DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–26]

The Pharmacy Place Order

On April 3, 2017, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to The Pharmacy Place (hereinafter, Respondent) of Plano, Texas. Administrative Law Judge Exhibit 1 (OSC), at 1. The OSC proposed to revoke Respondent's DEA Certificate of Registration No. FT4134805 and deny any pending applications for a modified or new DEA registration pursuant to 21 U.S.C. 823(f) because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ–5. The first two sessions of the hearing in the matter were held in Dallas, Texas from September 12–13, 2017. The Respondent's expert, however, failed to appear on either of those days. To accommodate the Respondent, the hearing was continued. On November 20, 2017, the hearing reconvened. The November 20, 2017 session of the hearing was conducted by video teleconference from the DEA Hearing Facility in Arlington, Virginia, with the parties and witnesses located at the DEA District Office in San Antonio, Texas.

On February 13, 2018, Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ) issued the incorporated Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, Recommended Decision or RD). Respondent filed Exceptions to the Recommended Decision on March 5, 2018, and, with the permission of the ALJ, a Show to the Contrary on March 14, 2018 (hereinafter, collectively Respondent's Exceptions or Exceptions). The Government filed a Response to Respondent's Exceptions and Show to the Contrary on March 28, 2018 (hereinafter, Govt Response). The record was then forwarded to me for final agency action.

Suggestion of Mootness

On October 18, 2018, the Government filed a Notice of Suggestion of Mootness (hereinafter, Suggestion of Mootness). The Government provided evidence that Respondent had closed and that Respondent's owner had transferred the inventory of controlled substances to a reverse distributor. Suggestion of Mootness, at 2, Exs. 1–3.[A] DEA regulations promulgated pursuant to the authority delegated by the Controlled Substances Act (CSA) provide that ''the registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . discontinues business or professional practice . . . .'' 21 CFR 1301.52. As Respondent discontinued business and transferred its controlled substances, pursuant to the regulation, its registration is terminated, and Respondent is no longer authorized to dispense controlled substances under federal law. *Id.* The Government argued that because Respondent no longer possesses a DEA registration, the case is now moot. Suggestion of Mootness, at 3 (citing *Louisiana All Snax, Inc.,* 76 FR 20034 (2011); *John G. Costino, D.O.,* 76 FR 4940 (2011)).

Since the Government filed its Suggestion of Mootness, however, the Agency has published two decisions that are directly applicable to the instant matter. The first, *Jeffrey D. Olsen, M.D.,* in which my predecessor ordered the revocation of an expired registration, stated that ''mootness does not play the same role in administrative agency adjudications as it plays in Article III court proceedings'' and '' '[t]he agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.' '' 84 FR 68474, 68478 (2019) (quoting *Tennessee Gas Pipeline* v. *Federal Power Comm'n,* 606 F.2d 1373, 1380 (D.C. Cir. 1979); 5 U.S.C. 554(e)); *see also Climax Molybdenum Co.* v. *Sec'y of Labor, Mine Safety and Health Admin.,* 703 F.2d 447, 451 (10th Cir. 1983) (''At the outset, we note that an administrative agency is not bound by the constitutional requirement of a 'case or controversy' that limits the authority of [A]rticle III courts to rule on moot issues.''). *Olsen* concluded, therefore, that the Agency was free to, and would, adjudicate orders to show cause to finality in matters with expired registrations. *Id.* at 68479.

The second, *Steven M. Kotsonis, M.D.,* applied *Olsen* to matters where a registration is terminated pursuant to 21 CFR 1301.52 for a surrender for cause after an ALJ had issued a recommended decision and transmitted the matter to the Administrator for final decision. 85 FR 85667, 85668 (2020). *Kotsonis* concluded that the termination of a DEA registration under 21 CFR 1301.52 does not preclude DEA from issuing a final decision on an order to show cause against that registration and stated that the Agency would assess such matters on a case-by-case basis to determine if a final adjudication is warranted or if the matter should be dismissed. *Id.* at 85668–69.

In this matter, as in *Kotsonis,* Respondent's registration terminated under 21 CFR 1301.52 after the ALJ had issued a recommended decision on the order to show cause and had transmitted the record to me for final decision. Accordingly, I am declining the Government's Suggestion of Mootness as the matter is not mooted by the termination. Instead, I have evaluated the particular circumstances of this matter and determined that the matter should be adjudicated to finality. As my predecessor identified in *Olsen,*

> [f]inal adjudications are particularly helpful in supporting the purposes of the CSA and my responsibilities to enforce the CSA because nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is a history of being denied a registration, or a history of having a registration suspended or revoked. As such, having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.

