁵⁶ *Id.* at 165.⁵⁷

h. A.G.

From December 20, 2013, to March 20, 2015, Respondent Pharmacy filled prescriptions for patient A.G., whose address on the fill stickers⁵⁸ was listed as Indian Harbor, Florida, which was 65 miles from the prescriber in Orlando, Florida. GX 19, at 1–68; RD, at 46 (citing Stipulation 39). Dr. Gordon testified that these prescriptions raised multiple red flags, including the fact that two immediate-release opioids were prescribed and dispensed at the same time, the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 167–168; RD, at 46. Respondents' Owner and PIC filled prescriptions for A.G. for oxycodone and hydromorphone on February 21, 2014. RD, at 46 (citing GX 19, at 9–12). The ALJ concluded that Respondent Pharmacy filled the two immediate-release opioids 17 times between December 20, 2013, and March 20, 2015. RD, at 46 (citing GX 19, at 1–68). The OSC alleged that A.G. presented both prescriptions every 28 days based on his 28-day prescription for hydromorphone, even though his prescription for 5 oxycodone tablets a day was for a 30-day supply.⁵⁹ OSC, at 8; RD, at 46 (citing GX 19, at 13–60). Therefore, the ALJ concluded, and I agree, that between March 21, 2014, and January 23, 2015, A.G. filled the oxycodone prescription early 11 times with 2 days of 5 tablets each amounting to 10 tablets extra each fill, and as a result, had received an extra 110 tablets of oxycodone over what had been prescribed. RD, at 46 (citing GX 19, at 19–20, 23–24, 27–28, 31–32, 34–36, 39–40, 43–44, 47–50, 55–58). Dr. Gordon testified that two days early she would

⁵⁶ The ALJ found, and I agree, that there was no evidence demonstrating that the patients themselves were driving their cars, but whether or not the patient was driving the car, the distances had to be traveled by some mode of transportation in order to obtain the prescriptions. Tr. 165. Further, I credit Dr. Gordon's testimony that traveling a long distance with lower back pain is a red flag. Tr. 98.

⁵⁷ Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for K.B.2; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

⁵⁸ There is no address on the prescriptions. GX 19.

⁵⁹ The oxycodone prescription was for 150 tablets of oxycodone 30 milligrams to be taken 5 times a day. GX 19, at 14. Therefore, filling the prescription in full every 28 days resulted in A.G. receiving two days extra of tablets of oxycodone.

let go, but she would not be willing to fill for a patient two days early repetitively. Tr. 233. Dr. Grant testified that “after a long period of time . . . There would be a considerable amount. But I don’t know until I have the conversation.” Tr. 510. He further testified that repeatedly filling a prescription two days early would require a conversation first with the patient and then with the prescriber. Tr. 510. Therefore, I agree with the ALJ that the record supports that the repeated filling of these prescriptions constituted an early refill and in accordance with the testimony of Respondents’ Owner and PIC, an early refill is a red flag. Tr. 727. There is no evidence that this red flag was resolved.⁶⁰

The patient’s profile notes a March 22, 2014, letter of medical necessity from Dr. K,⁶¹ four months after Respondent Pharmacy began filling A.G.’s prescriptions. GX 19, at 69. The letter stated that it was necessary for A.G. to use this medication, but did not identify the type of medication. GX 19, at 70; RX H, at 334. Dr. Gordon testified that nothing in the file resolves the red flags and the treatment plan “does not address why there’s two—why the need for two immediate-release opioids, because that doesn’t make any pharmacological sense.” Tr. 168–69; 171. Further, Dr. Gordon stated that the MRI that was included for A.G. raised additional questions, because it was from 2011 and was “dated.” Tr. 305. She concluded that the prescriptions dispensed to A.G. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 169.

i. K.B.1 and C.K.

Respondent Pharmacy filled prescriptions for patients K.B.1 and C.K., whose prescriptions lack addresses. GX 20. The address on fill stickers for K.B.1 was listed as Malabar, Florida, which is 73 miles from the prescriber in Orlando, and the address

for C.K. is listed as Cocoa Beach, Florida, which is 51 miles from the same prescriber. GX 20, at 1–64; RD, at 47 (citing Stipulations 40 and 42). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication being a commonly sought-after opioid (oxycodone) of the highest dosage,⁶² the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 172–175; RD, at 47. Furthermore, Dr. Gordon pointed out that these two patients obtained their prescriptions from the same provider on the same date, so it “seems this was a group, a small group of two going to the same doctor on the same date and filling similar prescriptions.” Tr. 173. Further, on March 31, 2015, K.B.1 and C.K. filled a prescriptions for oxycodone prescribed on the same day from Dr. K. with sequential fill numbers. GX 20, at 29–30, 64–65; Tr. 173–174. The ALJ further found that Respondent Pharmacy filled prescriptions for “these two individuals on the same day 14 times between April 1, 2014, and March 31, 2015.” RD, at 48; (citing GX 20, at 3–30, 37–64).⁶³ Respondents’ Owner and PIC filled two prescriptions for oxycodone for these two patients one minute apart on May 28, 2014, and November 11, 2014. RD, at 48 (citing GX 20, at 7–8, 41–42, 19–20, 53–54).

The patient’s profile for C.K. notes an April 15, 2013, letter of medical necessity from Dr. K. GX 20, at 67. The letter seemed to be in response to a letter from Respondent Pharmacy requesting medical necessity, because it was attached to the letter, and it referred to an attached MRI, which was not in the file. GX 20, at 68–69. The patient’s profile for K.B.1 notes receipt of a letter of medical necessity on April 1, 2014, which gives his diagnosis and does not identify the medication. *Id.* at 65. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 174–76. She concluded that the prescriptions dispensed to C.K. and K.B.1 were not dispensed within the usual course of

professional practice and the pharmacist did not fulfill his or her corresponding responsibility in dispensing these prescriptions. *Id.* at 175–76.

j. J.M. and M.M.

Respondent Pharmacy filled prescriptions for patients J.M. and M.M., whose prescriptions lack addresses, but the address on fill stickers for both patients was listed as Satellite Beach, Florida, which is about 65 miles from Dr. K., the prescriber, in Orlando. GX 21, at 1–42; RD, at 49 (citing Stipulations 46–47). Dr. Gordon testified that these prescriptions raised multiple red flags, including the medication, the distance traveled to the prescriber, drug cocktails of Xanax and oxycodone and carisoprodol and oxycodone and that the doctor’s education was not in pain management, but OB–GYN.⁶⁴ Tr. 177–80; RD, at 49. The OSC also alleged and the evidence clearly supports that “M.M. always sought to pay cash for the prescriptions and J.M. occasionally sought to pay cash.” OSC, at 8. Dr. Gordon also identified a red flag in that the records show a group of patients “going to the same doctor on the same day and then going to the pharmacy and getting their medications dispensed on the same day.” Tr. 178. The ALJ further found that Respondent Pharmacy filled prescriptions for “these two individuals on the same day 15 times between January 7, 2014, and March 31, 2015.” RD, at 49 (citing GX 21, at 3–30, 37–64). It is noted also that these individuals were coming in sequentially during the same timeframe as the C.K. and K.B.1 and all four were patients of Dr. K. The ALJ further found that “many times the prescriptions [sic] numbers on the fill stickers were sequentially only one number apart, and other times they were separated only by a few numbers, and the prescriptions were frequently picked up within minutes of each other.” *Id.* (citing GX 21, at 1–12, 15–30, 33–36, 39–42, 57–60, 63–66, 69–76, 79–82, 85–88, 95–102, 105–116, 119–22, 129–32, 135–38; RX H, at 419). Respondents’ Owner and PIC filled sequential prescriptions for oxycodone for these two patients on January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. RD, at 48 (citing GX 21, at 1–4, 23–26, 33–36, 63–66, 69–72, 79–82, 85–88, 109–12, 135–38.). These prescriptions were dropped off within minutes of each other and the fill numbers were in sequence in all but one instance. *Id.* Additionally, the majority of the prescriptions that Respondent

⁶⁰ Although I agree with the ALJ that these early fills were a red flag, I find that the other red flags for A.G. were egregious enough to demonstrate that filling his prescriptions violated the pharmacist’s corresponding responsibility.

⁶¹ Dr. Gordon remarked that Dr. K’s residency was an OB–GYN and that a pharmacist should look up a practitioner’s credentials where there is a red flag. Tr. 168, 177. She further explained in relation to other patients of this doctor that she thought that the education of the doctor as an OB–GYN was a red flag, because she “didn’t specialize in pain management.” *Id.* at 177. Although I accept Dr. Gordon’s rationale as to why the doctor’s education is a red flag, her practice at the time of the prescriptions was clearly in pain management, and therefore, I am not relying on this possible red flag in my final determination. See GX 19, at 70.