84 FR at 68479. Absent a final adjudication, there would be no final record of the allegations and evidence from this matter.[B] Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Respondent's owners, employees, or other persons who were associated with Respondent. As additionally noted in *Olsen,* ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community,'' and adjudications inform stakeholders, such as legislators and the public, about the Agency's work and allow them to provide feedback to the Agency, thereby helping shape how the Agency carries out its responsibilities under the CSA. *Id.* Adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrant pharmacies under the CSA and allow stakeholders

[A] The Government also provided electronic correspondence between a DEA attorney and Respondent's attorney informing Respondent that DEA would treat the discontinuation of business as ''a surrender for cause and the registration history [would] be documented as such.'' Suggestion of Mootness, Ex. 4 (citing 21 CFR 1301.76).

[B] Contrast with *Kotsonis* in which the plea agreement and judgment from the respondent's concurrent criminal case provided a final record on which the Agency could rely in any future interactions with the respondent. 85 FR at 85667.

to provide feedback regarding the Agency's enforcement priorities and practices.

Having determined that this matter should be adjudicated to finality and considered the record in its entirety, including the Respondent's Exceptions and the Govt Response, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and proposed sanction from the Recommended Decision, with minor modifications, where noted herein.[C] A discussion of Respondent's Exceptions follows.

Respondent's Exceptions

Respondent filed 49 exceptions—19 exceptions to the RD's Findings of Fact and 30 exceptions to the RD's Analysis and Conclusions of Law, the final two of which were expounded upon in greater detail in Respondent's Show to the Contrary.

Respondent's Exceptions to the Findings of Fact

I find that the majority of Respondent's exceptions to the Findings of Fact do not actually dispute the RD's findings of fact but rather provide explanations, arguments, or interpretations. Consequently, I reject Respondent's Exceptions 1–2, 7, 9, 11–14, and 16–18. I also reject Respondent's Exceptions 3, 6, 8, and 19. I have reviewed the findings of fact to which Respondent objected in those exceptions and have determined that the findings are supported by the administrative record.

I am partially sustaining Respondent's Exceptions 10 and 15. In Exception 10, Respondent objected to the ALJ's finding that ''Ms. Igwe is familiar with the Texas regulation that requires a pharmacist to document notes regarding the resolution of red flags.'' RD, at 29 (citing Tr. 585). Respondent stated in its exceptions that

> Ms. Igwe is familiar with the Texas regulations that require a pharmacist to document notes, but not every red flag, or its resolution must be documented under Texas law. See 22 TAC § 291.33(c)(2)(A)(ii) and (iv). (ii) requires documentation when a clinically significant condition exists that is resolved by the pharmacist, and (iv) requires documentation when the pharmacist has a question about the drug regimen review per (A) of that regulation.''

Respondent's Exceptions, at 4. While I find that Respondent's explanation for Exception 10 provides an argument on what it believes to be the correct interpretation of the Texas regulation rather than disputing the factual finding, I am partially sustaining the exception because I find that the RD's characterization of Ms. Igwe's testimony was incomplete. When asked by the ALJ if she was familiar with ''a Texas regulation that requires that if you check with a doctor about a particular prescription, that you're supposed to document that,'' Ms. Igwe answered ''Yes.'' Tr. 585. However, Ms. Igwe qualified her answer stating ''[b]ut . . . it depends on what I check with the doctor about . . . so it would depend—if I'm calling the doctor and saying anything that isn't clinical in nature, I may not necessarily document it.'' *Id.* The RD, therefore, correctly found that Ms. Igwe was familiar with the regulation the ALJ was referencing in his question; however, I will add the clarification to the finding that Ms. Igwe did not expressly testify that the regulation requires a pharmacist to document notes regarding the resolution of red flags.

Respondent's Exception 15 took exception to the RD's finding of fact that

> [t]he prescription that [L.R.] wrote for [M.W.] raises the following red flags: No patient address; no provider DEA number; large quantity of high-alert controlled substance; the prescription was written on July 29, 2014, but not faxed to the Pharmacy until August 1, 2014 and not picked up until August 4, 2014; and an unusual path and distance to obtain the prescription and get it filled.

RD, at 33–34 (citing Tr. 188–85). Respondent argues that ''[p]ursuant to Dr. Witte, the prescription for hydrocodone that '[M.W.]' received was a typical or therapeutic dosage.'' Respondent Exceptions, at 5 (citing Tr. 176, 283, 366, 679). I have reviewed Dr. Witte's testimony regarding the red flags on the ''M.W.'' prescription and find that while Dr. Witte did testify that the prescription was for a ''large quantity,'' when asked if the quantity was a red flag, she stated that ''[i]t *could* be.'' Tr. 189 (emphasis added). I, therefore, will partially sustain Respondent's Exception 15 as Dr. Witte did not unequivocally testify that the quantity of the controlled substance in the M.W. prescription was a red flag, only that such a quantity could be a red flag on a prescription.

I have amended Findings of Fact 94 and 135 of the Recommended Decision to reflect my determinations on Respondent's Exceptions to the Recommended Decision's findings of fact.

Respondent's Exceptions to the ALJ's Analysis and Conclusions of Law

Respondent filed 30 exceptions to the Recommended Decision's Analysis and Conclusions of Law and a Show to the Contrary that provided further explanation and documentation for its final two exceptions. I have reviewed the exceptions and find they can be grouped into five general exceptions:

(1) Respondent objects to the Government's allegation that there was no evidence of Respondent filling prescriptions prior to July 7, 2014;[D]

(2) Respondent objects to the ALJ's official notice of 22 Tex. Admin. Code § 291.33(c)(7)(A);[E]

(3) Respondent argues the Recommended Decision did not properly weigh the five factors from 21 U.S.C. 823(f);[F]

(4) Respondent objects to the ALJ's determination that it violated various federal and state regulations when it dispensed controlled substance prescriptions that raised red flags without properly resolving the red flags and documenting the resolution;[G] and

(5) Respondent argues the recommended sanction is not supported by the record.[H]

1. Prescriptions Filled Prior to July 7, 2014

Respondent filed an exception against ''[t]he Government's alleg[ation] that there was no evidence of prescriptions being filled prior to July 7, 2014 due to the lack of earlier information in the patient profiles.'' Exceptions, at 13 (citing Gov. Ex. 6). Respondent's exception, however, does not object to any of the ALJ's findings or conclusions from the Recommended Decision. As Respondent stated itself in the exception, the ALJ ''found evidence of prior filled prescriptions.'' *Id.* (citing RD, at 51 n.34 (''The Respondent did produce evidence of dispensing prior to July 7, 2014 . . . Those records, however, were not produced until long after the Pharmacy was required to produce them.'')). *See also* RD, at 24 (citing Tr. 60, 76) (''The dispensing records showed that the first dispensing took place on July 7, 2014, but the PMP showed that the Pharmacy filled prescriptions for hydrocodone between January and June 2014.''). Pursuant to

[C] I have made minor modifications to the Recommended Decision. I have substituted initials or titles for the names of witnesses and practitioners to protect their privacy, and I have made minor, nonsubstantive grammatical changes. Where I have made substantive changes to align the RD with my findings on Respondent's Exceptions or otherwise added to or modified the ALJ's decision, I have placed the edited text in brackets and included a specific description of the modification in a footnote marked with an asterisk.

[D] Exceptions, at 13, no. 38.

[E] Exceptions, at 17, nos. 48–49; Respondent's Show to the Contrary.

[F] Exceptions, at 10; nos. 31–32.

[G] Exceptions, at 6–13, 16–17; nos. 20–30, 33–37, 39, 45–47.

[H] Exceptions, at 14–16, nos. 40–44.

21 CFR 1316.66, an exception must be to ''the recommended decision, findings of fact and conclusions of law contained in the report'' from the ALJ to the Administrator. Respondent's ''exception'' is, therefore, invalid.