⁶² The ALJ noted and I agree that initially the prescription for K.B.1 was for 15 mg of oxycodone, but it was increased to 30 mg on September 16, 2014. RD, at 47 n.25 (citing GX 20, at 3–4, 15–16).

⁶³ Although Respondents argued that the Government had not presented evidence that the two patients were visiting Respondent Pharmacy as a group, Respondents’ Owner and PIC testified that “I don’t know why they would come in at the same time. But in recollection, they do, I think they do know each other, but I don’t know the relationship.” Tr. At 671; Resp Posthearing, at 34. Respondents’ Owner and PIC testified that she could resolve the red flag of coming in together “by handling them individually.” Tr. 672. However, Dr. Gordon testified that the red flag was presented by the fact that they were a group—handling them individually would ignore the red flag entirely.

⁶⁴ As explained above, I am not considering the doctor’s training as a red flag.

Pharmacy filled for these two patients were for drug cocktails of oxycodone and Soma, and oxycodone and Xanax. RD, at 48–49. Respondents' Owner and PIC filled drug cocktail prescriptions for these two patients on January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. *Id.* (citing GX 21, at 3–4, 89–90, 25–26, 103–04, 33–34, 111–12, 35–36, 109–10, 63–64, 127–28, 65–66, 125–26, 69–70, 133–34, 79–80, 137–38, 81–82, 135–36, 87–88, 139–40).

The patient's profile for J.M. notes a March 29, 2013 letter of medical necessity from Dr. K. GX 21, at 143. The letter states that Dr. K. "feels it medically necessary to prescribe Roxycodone 15 mg" and attaches an MRI stating Lumber IVD degeneration. *Id.* at 144–45. The patient's profile for M.M. notes receipt of a letter of medical necessity on March 14, 2013, which gives his diagnosis and attaches an MRI of his ankle showing mild-to-moderate arthritis and mild synovitis/arthritis in his elbow. *Id.* at 147–49. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 181–82. She testified that the file contained a drug test for M.M., "which is "[g]etting better," but the ALJ noted, and I agree, that it is unclear what the drug test indicates as a "pass." *Id.* Dr. Gordon concluded that the prescriptions dispensed to J.M. and M.M. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 183–84.

k. H.B.

From November 27, 2013, to March 31, 2015, Respondent Pharmacy filled prescriptions for patient H.B. whose address on some of the fill stickers⁶⁵ was listed as Melbourne, Florida, which was approximately 54 miles from multiple prescribers in Orlando, Florida.⁶⁶ GX 22, at 1–122; RD, at 51

⁶⁵ As the ALJ remarked, "[i]t is unclear where H.B. actually lived, because [GX] 22 reports several different addresses;" however, the OSC did not contain any allegations regarding H.B.'s address. RD, at 51; see GX 22.

⁶⁶ Respondents noted that, "[O]n February 3, 2015, the patient transferred to another provider" who prescribed the same medication and whose office was within Respondent Pharmacy's county. Resp Posthearing, at 37 (citing GX 22, at 109). It is noted that the prescriptions written on February 3, 2015, March 3, 2015, March 31, 2015, appear to be written from a different physician in Merritt Island, FL, which does not pose the same distance concern from the pharmacy or residence. (GX 22, at 109, 111, 113). Respondents note that the new doctor prescribed H.B. Oxycodone 30 mg., "the same medication prescribed by Dr. [S.] on previous occasions;" however, Dr. S. notably did not prescribe the duplicative prescriptions of oxycodone that H.B. had received previously. RX H, at 435; Resp Posthearing, at 37. Furthermore,

(citing Stipulation 48). Dr. Gordon testified that these prescriptions raised multiple red flags. Tr. 185–190. She testified that H.B. was receiving "uppers and downers" including Adderall, which is an amphetamine and central nervous system (hereinafter, CNS) depressant, and a red flag was "the necessity for Ambien and Xanax at the same time. Both suppress the CNS system." *Id.* at 185. She stated that the combination of an amphetamine with a depressant is contraindicated, "because one suppresses the central nervous system and one stimulates the central nervous system. They're working against each other." *Id.* at 189. Further, Dr. Gordon noted that a doctor in Orlando was prescribing H.B. oxycodone and the distance traveled was a red flag. *Id.* at 186. H.B. was also obtaining prescriptions for both 15 mg. and 30 mg. of oxycodone at the same time, which Dr. Gordon testified is "called therapeutic duplication." *Id.* at 186–87. Dr. Gordon testified that H.B. was also receiving the highest dose of Ambien, "[s]o on top of the Xanax and on top of the oxys, it's just a dangerous combination. Cocktail." *Id.* at 187. The ALJ found that Respondents' Owner and PIC filled prescriptions constituting therapeutic duplication on July 1, 2014, and one⁶⁷ of the two prescriptions constituting therapeutic duplication on September 23, 2014. RD, at 51 (citing GX 22, at 15–26, 49–52, 71–72). She also filled one of the two prescriptions constituting therapeutic duplication on May 8, 2014—the other was dispensed on May 7, 2014. GX 22, at 41 and 40.

I agree with the ALJ's findings that Respondent Pharmacy filled multiple drug cocktails for H.B. between February 12 and February 20, 2014, for oxycodone, Xanax, and Ambien, on March 12, 2014, for two prescriptions of oxycodone and one of Adderall, and on February 3, 2015, for oxycodone and Soma. RD, at 52 (citing Tr. 187–90; GX 22, at 15–18, 21–26, 28–32, 109–112).

The OSC alleged that H.B. also received early refills. OSC, at 9. The ALJ found, and I agree, that H.B. received early refills: On February 12, 2014, for Adderall, after having received a 30-day supply on January 31, 2014; on February 20, 2014, for alprazolam, after having received a 30-day supply on February 12, 2014; and on February 3, 2015, after

although I find that the prescriptions on March 3, 2015, and March 31, 2015, do not present the red flag of distance traveled or therapeutic duplication, the red flag of drug cocktail remained unresolved, and the February 3, 2015 prescriptions were for a drug cocktail and one was refilled early.

⁶⁷ The ALJ noted and I agree that it appears that B.S. filled the other duplicative prescription. RD, at 51 n.32.

having received a 30-day supply on January 13, 2015. RD, at 51–52 (citing GX 22, at 13–14, 19–20, 21–22, 25–26, 107–10). Respondents' Owner and PIC admitted that a fill with a similar timeframe was an early fill and that an early fill was a red flag. See *supra* Section II(G)(2)(k) (citing Tr. 727).

The records for H.B. include two letters of medical necessity for H.B. GX 22, at 124–25. The letter from Mid Florida Health stated that it was necessary for H.B. to have her medications, but did not identify the type of medication, nor was it clear which prescriptions in H.B.'s file originated from this practice. GX 22, at 124. The other letter is an unsigned form letter from Dr. S. describing office diversion protections with H.B.'s name and her diagnosis as a "lumber tear" and "lumbago," but does not, as the ALJ pointed out, explain why it was necessary to have the medications or what they were. Dr. Gordon testified that nothing in the file resolved the red flags. Tr. 190. Dr. Gordon also stated that she "didn't see any documentation that showed that the pharmacy contacted one doctor and told them what was going on with the other doctor," which would be done under the normal standard of practice. *Id.* at 189.⁶⁸

Based on all of the record evidence, I find that the prescriptions for J.C., M.B., C.A., D.B., J.D., K.B.3, K.B.2, A.G., K.B.1, C.K, J.M., M.M., H.B. raised red flags, because customers arrived in groups, purchased prescriptions with cash, traveled long distances, refilled their prescriptions early, and because the prescriptions were for highly sought after controlled substances at highest strengths. I further find that the letters of medical necessity in Respondents' files did not resolve the multiple red flags on these prescriptions and that, even if these red flags were resolvable, Respondent Pharmacy produced no contemporaneous documentary evidence to support its claim that it resolved them before it filled the prescriptions.

H. Relationship Between Respondent Pharmacy and Respondent LLC

The OSC was addressed to both Respondent Pharmacy and Respondent LLC, but the allegations in the OSC

⁶⁸ Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for H.B.; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

relate only to the actions of Respondent Pharmacy, and not Respondent LLC.⁶⁹ OSC, at 1; RD, at 100; Resp Posthearing, at 77. However, the ALJ found, and I agree, that Respondents are “essentially one and the same.” RD, at 100. In particular, Respondent Pharmacy and Respondent LLC share the same Owner and PIC.⁷⁰ RD, at 52 (citing Tr. 337–43; 345–46; 348–52, 356; GX 27,⁷¹ 28). The DI testified that, although Respondents have separate doors, they share a lobby entrance, entering either door allows access to either business, and they are “separated by a partition wall which comes approximately three-quarters of the way up through the business but stops just shy of the lobby.” Tr. 347; RD, at 52. Further he testified that “the offices in the back seem to be collocated,” and that “during the execution of the admin warrant, the computer that [DEA was] using to access [Respondent Pharmacy’s] data was located on the [Respondent LLC] side of the wall in an office.” Tr. 347.