2. Official Notice of 22 Tex. Admin. Code § 291.33(c)(7)(A)

In the RD, the ALJ took official notice of 22 Tex. Admin. Code § 291.33(c)(7)(A), which sets forth several requirements for labels on prescription bottles. RD, at 59 n.41. Respondent objected to the ALJ's notice of 22 Tex. Admin. Code § 291.33(c)(7)(A), or in the alternative, requested an opportunity to show to the contrary pursuant to 21 CFR 1316.59(e). The ALJ issued an Order Granting Respondent Request for Opportunity to Show to the Contrary on March 6, 2018. In his Order, the ALJ cited two instances in the record where taking notice of this regulation was helpful. First, the ALJ ''looked to the regulation for additional support for Dr. Witte's testimony that the dispensing pharmacist's initials must be associated with each prescription and that [PIC] Igwe was the pharmacist who filled all the prescriptions in the Administrative Record.'' *See* RD, at 39; Tr. 389–90. Second, the ALJ stated that he relied on the regulation in determining when a prescription was filled by Respondent, as the regulation requires the label to include the date the drug was dispensed.

I can find no reason why Respondent objected to the ALJ's official notice of 22 Tex. Admin. Code § 291.33(c)(7)(A) or why Respondent filed the Show to the Contrary with documentation of labels from the prescriptions at issue in this matter—all of which display the initials of Respondent's Pharmacist in Charge Ijeoma Igwe (hereinafter, PIC Igwe) and a date. Respondent asserts in the Show to the Contrary that the labels demonstrate that Respondent fully complied with section 291.33(c)(7)(A), but there was never any allegation that Respondent did not. In the RD, the ALJ assumed that Respondent had fully complied with the regulation when labeling prescription bottles.

To the extent, if any, Respondent is objecting to the ALJ's official notice of 22 Tex. Admin. Code § 291.33(c)(7)(A), Respondent's objection is denied as the RD properly characterized the content of the regulation and Respondent acknowledges the regulation applied to Respondent's pharmacy practice.

3. Weighing the Factors From 21 U.S.C. 823(f)

Respondent filed exceptions arguing that the ALJ did not properly weigh all five factors from 21 U.S.C. 823(f). Specifically, Respondent argues the ALJ did not properly consider that (1) ''there is no evidence that the State licensing board has taken a disciplinary action against [Respondent]'' or (2) Respondent's experience dispensing or conducting research with respect to controlled substances. Exceptions, at 10.

The DEA considers the five public interest factors from 21 U.S.C. 823(f) separately. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *Drug Enf't Admin.,* 861 F.2d 72, 76–77 (4th Cir. 1988). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009) (basing sanction on all evidence on record).

Having reviewed the Recommended Decision, I find that the ALJ did properly weigh the public interest factors. First, as stated above, the ALJ was not required to enter findings on each of the factors or to consider a factor in any given level of detail. Second, contrary to Respondent's assertion, the ALJ did enter findings regarding the recommendation of the State licensing board and concluded that Factor One (21 U.S.C. 823(f)(1)) does not weigh for or against revocation in this matter. The RD found that ''it is undisputed that the Respondent holds a valid state pharmacy license in Texas'' and ''[t]he record contains no evidence of a recommendation regarding the Respondent's privilege to operate as a pharmacy by a relevant state licensing board or professional disciplinary authority.'' RD, at 54. As accurately stated in the RD, ''Agency precedent establishes that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation.'' *Id.* (citing *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011)). Accordingly, I agree with the ALJ's findings and conclusions regarding Factor One.

Finally, I find that Respondent's assertion that the ALJ failed to adequately consider evidence of Respondent's ''experience with her other patients'' is without merit. Exceptions, at 10 (citing *Jayam Krishna-Iyer,* 249 F. App'x 159 (11th Cir. 2007). Respondent argued that Respondent ''dispensed over 900 hydrocodone/APAP prescriptions prescribed from the 5 or 6 clinics under investigation, and only 75 prescriptions were submitted for adjudication for approximately 27 patients.'' *Id.* Under Factor 2, 21 U.S.C. 823(f)(2), the Agency must consider a registrant's experience dispensing controlled substances. As previously stated, however, 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* v. *Drug Enf't Admin.,* 664 F.3d 808, 821 (10th Cir. 2011).

In this matter, even presuming that the hundreds of other prescriptions Respondent has referenced were legally dispensed, those prescriptions do not render Respondent's unlawful dispensing of the subject prescriptions any less unlawful or ''any less 'acts which are inconsistent with the public interest.' '' *Jayam Krishna-Iyer,* 74 FR at 462–463 (quoting 21 U.S.C. 823(f)). Moreover, the unlawful dispensings were not an isolated incident—the Government has proven by substantial evidence that Respondent dispensed 75 prescriptions that raised multiple red flags to over two dozen patients in less than a year. RD, at 88. The Agency has consistently taken the position that a registrant's positive dispensing experience under Factor 2 can be outweighed by acts held to be inconsistent with the public interest. *See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62340 (2012); *Paul J. Cargine, Jr.,* 63 FR 51592, 51560 (1998) (''[E]ven though the patients at issue are only a

small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). I find that Respondent's repeated, serious violations of federal and state laws related to controlled substances support the ALJ's finding that the Government has made a *prima facie* case showing that the Respondent's registration is inconsistent with the public interest.

4. Unlawful Dispensing Allegations

Respondent has filed exceptions against the ALJ's determination that Respondent dispensed 75 controlled substance prescriptions that raised red flags without resolving those red flags and documenting the resolution in contravention of Respondent's corresponding responsibility under 21 CFR 1306.04; outside the usual course of professional practice in violation of 21 CFR 1306.06; and in violation of 22 Tex. Admin. Code § 291.33(c)(2).[I] Respondent has stated in its Exceptions that, contrary to the ALJ's findings, the subject prescriptions did not display the red flags of pattern prescribing, distance, and cash payments, and, to the extent that there were red flags on the subject prescriptions, Respondent cleared the red flags before filling the prescriptions.

Red Flags on the Subject Prescriptions

Pattern Prescribing

As fully explained in the Recommended Decision, pattern prescribing occurs when a provider or group of providers repeatedly prescribe patients the same drug and the same quantity without any difference in treatment. RD, at 25, 60–62 (citing Tr. 171, 228–29, 232–33, 244, 250, 264–65, 279, 289, 353, 745). The expert witnesses in this matter testified that pattern prescribing raises a red flag because the lack of individualized therapy can indicate the prescriber is not prescribing the controlled substances for a legitimate medical purpose. Tr. 171, 244, 745. *See Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79188, 79195 (2016) (citing *E. Main St. Pharmacy,* 75 FR 66149, 66163 (2010)); 21 CFR 1306.04 (''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose . . .''). Unlike some red flags, such as distance and cash payments, pattern prescribing can manifest over an extended period of time and may not be immediately recognizable to a pharmacist. Tr. 210, 239–40, 333, 358–59. Both experts agreed that a pharmacist can resolve a red flag of pattern prescribing raised by a prescription by speaking with the prescriber and receiving information that satisfies the pharmacist that a prescription was issued for a legitimate medical purpose. Tr. 240, 332–334, 660. The Government's expert, Dr. Witte, stated that if the pharmacist is not satisfied by the prescriber's responses to their questions, the pharmacist should refuse to fill the prescriptions. Tr. 171, 333–34.

In its Exceptions, Respondent objects to the ALJ's finding that many of the subject prescriptions exhibited the red flag of pattern prescribing and that Respondent filled the prescriptions without resolving the red flag. Exceptions, at 10–12. Respondent claims that it resolved the red flag of pattern prescribing in the subject prescriptions by calling the prescriber whenever a patient presented a controlled substance prescription for the first time. *Id.*

Respondent claims in the Exceptions that ''[e]ach new time a new patients [sic] comes to [Respondent], or an existing patient received a change in medication, the pharmacist places a call to the practitioner to ensure the doctor/patient relationship, to verify the dosing and prescriptions, and to inquire as to the condition or illness being treated.'' Exceptions, at 11 (citing Tr. 477–78). Respondent's claim, however, is unsupported by the record evidence and misrepresents PIC Igwe's testimony. In the portion of PIC Igwe's testimony cited by Respondent, PIC Igwe said ''if I have a patient who is a controlled drug [sic] and they haven't been before, I would call the clinic and make sure that the clinic did write the prescription, and the number that I would use would not be—would be like a number in the—you know, on my—it wouldn't be what's on the prescription, in case it was no—it was forged, for example.'' Tr. 477–78. In other words, PIC Igwe testified that she called the prescriber's office to ensure the prescription was not forged, but she did not testify that she ''verif[ied] the dosing'' or ''inquire[d] as to the condition or illness being treated'' as Respondent claims in its Exceptions.[J] Checking that a prescription was, in fact, issued by a clinic would show that the prescription is not an outright fraud, but it would not ensure that the prescription was issued for a legitimate medical purpose. 21 CFR 1306.04(a); *Pharmacy Doctors Enterprises d/b/a/ Zion Clinic Pharmacy,* 83 FR 10,876, 10,897 (2018), *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019).