The DI testified that he had confirmed through Florida Department of Revenue that M.P. was the only employee of Respondent LLC during the last two quarters of 2016. Tr. 354–55; RD, at 53. M.P. testified that he is the Manager of Respondent LLC and his boss is Respondents’ Owner and PIC. Tr. 409–410. M.P. also handles human resources, discipline, interviewing, and payroll for Respondent Pharmacy, but he considers himself to be employed by Respondent LLC, because he is paid out of its funds.⁷² *Id.* at 395, 404, 410; RD,

⁶⁹ Respondents also argue that the claims against Respondent LLC should be “dismissed as a matter of law for lack of notice.” Resp Posthearing, at 77. The OSC clearly is addressed to both Respondents and the hearing proceeded with the consent of the Respondents to consolidate the two cases; therefore, I find this argument meritless.

⁷⁰ Records from the Florida Health Department show Respondents’ Owner and PIC as the Supervising Pharmacist for both Respondents. GX 27, at 8–9; GX 28, at 8–9; Tr. 350–51. Additionally, she is listed as the point of contact on both DEA registrations. GX 27, at 1; GX 28, at 1; Tr. 338–39.

⁷¹ Respondents’ counsel objected to Page 2 of GX 27, because he noted that it cannot be considered a business record due to its inclusion of notes related to the investigation. Tr. 363. This part of the exhibit was produced only to demonstrate that Respondents’ Owner and PIC was listed as the point of contact for both DEA registrations. Respondents’ Owner and PIC testified that she was “the sole owner of both;” and the record does not reflect that there is any dispute of fact about the Respondents’ Owner and PIC’s ownership of both entities, to which she, herself, attested. Tr. 529.

⁷² M.P. testified that he had “never been employed by Respondent Pharmacy,” but to the extent that his statements were intended to demonstrate that he lacked authority over Respondent Pharmacy or support the notion that the two entities were distinct, I do not find his testimony to be credible. Tr. 395. He admitted that he was basing his definition of employment only on the origin of his paycheck. *Id.* He also admitted that

at 53. Additionally, M.P. has been engaged in “managing marketing, and developing [Respondent Pharmacy] for over nine years” and he is the senior individual in both Respondents other than the Respondents’ Owner and PIC. GX 30, at 8; Tr. 395, 416.

The DI testified that he inquired with Respondents’ supplier and Respondent LLC had never purchased any controlled substances under its DEA registration; therefore, the ALJ concluded, and I agree, that Respondent LLC “does not handle controlled substances.” RD, at 53; Tr. 356.

III. Discussion

A. Allegation That Respondents’ Registrations Are Inconsistent With the Public Interest

Under Section 304 of the Controlled Substances Act (hereinafter, CSA), “[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). In the case of a “practitioner,” defined in 21 U.S.C. 802(21) to include a “pharmacy,” Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The applicant’s experience in dispensing . . . controlled substances.

(3) The applicant’s conviction record under Federal or State laws relating to the . . . 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).

According to Agency decisions, I “may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether” to revoke a registration. *Id.*; see also *Jones Total Health Care Pharmacy, LLC v. Drug*

he identified himself as the manager of Respondent Pharmacy on the Notice of Inspection. *Id.* at 320; GX 32. I do not find that the information related to which of Respondents employed M.P. to be relevant to the underlying issues in this case, because I do not find that the Government unlawfully searched Respondent Pharmacy. See *infra* III(B)(1).

Enft Admin., 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enft Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enft Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enft Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enft Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); see also *Hoxie*, 419 F.3d at 482. “In short, . . . 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; what matters is the seriousness of the registrant’s misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

Under DEA’s regulation, “[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government’s evidence in support of its *prima facie* case is confined to Factors Two and Four.⁷³ I find that the Government’s

⁷³ Respondents note that the Florida Board of Pharmacy has not made a recommendation in this matter, nor have the Respondents been convicted of any state or federal crimes related to controlled substances. Resp Posthearing, at 50. As Respondents have noted, the record in this case contains no evidence of a recommendation regarding Respondent Pharmacy’s privilege to operate as a pharmacy by the relevant state licensing board or professional disciplinary authority or any action by the state licensing board that demonstrates that it has considered the same facts in relation to Respondent Pharmacy’s continued licensure. See *John O. Dimowo*, 85 FR 15,800, 15,809 (2020). Prior Agency decisions have found that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation. See, e.g., *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5490 (2019) (finding that “where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.”); *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,340 (2012); *Roni Dreszer, M.D.*, 76 FR 19,434, 19,444 (2011). Accordingly, I agree with the ALJ’s finding that Factor One does not weigh for or against revocation in this matter. RD, at 61. I also agree with the ALJ that, because there is no evidence related to any convictions “relating to the manufacture, distribution, or dispensing of controlled substances,” Factor Three does not weigh for or against revocation in this case. RD, at 61 (citing 21 U.S.C. 823(f)(3)).

evidence with respect to Two and Four satisfies its *prima facie* burden of showing that Respondents' continued registrations would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). I further find that Respondents failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors Two and Four—The Respondents' Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under the CSA, it is "unlawful for any person knowingly or intentionally . . . to . . . distribute[] or dispense, or possess with intent to . . . distribute[] or dispense, a controlled substance" "except as authorized" by the Act. 21 U.S.C. 841(a)(1). A pharmacy's registration authorizes it to "dispense," or "deliver controlled substance to an ultimate user . . . by, or pursuant to the lawful order of . . . a practitioner." 21 U.S.C. 802(10).

(a) Allegations Regarding Respondent Pharmacy's Failure To Exercise its Corresponding Responsibility

According to the CSA's implementing regulations, an effective controlled substance 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).

The evidence in this case demonstrates that Respondent Pharmacy filled prescriptions from a group of Dr. R's patients repeatedly "at approximately the same time, one after the other." RD, at 71; *supra* Section (II)(G)(1)(a). Dr. Gordon testified that these red flags are not resolvable and she would not have filled the prescriptions. *Id.*; Tr. 111. The record demonstrates numerous red flags associated with the prescriptions issued to patients of Dr. R. For example, S.P. and E.H. made a 340 and 350 mile-round trip respectively to see Dr. R. and received the highest dosage of opioids and paid cash. RD, at 72; *supra* Section (II)(G)(1)(a), (e). In addition, J.S.1 and J.S.2 lived at the same address, received their prescriptions often on the same day for highly diverted and abused controlled substances, and travelled long distances. RD, at 75. In accordance with the testimony of Dr. Gordon, these prescriptions should not have been filled and Respondent Pharmacy violated its corresponding responsibility in filling them. Further, the ALJ found, and I agree, that nothing in Respondent Pharmacy's files resolved any of the red flags for the prescriptions for the patients of Dr. R., where they may have been resolvable, and Respondent Pharmacy violated its corresponding responsibility by filling the prescriptions in the Government's evidence for Dr. R.'s patients. RD, at 71–80; *supra* Section (II)(G)(1).

Further, the evidence shows that Respondent Pharmacy filled prescriptions written by other physicians that contained multiple red flags indicating that the prescriptions were not issued for a legitimate medical purpose. J.C. presented five prescriptions for the same short-acting opioid and the doctor's instructions allowed J.C. to be taking all of them at once. Dr. Gordon testified that she would not have filled these prescriptions. Respondents' Owner and PIC offered two different justifications for filling them. There is nothing in Respondent Pharmacy's records that resolves the red flags and Respondents' post-hoc justification is inconsistent,

which clearly demonstrates that her memory of events is not adequate to determine whether the red flags were resolved. Section (II)(G)(2)(a). The prescriptions that Respondent Pharmacy filled for M.B. raised unresolved red flags for highly abused opioids and cocktails, payment by cash, long distances to obtain and fill prescriptions, and high dosages. Finally, the ALJ found, and I agree, that Respondent Pharmacy filled prescriptions for C.A., D.B., J.D., K.B.3, K.B.2, and A.G. in violation of its corresponding responsibility and outside the course of professional practice of pharmacies, because the numerous red flags of highly diverted and abused controlled substances, distance travelled, cash payments, early refills, and cocktails were unresolved.

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

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 as evidenced by it “repeatedly distribut[ing] controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion.” Govt Posthearing, at 41.

As I already found, many prescriptions from Respondent Pharmacy presented multiple, red flags including long distances, cash payments, drug cocktails, high doses/quantities of high-alert controlled substances, patients with the same address presenting the same prescription within a short period of time, patients sequentially presenting prescriptions prescribed by the same doctor on the same day, therapeutic duplication (two drugs in the same class prescribed together), and early refills. 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 10,876, 10,898, *pet. for rev. denied*, 789 F. App’x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy*, 81 FR 49,816, 49,836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe*, 79 FR 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS*, 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy*, 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other

pharmacies’ refusals to fill the prescriptions). Dr. Gordon credibly testified as to the presence of red flags on the prescriptions that Respondent Pharmacy filled. Respondents’ Owner and PIC also testified that she recognized red flags on the prescriptions.