There is also no documentary evidence in the record that PIC Igwe ''verif[ied] the dosing,'' ''inquire[d] as to the condition or illness being treated,'' or otherwise resolved the red flag of pattern prescribing on the subject prescriptions as Dr. Witte testified was required for a pharmacist following the accepted standard of practice of pharmacy in Texas. *See, e.g.,* Tr. 210–211. There are no notes in any of Respondent's patient profiles documenting conversations with prescribers. Tr. 210, 244*; see* GX 2. And while PIC Igwe testified that she would sometimes mark a prescription with a ''V'' to indicate she had verified a prescription, Tr. 477, 482, only one of the subject prescriptions is marked with a ''V'' and that prescription was the sixth time Respondent had filled that prescription for the patient, GX 2, at 44–46, 53–55. The credibility of Respondent's claim that PIC Igwe always checked with the prescriber the first time she filled a controlled substance prescription for a patient was also brought into question by her testimony that she had never had a conversation with Dr. C.V. regarding a patient and the only time she had spoken to him was when Dr. C.V. called her to ask for the pharmacy's fax number. Tr. 561–62. Yet, Dr. C.V. prescribed 14 of the subject prescriptions for hydrocodone, GX 2; and Respondent's dispensing logs show that Respondent filled hundreds of additional hydrocodone prescriptions from Dr. C.V., including 8 hydrocodone prescriptions in a single day.[K] GX 6; RX G at 44–45; Tr. 424–25. Given the lack of documentary evidence and the contrary testimony from PIC Igwe, I agree with the ALJ and find that Respondent did not clear the red flags of pattern prescribing before dispensing the subject prescriptions. Accordingly, I

[I] The Recommended Decision also found that Respondent violated other state laws when dispensing the subject prescriptions, but Respondent has not filed exceptions against those findings.

[J] *Compare* PIC Igwe's testimony at Tr. 477–78 *with* Respondent's Exceptions at 11.

[K] The OSC did not allege that Respondent unlawfully dispensed any prescriptions prior to August 2014. Accordingly, while Respondent's dispensing history prior to August 2014 is relevant to rebutting Respondent's claim that the subject prescriptions did not display the red flag of pattern prescribing or that PIC Igwe had resolved the red flags prior to dispensing the subject prescriptions, any deficiencies in Respondent's prescription dispensing practices outside of the subject prescriptions do not weigh for or against Respondent retaining its registration.

reject Respondent's exceptions to the ALJ's findings on pattern prescribing.[L]

Distance

The ALJ found that the distances the patients travelled to obtain the subject prescriptions were a red flag that Respondent failed to clear before dispensing the prescriptions. RD at 63–65, 72–73, 76, and 79. Dr. Witte credibly testified that the distance or route a patient travels to fill a prescription can be a red flag, Tr. 172–76; and Agency decisions have long found that the distance a patient is willing to travel to obtain a prescription is a factor a pharmacist must consider pursuant to their corresponding responsibility; *e.g., Morning Star Pharmacy & Medical Supply 1,* 85 FR 51045, 51052 (2020); *Hills Pharmacy, L.L.C.,* 81 FR 49,815, 49841 n. 45 (2016); *East Main Street Pharmacy,* 75 FR 66149, 66165 (2010). Texas regulations also require pharmacists to ''exercise sound professional judgment with respect to'' the legitimacy of a prescription, 22 Tex. Admin. Code § 291.29(a), and provide a non-exhaustive list of circumstances a pharmacist should weigh when evaluating a prescription's legitimacy, including ''the geographical distance between the practitioner and the patient or between the pharmacy and the patient.'' 22 Tex. Admin. Code § 291.29(c)(4).

Respondent filed exceptions against the ALJ's determination that the distances traveled by the subject patients were a red flag. Exceptions, at 16–17. Respondent argues that ''various pharmacists have various thresholds for distances traveled,'' and that its expert, Mr. Litman, testified that he would only be concerned about distance if a patient were coming from out-of-state. *Id.;* Tr. 695–96, 730. Mr. Litman, however, was not aware of DEA cases that deal with pharmacy customers who had travelled long distances to obtain their prescriptions and have them filled. Tr. 727. He was also not admitted as an expert on Texas pharmacy practice or law (Mr. Litman was a practicing pharmacist in Florida), Tr. 624, 655–56; and while Mr. Litman stated that he had reviewed the Texas regulations for pharmacists, Tr. 657, he seemed to be unaware of the Texas regulation that requires pharmacists to consider the distance a customer traveled to fill a prescription, *see* Tr. 727, 739. For these reasons, I agree with, and will follow, the ALJ's decision to give no weight to Mr. Litman's testimony that the distance the patients travelled to obtain the subject prescriptions was not a red flag. *See* RD, at 65.

In contrast to Mr. Litman, the Government's expert, Dr. Witte, testified that it would be outside the usual course of professional practice in the state of Texas for a pharmacist to dispense a prescription for a controlled substance without considering the distance the patient traveled to obtain and fill the prescription. Tr. 171–76. The Government provided evidence that the roundtrip distance between the subject patients' homes, providers, and Respondent ranged between 55–121 miles through urban areas. Stipulations 9–45. Dr. Witte testified that the distances traveled by the patients were a red flag, noting concern about patients driving across the city of Dallas to Respondent in Plano to fill the prescriptions because ''more than likely, there are many pharmacies located between . . . where the patient lives and where the clinic is.'' Tr. 174–75, 189–94, 281, 321. I credit Dr. Witte's testimony that the distances traveled by Respondent's patients to obtain the subject prescriptions were a red flag and, accordingly, reject Respondent's exceptions.[M]

Cash Payments

The ALJ found that paying cash for a prescription can be a red flag and determined that cash payments, combined with other red flags, can be enough to find a pharmacist violated 21 CFR 1306.04. RD, at 66. This determination is consistent with the testimony of both the Government and Respondent's expert witnesses, *see, e.g.,* Tr. 172–73; and with other Agency decisions, which have found that paying cash for controlled substances, rather than billing insurance, can be a red flag that the patient is seeking the substances for illicit purposes*; see, e.g., Morning Star Pharmacy and Medical Supply 1,* 85 FR 51045, 51052 (2020), *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.,* 81 FR 79,188, 79191 (2016); *E. Main St. Pharmacy,* 75 FR 66149, 66158 (2010).

Respondent concedes that cash payments can be a red flag. Exceptions, at 13. Respondent, however, argues that the cash payments made on the subject prescriptions were not red flags because ''many of [Respondent's] patrons paid in cash'' and because many of the cash payments for the subject prescriptions were ''just over'' $200, which Respondent's expert, Mr. Litman, ''gave [as] a ceiling . . . for a pretty reasonable average cash payment.'' *Id.* I am rejecting Respondent's exception because it is inconsistent with the testimony of Respondent's PIC and Mr. Litman and ignores the credible testimony of Dr. Witte. RD, at 7.

Dr. Witte testified that cash payments for controlled substance prescriptions, such as those for the subject prescriptions, are a red flag. *E.g.,* Tr. 172–73, 226, 313. The large majority of patients who received the subject prescriptions paid Respondent $179.99 for 90 tablets of hydrocodone and $59.99 for 60 tablets of alprazolam. GX 2. When a patient purchased prescriptions for both hydrocodone and alprazolam at the same visit, the patient would pay $239.98. *Id.* Respondent's expert, Mr. Litman, testified that he would be concerned about cash payments in excess of $200. Tr. 692, 753. Mr. Litman downplayed the significance of cash payments as a red flag because ''cash payments are more common these days.'' Tr. 753. PIC Igwe testified, however, that the majority of Respondent's customers used insurance to pay for their prescriptions, which brings into question why all of the subject patients paid with cash. Tr. 496.

Accordingly, I reject Respondent's exceptions to the findings in the Recommended Decision that the cash payments for the subject prescriptions were a red flag.

ALJ's Determinations That Respondent Violated 21 CFR 1306.04 and 1306.06

In addition to arguing that the subject prescriptions did not raise the red flags of distance, cash payments, and pattern prescribing and/or those red flags were resolved before Respondent filled the prescriptions, Respondent argues in its Exceptions that the Government failed to establish that PIC Igwe had the requisite degree of scienter to prove a violation of her corresponding responsibility under 21 CFR 1306.04(a). Exceptions, at 7–9, 12–13. Respondent