I agree with the ALJ that Respondent Pharmacy “repeatedly filled numerous prescriptions for highly abused and diverted controlled substances in the face of blatant red flags. The Pharmacy did little to nothing to resolve these numerous red flags, but instead relied on ‘rubber stamped’ types of letters of medical necessity that were often not tailored towards a particular patient, and were obviously missing information.” RD, at 97. When asked by Respondents’ counsel if she “believe[d] pharmacists can make decisions about the treatment of patients’ medical conditions,” Dr. Gordon testified, “Pharmacists are part of the medical care team. We’re there, we’re the stop gate to make sure that that patient is safe and taking a medication that’s appropriate for them.” Tr. 217. The evidence in this case shows that Respondent Pharmacy failed at the responsibility described by Dr. Gordon.

Dr. Gordon credibly testified that a Florida pharmacist should have recognized these red flags and that a Florida pharmacist exercising his or her corresponding responsibility would not dispense controlled substances without investigating, documenting the investigation, and resolving any red flags. Respondents’ Owner and PIC also admitted during her testimony that she had actual knowledge of some of the red flags on the prescriptions, but that she felt like she had resolved them.

I have considered and reject Respondent Pharmacy’s claim that it investigated and resolved the red flags on the subject prescriptions before they were filled and therefore complied with its corresponding responsibility. Tr. 796. Respondents’ Owner and PIC testified that she relied on written policies and procedures that she stated Respondent Pharmacy had in place, which by virtue of being followed would have resolved the red flags prior to dispensing; however, Respondent Pharmacy produced neither the procedures themselves⁷⁴ nor any

⁷⁴ Respondents contest that requiring them to document their resolutions of red flags is inappropriately “requiring Respondents to prove their innocence.” Resp Exceptions, at 17. The Government in this case demonstrated that the standard of practice in Florida required documentation of the resolution of red flags and Respondent Pharmacy did not document. The Government proved that Respondent Pharmacy

evidence that, if they had been in place, they had been followed. For example, she stated that payment of cash is not a red flag because Respondent Pharmacy’s policy was to ask for insurance from every customer, and then concluded that if a customer paid cash, it was a result of a negative answer regarding insurance, thereby resolving the red flag. Tr. 719. She stated that she is not assuming it happened, because “it is the policy.” *Id.* However, despite the policies that she so strongly asserted were in place, according to her testimony, B.S. filled dozens of prescriptions in violation of those policies and had to be counseled. *Id.* at 560, 770. In addition, she admitted to making exceptions to the policies herself without documenting her rationale for the departures. Tr. 773. The prescriptions or patient profiles from Respondent Pharmacy do not contain pharmacist remarks regarding the resolution of red flags on the prescriptions, and Dr. Gordon testified that the letters from the prescribers, which were often issued after controlled substances had already been dispensed, did not adequately resolve the red flags. *See United States v. Hayes*, 595 F.2d at 260 (“Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder’s concluding that the pharmacist had the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.”). Furthermore, Dr. Gordon credibly testified that some of the prescriptions, particularly to groups of Dr. R.’s patients, contained red flags that were not resolvable and the prescriptions should not have been filled. *Id.* at 110–11. Finally, I agree with the ALJ that Respondents’ Owner and PIC’s testimony was not always credible, particularly where she exaggerated her relationship with her customers in order

repeatedly filled multiple prescriptions with red flags demonstrating that Respondent Pharmacy had violated its corresponding responsibility and that Respondent Pharmacy’s registration is inconsistent with the public interest. The burden shifts to the Respondents to show why they can be entrusted with the responsibility carried by their registrations. *Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (citing *Samuel S. Jackson*, 72 FR 23,848, 23,853 (2007)).

to suggest that she had resolved red flags. RD, at 13–14.

Respondents further contest that when Respondents' Owner and PIC was confronted with one employee, B.S., who "exercised his own independent judgment and filled prescriptions from South Florida, she halted the practice and counseled the employee." Resp Posthearing, at 52. Although Respondents' Owner and PIC stated that, although she had no personal knowledge that the prescriptions were legitimate, she thought that Dr. R. was legitimate, but she also stated that she had counseled B.S., "because we don't want the scrutiny of it." *Id.* at 560, 770, 557; RX H, at 62. She clearly understood that there was a high probability that the prescriptions were illegitimate due to the red flags that they presented and that they suggested the need for "scrutiny." Yet in filling the prescriptions, neither she nor B.S. provided any documentation regarding the "scrutiny" that the prescriptions presented. As stated above, she also testified that she, herself, filled Dr. R.'s prescriptions twice. Tr. 771; 560.

Further, I reject the insinuation that Respondent Pharmacy should not be held responsible for the actions of its pharmacist B.S. When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge. *See Pharmboy Ventures Unlimited, Inc.*, 77 FR 33,770, 33,772 n.2 (2012) ("DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.'"); *S&S Pharmacy, Inc.*, 46 FR 13,051, 13,052 (1981) (the corporate pharmacy acts through the agency of its PIC). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.

At times during her testimony, Respondents' Owner and PIC stated that she relied on the personal judgment of her pharmacists, while also stating that the pharmacy's policy is "updated regularly, but it's generally just a day-to-day hands-on training. I'm there all the time." Tr. 709. Ultimately, as the Owner and PIC, she is responsible for the actions of Respondents, and her own statements support that notion. She chose to hire someone while knowing that he had a criminal history and Board of Pharmacy disciplinary history, she had the means to meaningfully supervise his work because she was present at Respondent Pharmacy "all the time," and further, as the individual

responsible for the entity, she had a duty⁷⁵ to ensure that the pharmacists she employed, while acting in the scope of their employment, were following her policies and the law. Finally, the violations of corresponding responsibility and standard of practice in this case are not limited to the actions of B.S. The Government's evidence clearly demonstrates that Respondents' Owner and PIC herself filled prescriptions with multiple red flags herself for customers such as H.B., C.A., D.B., K.B.2, and J.S.2.

I have also considered and reject Respondents' argument that Dr. Gordon relied only on DEA decisions to identify red flags. Resp Exceptions, at 7. Dr. Gordon testified that "[r]ed flags is just a term . . . that the lawyers and the Courts have come up with, but . . . there's always been red flags, since inception of pharmacy." Tr. 209–10. She further stated that "[t]he Courts called it red flags. Pharmacists just call it checking to make sure that that medication is safe or legitimate." *Id.* at 211. Dr. Gordon's testimony is further supported by Respondents' Owner and PIC's testimony, that she was aware that when a pharmacist spots a red flag for a prescription, that she must "resolve it, and if [she] cannot resolve it, not to fill it." Tr. 566; RD, at 24. Respondents' Owner and PIC also testified that she understands the concept of red flags and that she recognized that there are red flags in Respondent Pharmacy's prescriptions. Tr. 796. There is no evidence that the Agency has set a standard independent of pharmacy practice as Respondents have contended. Resp Exceptions, at 9. Dr. Gordon testified repeatedly that

⁷⁵ I reject Respondents' claim that imposing a duty on its pharmacists to ensure that they were meeting their corresponding responsibility would violate Florida Rule 64B16–27.831(2)(a), which provides that "[w]hen validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment." Resp Posthearing, at 69 (quoting Fla. Admin Code Ann. r. 64B16–27.831(2)(a)). There is no evidence that the State of Florida's provision would prevent an employer from ensuring that an employee was resolving and documenting red flags. The judgment in question is resolving "any concerns about the validity of the prescription," not complying with pharmacy policies, to include documenting the pharmacist's rationale for deciding to fill a prescription whose legitimacy was in question. *Id.* In fact, the regulation itself requires that the pharmacist resolve the concerns. *Id.* I decline to permit Respondent Pharmacy to hire an employee, whom it knew to have disciplinary issues and a criminal record, to fill dozens of prescriptions whose legitimacy was in question and then to relinquish all responsibility for that pharmacist's actions. The DEA registration is issued to the pharmacy, not the individual pharmacist, and the pharmacy has responsibility under federal law to ensure compliance with the law in order to maintain its registration.

documentation was "the standard of practice, if there's something questionable about a prescription, you document it after you speak with the patient or the doctor," and further, she gave a credible rationale as to why it was the standard of practice, "so that you can let other pharmacists know what happened the time before." Tr. 215, 44–45. If there were red flags on a prescription, which were necessary to be resolved in order to confirm the prescription's legitimacy, it is unclear how another pharmacist filling a subsequent prescription would know that they had been resolved without documentation. Dr. Gordon's testimony is supported by the facts in this case, because Respondents' Owner and PIC blamed B.S. for filling prescriptions not in accordance with policy, but then filled prescriptions for the same patients with the same red flags. Without documentation of the resolution of the red flags, there was no way for her to know whether B.S. had resolved them, or in fact, whether she had resolved them. Her memory of her own conversations with customers that supposedly resolved the red flags did not always prove to be reliable. *See e.g.*, Tr. 596, 671, 673, 716, 720.

Respondents argue in their Exceptions that DEA is acting outside of its statutory authority in determining that the course of professional practice in Florida requires a pharmacist to resolve and document red flags. Resp Exceptions, at 8–10. Part of Respondents' argument is that the Florida statutes cited by the Government do not require the documentation of red flags. *Id.* at 10. Respondents admit that under Florida law, "if a pharmacist identifies one of the enumerated 'red flags' in the regulations, 'the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'" Resp Exceptions, at 11 (quoting Fla. Admin. Code Ann. r. 64B16–27.810.) However, Respondents argue that the regulations do not require the documentation of the resolution of such red flags. *Id.*

The Florida Board of Pharmacy requires a pharmacist to conduct prospective drug use review on each prescription and identify such issues as "[o]ver-utilization," "[d]rug-drug interactions," "[i]ncorrect drug dosage," and "[c]linical abuse/misuse," and shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber. Fla. Admin. Code Ann. r. 64B16–27.810 (2020). A preceding section of the regulations

states that “a patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.” Fla. Admin. Code r. 64B16–27.800(1). The regulation further states that among the information required to be maintained in the patient records is the “pharmacist comments relevant to the individuals’ drug therapy, including any other information peculiar to the specific patient or drug.” *Id.* at (1)(f). Respondents argue that “there is no definition available as to what constitutes ‘peculiar’ information” and that it “should be read to mean peculiar information relevant to treatment.” Resp Exceptions, at 11. The Government argued, and the ALJ found, that Florida law requires not only the resolution of red flags, but also a “pharmacist is required to maintain a patient record, allowing for immediate retrieval of information relative to previously dispensed drugs and those records are to include comments peculiar to the patient, and information provided by a licensed health care provider.” RD, at 65.

Agency decisions have examined whether the resolution of red flags is required by these provisions of Florida law. *See Trinity Pharmacy II*, 83 FR 7304, 7329–30 (2018); *Superior Pharmacy I and II*, 81 FR 31,310, 31,336 (2016) (stating that the regulation required documentation of the prospective drug review in the patient profiles). The Respondents do not argue that the drug review provision is inapplicable, merely that the documentation requirement is more appropriately read to require documentation of information “relevant to treatment.” Resp Exceptions, at 11. The drug review in Florida law appears to be an affirmative obligation on the part of the pharmacist, and therefore, it would be consistent with such an affirmative obligation to read the preceding section of the regulation to require documentation of the prospective drug review. As stated above, the documentation requirements in this section “shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.” Fla. Admin. Code r. 64B16–27.800(1). In its Posthearing Brief, the Government cited to these regulatory provisions, not as an

individual violation of Florida law,⁷⁶ but as further evidence that Respondent Pharmacy filled prescriptions for controlled substances outside the usual course of practice in Florida. Gov Posthearing, at 44–45. I ultimately do not find it necessary to find a violation of this regulation in this case, because the Government has proven by substantial evidence that Respondent Pharmacy violated its corresponding responsibility and filled prescriptions outside the standard of practice in Florida by not documenting the resolution of the red flags through credible expert testimony. I do consider this regulation to further support the testimony of Dr. Gordon regarding the importance of documentation in the standard of practice of pharmacy in Florida.

Dr. Gordon testified repeatedly that the standard of practice of pharmacy in Florida required documentation of the resolution of red flags. When Respondents’ counsel summarized her testimony and asked if she was stating that documentation was “a requirement for pharmacists in the State of Florida to document red flags,” she stated, “Yes. To show that—for each red flag, if there was a specific situation where you felt that the medication was for a legitimate medical purpose, that should be documented.” Tr. 206. Dr. Gordon is not a lawyer and is not an expert in the details of state law, but she is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in her state, whether that is derived from state law, mandatory training, standards of care or otherwise. Respondents imply that Dr. Gordon’s inability to draw a solid conclusion as to where the requirement to document the resolution of red flags is written somehow demonstrates that there is no such requirement in the standard of practice. Resp Exceptions, at 10. I reject such fallacious reasoning. In this case, I find that Florida state law can be reasonably interpreted to support Dr. Gordon’s testimony, but that her testimony is independently credible that documentation of the resolution of red flags is a requirement of the practice of pharmacy in the State of Florida.

Accordingly, in summary, I agree with the ALJ’s finding in the RD that the Government has proven by substantial evidence that Respondent filled prescriptions for controlled substances that the pharmacists knew were not prescribed for legitimate medical

⁷⁶ The Order to Show Cause alleged that in filling prescriptions with multiple red flags and not documenting their resolution, Respondent Pharmacy violated Fla. Admin. Code Ann. r. 64B16–27.800 and 64B16–27.810. OSC, at 10.

purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a) and outside the usual course of professional practice in violation of 21 CFR 1306.06. I find these violations of federal law and negative dispensing experience to weigh against the Respondents’ continued registrations under Factors Two and Four.

I further find that the Government has demonstrated that pharmacists at Respondent Pharmacy violated Fla. Stat. § 893.04(2)(a) (2009). During the time period covered by the Show Cause Order, Florida law required that a pharmacist, before dispensing a controlled substance listed in schedules II through IV, first determine “in the exercise of her or his professional judgment . . . that the order is valid.” Fla. Stat. § 893.04(2)(a) (2009); *see also* Fla. Stat. § 893.02(22) (2011) (defining a “prescription” as an order for drugs “issued in good faith and in the course of professional practice . . . and meeting the requirements of s. 893.04.”). In this case, I have found that the Government established by substantial evidence that pharmacists at Respondent Pharmacy filled prescriptions outside the usual course of professional practice of pharmacy. I find that the pharmacists did not exercise their professional judgment in acting outside of the usual course of practice and that this is evidence of Respondent Pharmacy’s noncompliance with state law, which I consider under Factor Four and weigh against Respondents’ continued registrations.

(b) Allegation That Respondent Pharmacy Filled Prescriptions Written for “Office Use” in Violation of 21 CFR 1306.04(b)

DEA regulations state that “[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.” 21 CFR 1306.04(b). As I found above, Respondent Pharmacy dispensed testosterone to Dr. I’s office on eight occasions and Dr. A’s office once, between September 23, 2014, and January 28, 2015. GX 3; RD, at 29; *supra* Section II(F). As I also found above, the Government’s expert witness testified that the fact that the prescriptions were labeled “for office use,” assigned a prescription number, issued fill stickers, and included the office name in the place of a patient’s name demonstrated that the prescriptions were issued outside of the usual course of professional practice. Tr. 64–65.

The Government's expert testified that "if there were an invoice and the prescription was issued to a practitioner," it would have resolved the issue, but clarified that it was not within the acceptable standard of practice to order controlled substances from a pharmacy to be distributed to a dispensing practitioner and then report it to the Florida Prescription Drug Monitoring Program (E-FORCSE). *Id.* at 278–79; 288–89. Respondents' Owner and PIC maintained that these were "wholesale transactions" and not prescriptions. Tr. 697. She maintained that Dr. I. was registered as a dispensing practitioner. Tr. 578. Respondents also argued that Dr. I. was administering the controlled substances to patients in the office.⁷⁷ Resp Posthearing, at 10. The Government argued that these claims were based solely on conjecture and that the clear evidence was that prescriptions with fill stickers were dispensed "for office use." Govt Exceptions, at 1–2; *id.* at 2 n.1.

The ALJ did not sustain the 21 CFR 1306.04(b) violation, because he found that in order to prove such a violation, "it was incumbent upon the Government to prove that Drs. [I and A] were going to be dispensing the controlled substances to patients." RD, at 69. He noted that the prescriptions stated that they were "for office use" and that was consistent with Respondents' Owner and PIC's testimony that the practitioners were administering the testosterone and not dispensing it and that therefore, the prescriptions fell into an exception to the regulatory requirement. *Id.* at 69–70. The Government argued in its Exceptions that the ALJ had applied an exception to the regulation that does not exist and that the ALJ's reasoning related to his finding under 1306.04(b) incorrectly implied that it was "incumbent upon the Government to prove that [the practitioners] were going to be dispensing the controlled substances to patients." RD, at 69; Govt Exceptions, at 3–4. The Government further argued that the ALJ's analysis of the "office use" prescriptions under Section 1306.04(b) was inconsistent with the Agency's decision in *Roberto Zayas, M.D.*, 82 FR 21,410, 21,424 (2017). Govt Exceptions, at 2.

Dr. Gordon clearly testified that if the purpose was to transfer the controlled substances, there was a lawful way in which to conduct such transactions, but issuing and dispensing pursuant to a prescription, using fill stickers and reporting to E-FORCSE was not within

the usual course of professional practice of pharmacy in Florida. If Respondent Pharmacy had intended these documents to be invoices, they facially did not appear to be so, and Respondent did not produce any additional documentation that justified the filling of these prescriptions issued for "office use."⁷⁸ I agree with the Government that the prescriptions themselves appeared to violate 21 CFR 1306.04(b). *See Roberto Zayas, M.D.*, 82 FR 21,410, 21,425 (2017) (holding that prescriptions written "for office use" violated 21 CFR 1306.04(b) and holding the prescriber responsible for calling in the prescriptions).

In this case, the Government initially stated that Dr. Gordon would testify that these prescriptions raised red flags that were not resolved. Govt Prehearing, at 8. The Government's expert did not discuss red flags related to these prescriptions, but did conclude that they were issued outside the usual course of professional practice. Tr. 65–66. In its Posthearing Brief, the Government argued that the prescriptions were issued in violation of 1306.04(b) "and accordingly were not dispensed in the usual course of professional practice." Govt Posthearing, at 9. However, the Government did not allege a violation of 21 CFR 1306.06⁷⁹ for these prescriptions, nor did it sufficiently establish through its expert witness that these prescriptions were dispensed in violation of Respondent Pharmacy's corresponding responsibility in violation of 21 CFR 1306.04(a), and even if the Government had established this, it appeared to abandon this theory in its Posthearing Brief. Therefore, I will not consider the allegation related to the prescriptions issued for "office use," because the Government has not

⁷⁸ Respondents claim that in November 2014, Respondent Pharmacy started using invoices in lieu of prescription pads. Resp Posthearing, at 64 (citing GX 3, at 5–13). The documents in question appear different from the other pages of the exhibit, with the exception of GX 3, at 11, but they state "Prescription Form" at the top. The Respondents have not adequately explained the difference between the different forms and there are fill stickers associated with all of them. However, ultimately, I have not sustained this allegation, so I find it unnecessary to determine the accuracy of Respondents' unexplained claim that some of the exhibits may have been invoices.

⁷⁹ Although the Government had alleged generally that Respondent Pharmacy acted outside the usual course of professional practice in the Order to Show Cause, the Government did not adequately notice a violation of 1306.06 in the context of the 1304.04(b) violation. I have reviewed the Respondents' filings on this matter and I do not find evidence that they were on notice of this theory regarding the 1306.06 violation in order to have litigated the issue by consent. *See Farmacia Yani*, 80 FR 29,053, 29,059 (2015).

adequately established a legal basis for my finding of a violation for Respondent Pharmacy's filling "office use" prescriptions in this case. *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 FR 10,876, 10,900 (2018) (noting that 21 CFR 1306.04(b) only prohibits the issuance of a prescription).

(c) Allegation That Respondent Pharmacy Filled Prescriptions That Were Issued by a Practitioner to Himself in Violation of Fla. Stat. § 458.331(1)(r)
The Order to Show Cause alleged that Respondent Pharmacy filled prescriptions for controlled substances "despite unresolved red flags includ[ing] . . . prescriptions [] written in violation of Florida law, Fla. Stat. 458.331(1)(r)." The ALJ found that "the Pharmacy violated its corresponding responsibility by filling prescriptions that J.S.3 wrote to himself" RD, at 68. Respondents argued that the ALJ incorrectly interpreted Florida state law relating to Respondent Pharmacy's filling of J.S.3's prescriptions to himself. Resp Exceptions, at 5.

Respondents' primary argument is that "[a] plain reading of the statute holds that a physician can prescribe to himself, so long as he is not the one dispensing the medication." Resp Exceptions, at 5. In making this argument, Respondents state that "the statute prohibits a physician from prescribing to himself, unless another practitioner 'prescribed, dispensed, or administered' the controlled substances,"^{80 81} *Id.* (citing Fla. Stat. § 458.331(1)(r) (emphasis added by Respondents)). Although the basis of the Respondents' argument that the term "or" would permit a physician to prescribe to himself as long as a different practitioner dispensed the controlled substance is well-grounded in canons of statutory construction, Respondent submitted, and I can find, no evidence that the State of Florida permits such a loophole in its prohibition against self-prescribing.⁸² If

⁸⁰ The prescriptions to J.S.3 involved testosterone and oxycodone, which are controlled substances under Fla. Stat. § 893.03.

⁸¹ The ALJ found that the Respondents' evidence included multiple documents that indicated that J.S.3 had not been treated by another doctor, but had been self-prescribing. RD, at 68 (citing RX H, at 2–3, 15–22, 40–41). I agree with the ALJ on this point. Respondents clarify in their Exceptions that their argument is not that there was another practitioner involved in the prescribing or treatment, but that Respondent Pharmacy itself created the exception by dispensing the controlled substances. Resp Exceptions, at 5.

⁸² For example, there is no indication or discussion of a distinction made on Respondents' alleged exception in this Florida disciplinary case on point, just that he violated Fla. Stat.

⁷⁷ It is noted that these two theories seem to contradict each other.

Respondents were correct in this interpretation, it would appear that a practitioner could only violate this law if he prescribed to himself and also dispensed the prescription to himself. Further, the testimony of Respondents' witnesses contradicts this reading of Florida law. D.M. and Respondents' Owner and PIC testified that the Board of Pharmacy visited in 2015 and told Respondents' Owner and PIC "that it was not lawful" to fill a prescription that a doctor had written for himself, after which D.M. changed his advice and Respondent Pharmacy did not fill any further prescriptions. Tr. 573; Tr. 809–10; *supra* Section III(E)(1). Therefore, the record contradicts Respondents' argument that the Florida Board of Pharmacy interprets the statute in the manner that Respondents suggest. However, as explained below, I do not believe that whether the law was or was not actually violated by J.S.3's self-prescribing is essential to a finding that Respondent Pharmacy violated its corresponding responsibility for these prescriptions.

The second argument that Respondents proffered is that Fla. Stat. § 458.331(1)(r) is only grounds for discipline of physicians, not pharmacists. The Florida statute specifically provides that its provisions do not apply to "[o]ther duly licensed health care practitioners acting within the scope of their practice." Fla. Stat. § 458.303(1)(a); Resp Exceptions, at 4. Fla. Stat. § 456.001(4) includes pharmacists in the definition of "health care practitioners." However, as established herein, Florida law clearly requires that a pharmacist, before dispensing a controlled substance listed in schedules II through IV, first determine "in the exercise of her or his professional judgment . . . that the order is valid." Fla. Stat. § 893.04(2)(a) (2009). Additionally, as found above, Dr. Gordon credibly testified that "[a] pharmacist should not have filled any prescription written by a physician that wrote it for himself, a controlled substance" and concluded that these prescriptions were not filled within the standard of practice of pharmacy in Florida. Tr. 62. Therefore, based on Dr. Gordon's testimony, I find that a pharmacist filling these prescriptions could not have been acting within the

scope of his or her practice in order to meet the exception set forth in Fla. Stat. § 458.303(1)(a), and the exception would not apply.

Most importantly, the Government's legal theory about these prescriptions was not that Respondent Pharmacy had directly violated this Florida statute in filling these prescriptions, but instead that J.S.3 wrote the prescriptions in violation of the law and the prescriptions raised red flags, which Respondent failed to resolve, resulting in a violation of its corresponding responsibility. OSC, at 4; Govt Prehearing, at 8; Govt Posthearing, at 7–8. *See supra* II(E)(1).

As to the testimony of D.M. that he had provided legal advice to Respondents' Owner and PIC in which he maintained that a physician could prescribe controlled substances to himself as long as a pharmacist dispensed the prescription, I do not find that this alleged advice resolved the red flags that were presented by these prescriptions for several reasons. First, Respondent did not produce documentation of the advice. Second, per D.M.'s testimony the advice was general and did not pertain to the particular circumstance of J.S.3's prescriptions. *Supra* II(E)(1). Most importantly, D.M. testified that at the time he used the word "scrutiny" in lieu of the term red flag, and that his advice was that "it wasn't prohibited and it was permissible but required scrutiny." *Id.*; Tr. 810. Dr. Gordon testified that the usual course of professional practice in Florida required that the red flags be resolved prior to the pharmacists' dispensing of the prescriptions and that those resolutions be documented. There is no evidence of Respondent Pharmacy's documentation regarding this red flag. As D.M. testified, the fact that there was even a question about whether the prescriptions violated Florida law presented such "scrutiny" or a red flag, and the record evidence demonstrates that Respondent Pharmacy was advised by its attorney that this scrutiny was "required." Therefore, I find that Respondent Pharmacy violated its corresponding responsibility⁸³ in dispensing prescriptions to J.S.3 without resolving the red flag due to Fla. Stat. § 458.331(1)(r), and that the filling of

these prescriptions is appropriately considered under Factor Four as evidence that Respondent Pharmacy was not in "compliance with applicable State, Federal or local laws relating to controlled substances." 21 U.S.C. 823(f)(4).

(d) The Legitimacy of the Prescriptions

Respondents cited,⁸⁴ and the ALJ applied, a clause written by one of my predecessors as part of a footnote in a prior Agency decision (hereinafter, the *Hills* footnote). *Hills Pharmacy, LLC*, 81 FR 49,816, 49,836 n.33 (2016) ("[I]t is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose."). The clause is footnoted in one other subsequent Agency decision. *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 FR 10,876, 10,899 n.36 (2018), *pet. for review den.*, 789 F. App'x 724 (11th Cir. 2019).

Although the sentence containing the clause is not entirely clear, the clause itself states as "true" that a pharmacist may not be found to violate his corresponding responsibility unless the prescription at issue violates 21 U.S.C. 829. The concept labeled "true" directly conflicts with DEA regulations and decades of Agency decisions interpreting those regulations.

I unequivocally reject the clause and the notion that a pharmacist may not be found to violate his corresponding responsibility unless the prescription at issue violates 21 U.S.C. 829. I affirm the part of the footnote rejecting the respondent's argument, which stated, "Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose . . . Respondent is mistaken."

A pharmacist's corresponding responsibility is to assess prescriptions according to the applicable standard of practice, which typically requires the pharmacist to recognize and resolve red flags on the prescriptions prior to filling them, and to act on that assessment by filling or declining to fill the prescription.

The language in 21 CFR 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons. *See*,

⁸³ 458.331(1)(r). *Department of Health vs. Nader W. Said, M.D.*, DOH Case No. 2014–08153 (December 19, 2016), at 19. Available at <https://apps.mqa.doh.state.fl.us/MQASearchServices/Document/Mjk1Nzc5ODY%3D>. If the statute were as limited as Respondents argue, then it would seem that a charge would necessitate including self-dispensing as well or additional facts related to the dispensing of the prescriptions.

⁸³ Respondents' final argument is that the Government did not demonstrate that the prescriptions to J.S.3 "lack[ed] a legitimate medical purpose." Resp Exceptions, at 6. The Respondents cite to the footnote in *Hills Pharmacy, LLC*, 81 FR 49,816, 49,836 n.33 to support this notion, which is further discussed *infra* Section III(A)(1)(d). I reject this argument the reasons discussed in relation to *Hills* below.

⁸⁴ Respondents argued that the Government must prove that the prescriptions Respondent Pharmacy filled lacked a legitimate medical purpose in order to show that Respondent Pharmacy violated its corresponding responsibility based on the language of the *Hills* footnote. Resp Exceptions, at 7.

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). A pharmacist must exercise professional judgment when filling a prescription issued by a physician.

Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, 55 FR 4729, 4730 (1990). Respondents have presented no good reason for me to depart from DEA's decades-long statement of a pharmacist's corresponding responsibility, and I decline to do so.⁸⁵

B. Other issues

1. Unlawful Search Allegation

Respondents alleged that many of the records in the Government's case were obtained as a result of an unlawful search. Resp Posthearing, at 77–78. As found above, the first inspection occurred on September 18, 2013, during which M.P. signed a DEA Form 82, identifying himself as the “manager” and consenting to the search. GX 32. Respondents objected to this search claiming that “21 CFR 880 mandates that the ‘owner, operator, or agent’ in charge of such premises must receive notice of the inspection.”⁸⁶ Resp Posthearing, at 77. Respondents contest that DEA's service was improper because: M.P. was not an employee of Respondent Pharmacy;⁸⁷ M.P. testified that he was never given authorization to sign the DEA Form 82; and Respondents' Owner and PIC confirmed that she did not authorize him to do so. *Id.* at 78 (citing Tr. 395; 541); see also Tr. 402. The ALJ rejected Respondents' argument, because the ALJ did “not find the testimonies of [Respondents' Owner and PIC] and [M.P.] to be credible that [Respondents' Owner and PIC] did not give [M.P.] authority to sign the Notice of Inspection on September 18, 2013.” RD, at 60 n.36. The ALJ further noted that Respondents' Owner and PIC arrived at Respondent Pharmacy shortly

⁸⁵In fact, I find compelling reasons to reject Respondents' proposed interpretation. For example, if I were to interpret a pharmacist's corresponding responsibility in the manner in which Respondents suggest, not only would it be a departure in the Agency position, but the administrative hearings would be mired in irrelevant complexity that is unnecessary given that a pharmacy must exercise its corresponding responsibility prior to the filling of a prescription in order to preserve the CSA's purpose of preventing addiction and abuse. See *Cove Inc. D/B/A Allwell Pharmacy*, 80 FR 29,037, 29,049 (2015) (finding that “[t]he obligations are referred to as ‘corresponding responsibilities,’ as they impose duties on pharmacies and pharmacists that correspond with those of the treating sources.”)

⁸⁶I have assumed that Respondents intended to cite to 21 U.S.C. 881.

⁸⁷Although, M.P. stated, “I do work for [Respondent] Pharmacy,” Respondents' Counsel clarified with him that the work he does for Respondent LLC overlaps. Tr. 404.

after M.P.'s signature and told the agents that she would provide copies of the pharmacy's records to them later, after which M.P. brought the records to the DEA Orlando District Office on September 23, 2013. *Id.*; GX 33 (DEA Form 12, Receipt for Cash or Other Items, signed by M.P.). I agree with the ALJ's determination that “it strains credulity⁸⁸ to suggest that [Respondents' Owner and PIC] did not willingly consent to delivering the documents to the DEA five days later.” RD, at 60 n.36

The second inspection was conducted as a result of an Administrative Inspection Warrant pursuant to 21 U.S.C. 880(d) in April of 2015, which the DI testified was obtained after Respondents' attorney D.M. failed to timely comply with a subpoena. *Supra* (II)(B)(2). Respondents did not appear to make any arguments related to the lawfulness of the second inspection.⁸⁹ See generally Resp Posthearing. I agree with the ALJ and reject Respondents' allegations regarding the legitimacy of the consent in the first DEA inspection. Respondents' Owner and PIC had five days to withdraw consent to the first inspection or refuse to provide copies of the documents, but nevertheless, she voluntarily chose to provide the documents using the same agent who had signed the initial consent form to deliver them.

2. Respondents' Integrated Enterprise

Respondents argue that DEA has not alleged a single violation against

⁸⁸I agree with the ALJ that Respondents' argument strains credulity, because Respondents' Owner and PIC provided copies voluntarily five days later. I also find that the argument strains credulity, because M.P. signed the DEA Form 82 writing in the word “Manager” in the blank in the statement “I hereby certify that I am the for the premises described in this Notice of Inspection,” and further stating that “I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.” GX 32 (DEA Form 82). M.P. admitted that he spoke with Respondents' Owner and PIC after DEA arrived and that he did not refuse entry or request that DEA “strike his signature.” Tr. 408. M.P. also signed two DEA Forms 12 on September 23, 2013, and October 14, 2016, in which he listed his title as “Manager.” GX 33, 34. The record evidence shows that M.P. held himself out on numerous occasions to have the authority to act on behalf of both Respondents as its agent within the meaning of 21 U.S.C. 880(c).

⁸⁹Respondents seem to conflate the facts surrounding the two inspections, alleging that the DI “presented the DEA Form 82 directly to [Respondent Pharmacy] rather than go through the pharmacy's counsel” and that the DI admitted to not knowing whether M.P. was authorized to sign the form. Resp Posthearing, at 78. However, the DI testified that he was not even present at the administrative inspection that occurred on September 18, 2013, so whether he knew about the status of M.P.'s authorization back in 2013, when he served the administrative warrant in April 2015 is irrelevant. Tr. 317–18.

Respondent LLC, and therefore it is inappropriate to revoke Respondent LLC's registration “simply because both companies share common ownership.” Resp Posthearing, at 77. The ALJ found, and I agree, that “Respondents' arguments ignore the obvious, that the Pharmacy and Smtree Medical are essentially one and the same.” RD, at 100. Agency decisions “treat[] two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities.” *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 FR 79,188, 79,222 (2016) (citing *MB Wholesale, Inc.*, 72 FR 71,956, 71,958 (2007) (citing *MB Wholesale, Inc.*, 72 FR 71,956, 71,958 (2007)). “[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy.” *Superior Pharmacy I and Superior Pharmacy II*, 81 FR 31,310, 31,341, n.71 (2016). Further, the Agency may revoke a registration, even if there is no misconduct that can be attributed to the registration, if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.*, 82 FR 21,410, 21,430 (2017) (revoking physician's DEA registration in Florida due to conduct attributed to a Texas registration that had expired).

Respondents argue that the terms of the CSA in requiring separate registrations for each entity or person and each principal place of business should be read to “suggest two (2) separate entities are not to be considered as one (1).” Resp Exceptions, at 18 (citing 21 U.S.C. 802(49)(a), 802(38), and 822(e)). When a practitioner registrant acts in a manner inconsistent with the public interest, in determining whether to revoke, DEA looks to whether the practitioner can be entrusted with a registration. See e.g., *Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016). If a practitioner holding multiple registrations cannot be entrusted with one, it would be difficult to justify entrusting the same practitioner with another in a separate location. Similarly, if a corporate entity is owned and operated by the same individuals, who have acted inconsistently with the public interest, I cannot ignore the fact that these same individuals have used one of their registrations not in

accordance with the law. Respondents quoted the DI stating that Respondent LLC “has never purchased any controlled substances under that DEA registration” and that the two entities “were two (2) separate businesses, one (1) supplying medication including controlled substances, the other involved in the sale of medical equipment;” however, the lack of Respondent LLC’s past use of the registration does not prevent it from using its registration in the future. Resp Exceptions, at 19–20.

The lens through which Congress has instructed me to assess each registration is whether or not such registration is inconsistent with the public interest. 21 U.S.C. 823(f). In this case, if Respondents were allowed to simply shift their operations to an entity with the same owner and essentially the same employees, the effect of the violations found herein against Respondent Pharmacy would be a nullity, and there would be nothing to prevent Respondent LLC from continuing to act in a manner inconsistent with the public interest. Contrary to Respondents’ contention, it would be inconsistent with the intent of the CSA to permit such an easily implementable loophole, and it is consistent with Agency decisions to close the loophole by treating the two overlapping entities as one integrated enterprise for purposes of sanction.

Therefore, I agree with the ALJ that “[b]ecause of the obvious commonality of ownership, management and operations, it is abundantly clear” that if I revoke Respondent Pharmacy’s registration, Respondent LLC “could pick up where the Pharmacy left off without missing a beat. Accordingly, due to that commonality, it is appropriate to treat the [Respondent] Pharmacy and [Respondent LLC] as one integrated enterprise.” RD, at 101.

Finally, Respondents argue that they were given no notice as to the charges against Respondent LLC and therefore a finding against Respondent LLC would violate Constitutional due process. I reject this argument, because the grounds for revocation of Respondent LLC’s registration are the precise grounds that form the basis of the revocation of Respondent Pharmacy’s registration, and Respondent Pharmacy has been afforded due process of law through this proceeding. Furthermore, the OSC was clearly issued to both Respondent LLC and Respondent Pharmacy. See OSC, at 1. Each was initially docketed separately, but prior to the hearing, the ALJ ordered that the two cases would be consolidated, to which the Respondents consented.

ALJX 14 (Prehearing Ruling). Respondents simply cannot argue that they did not know that the adjudication of the alleged violations committed by Respondent Pharmacy were also being adjudicated against Respondent LLC.

C. Summary of the Public Interest Factors

As found above, Respondent Pharmacy filled hundreds of controlled substance prescriptions in violation of its corresponding responsibility and Florida law and outside the usual course of professional practice. Thus, I conclude that Respondent Pharmacy has engaged in misconduct which supports the revocation of its registration, and as explained above, it would be inconsistent with the public interest to permit Respondent LLC to maintain its registration given that Respondents are an integrated enterprise. I therefore find that the Government has established a *prima facie* case that Respondents’ continued registrations “would be inconsistent with the public interest.” 21 U.S.C. 823(f).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that the Respondents’ continued registration is inconsistent with the public interest due to their violations pertaining to controlled substance dispensing, the burden shifts to the Respondents to show why they can be entrusted with the responsibility carried by their registrations. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (citing *Samuel S. Jackson*, 72 FR 23,848, 23,853 (2007)). 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). This authority specifically relates “to ‘registration’ and ‘control,’ and ‘for the efficient execution of his functions’ under the statute.” *Gonzales v. Oregon*, 546 U.S. at 259. A clear purpose of this authority is to “bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.” *Id.* at 270. 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)). “Moreover, because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.” *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009) (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); see also *Jackson*, 72 FR at 23,853; *John H. Kennedy, M.D.*, 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62,884, 62,887 (1995). 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, I agree with the analyses and conclusions contained in the Recommended Decision. RD, at 101–04. I agree with the ALJ that there is nothing in the record that suggests Respondent Pharmacy has accepted responsibility for its actions. In fact, as the ALJ found, “the evidence is clear in this case that the Pharmacy has taken no responsibility for its egregious and repeated failure to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The evidence is clear because the Pharmacy has specifically denied responsibility.” RD, at 101. In fact, Respondents’ attorney made very clear that Respondents were not accepting any responsibility. He stated, “I’m well aware that I can’t go into remediation unless we were to accept responsibility. Your Honor. And we won’t unless we do.” Tr. 567; RD, at 99. Further, even after the Florida Board of Pharmacy had told Respondents’ Owner and PIC that a practitioner could not prescribe to himself, Respondents maintained that the law permitted them to fill those prescriptions. See Resp Exceptions; Tr. 573, 809–10. Respondent Pharmacy did cease filling the prescriptions as a result of the Board of Pharmacy’s instructions; however, the fact that Respondent Pharmacy

relied on an interpretation involving a legal loophole to fill the prescriptions in the first place, and then continued to argue that the behavior was lawful in spite of the state's assertions to the contrary, not only demonstrates no remorse, but also demonstrates a willingness to push the boundaries of the law to maximize business. Such a willingness does not inspire optimism about Respondents' future compliance with the CSA.

I agree with the ALJ that the egregiousness of Respondent Pharmacy's conduct and the interests of specific and general deterrence support a sanction of revocation. RD, at 99. "Specifically, pharmacists employed by the Pharmacy, as well as [Respondents' Owner and PIC], dispensed numerous prescriptions of controlled substances in violation of their corresponding responsibility." *Id.*

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, 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. Further, the ALJ found, and I agree, that if I revoke Respondent Pharmacy's registration, Respondent LLC "could pick up where the Pharmacy left off without missing a beat. Accordingly, due to that commonality, it is appropriate to treat the Pharmacy and Suntree Medical as one integrated enterprise." RD, at 101. Due to the commonality of ownership and procedures, I cannot entrust Respondent LLC with a registration any

more than I can entrust Respondent Pharmacy with one.

Therefore, I shall order the sanctions the Government requested, as contained in the Order below.

V. 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 Certificates of Registration Nos. BS7384174 and FS2194289 issued to Suntree Pharmacy and Suntree Medical Equipment LLC. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Suntree Pharmacy and Suntree Medical Equipment to renew or modify these registrations, as well as any other pending application of Suntree Pharmacy and Suntree Medical Equipment for registration in Florida. This order is effective December 21, 2020.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ECO Apothecary, LLC; Decision and Order

On December 2, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Eco Apothecary, LLC (hereinafter, Registrant or Registrant Pharmacy), of Salt Lake City, Utah. Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FE7288497. It alleged that Registrant is without "authority to handle controlled substances in the State of Utah, the state in which [Registrant] is registered with the DEA." *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that Registrant's Utah pharmacy license is expired. *Id.* The OSC further alleged that, because Registrant's Utah pharmacy license is expired, Registrant lacks the authority to handle controlled substances in Utah, and is, therefore, ineligible to maintain a DEA registration. *Id.* at 1-2.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right

to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 2-3 (citing 21 U.S.C. 824(c)(2)(C)).

I. Adequacy of Service

A DEA Diversion Investigator declared that he personally served James Ammon, Rph, with the OSC at the Registrant Pharmacy on December 10, 2019. RFAAX 4 (Declaration of Diversion Investigator). James Ammon signed Registrant's online application for a DEA registration on November 23, 2017. RFAAX 1 (Certification of Registration History). The DEA Diversion Investigator declared that he recognized James Ammon because the Diversion Investigator had previously met with him. RFAAX 4.

The Government forwarded its RFAA, along with the evidentiary record, to this office on May 19, 2020. In its RFAA, the Government represents that "Registrant has not requested a hearing" RFAA at 1. DEA did receive a letter from Registrant dated February 25, 2020, which stated that the purpose of the letter was "to complete its duty, and report to the DEA the record of the pharmacy's final inventory, as well as report to the DEA its disposition and transfer of control of the controlled substances previously in the pharmacy's control." RFAAX 6, at 1. Registrant's February 25 letter did not request a hearing and was sent more than thirty days after Registrant received the OSC. *See id.*

Based on the Diversion Investigator's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on December 10, 2019. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).