[L] Respondent also argues that the ALJ's finding that many of the subject prescriptions presented the red flag of pattern prescribing was inappropriate because the prescribers engaged in ''masking.'' Exceptions, at 12. Respondent's argument is contrary to the expert testimony presented at the hearing. Both the Government's expert, Dr. Witte, and Respondent's own expert, Mr. Litman, testified that the subject prescriptions raised the red flag of pattern prescribing. *E.g.,* Tr. 745 (''Judge Dorman: 'Do you consider pattern prescribing to be a red flag?' [Mr. Litman]: 'Yes.' Judge Dorman: 'Okay. Did you see anything in the documentation that you were provided that would suggest pattern prescribing?' [Mr. Litman]: 'Yes.' '')

[M] As the ALJ noted in the Recommended Decision, Dr. Witte was accepted as an expert in the field of pharmacy in the state of Texas, not geography. Tr. 169; RD, at 64. Thus, I do not credit her testimony concerning distances and the availability of pharmacies as that of an expert; I do, however, credit it as a reasonable observation based upon common experience. As the ALJ found, common experience suggests that one is more likely to pass a pharmacy in an urban area than a rural one and that, in general, it is more time consuming to travel a specific distance in an urban area than a rural one. RD, at 64.

also argues that the Government has not met its burden under 21 CFR 1306.06 ''to prove the pharmacist repeatedly filled controlled substance prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags, based on a lack of documentation of the resolution, or a failure of the corresponding responsibility.'' *Id.* at 6.

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

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

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

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

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 29. *See also* OSC, at 5 (''Pharmacy Place's pharmacists were willfully blind to or deliberately ignorant of the high probability that the [subject prescriptions] lacked a legitimate medical purpose. Pharmacy Place pharmacists were willfully blind to the fact that large numbers of customers seeking controlled substance prescriptions, often prescription cocktails, and residing long distances from Pharmacy Place's location and/or their respective physicians created a suspicious situation requiring increased scrutiny.'').

As partially discussed above, I agree with the ALJ's findings that the subject prescriptions presented multiple red flags including pattern prescribing, distance, cash payments, drug cocktails, high doses/quantities of high-alert controlled substances, and prescriptions lacking the patient's address or the prescriber's DEA number. 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., Morning Star Pharmacy and Medical Supply 1,* 85 FR at 51061 (pattern prescribing; distance; cash payments; drug cocktails; high doses/quantities of high-alert controlled substances; different doctors prescribing controlled substances to the same patient; prescriptions lacking the patient's address or the prescriber's DEA number); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR at 10898 (long distances; pattern prescribing; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers filling prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62317–22 (2012) (long distances; pattern prescribing; cash payments); *East Main Street Pharmacy,* 75 FR 66149, 66,163–65 (2010) (long distances; pattern prescribing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Dr. Witte credibly testified that a Texas pharmacist acting in the usual course of professional practice would have recognized these red flags and that a Texas pharmacist acting in the usual course of professional practice and fulfilling her corresponding responsibility will not fill prescriptions for controlled substances without investigating, documenting the investigation, and resolving any red flags. *E.g.,* Tr. 171–82, 195, 210–211, 216–17, 227.

PIC Igwe also admitted during her testimony that she had *actual* knowledge of some of the red flags on the prescriptions. *See, e.g.,* Tr. 546–47. For example, PIC Igwe testified that she

was aware of, but unconcerned by, the distances the patients were traveling and the large number of substantially identical prescriptions for hydrocodone and alprazolam from the clinics that prescribed the subject prescriptions because she assumed the clinics were pain management clinics and based her dispensing decisions on that assumption. Tr. 516, 537–38. In the State of Texas, pain management clinics must be certified by the state, 22 Tex. Admin. Code §§ 195.1–195.44; and the Texas regulations governing the professional responsibilities of pharmacists state that a ''prescription drug order may not be dispensed or delivered if issued by a practitioner practicing at a pain management clinic'' that is not certified. 22 Tex. Admin. Code § 291.29(e) (2011).[N] Yet, PIC Igwe testified that she never checked if the clinics were certified as pain management clinics. Tr. 537–38. Moreover, Dr. Witte testified that a Texas pharmacist should still investigate and resolve the red flags on the subject prescriptions even if they were from a specialty clinic, such as a pain management clinic. Tr. 276–277; *see also* 22 Tex. Admin. Code § 291.29(d) (2011) (''A pharmacist shall ensure that prescription drug orders for the treatment of chronic pain have been issued in accordance with the guidelines set forth by the Texas Medical Board in 22 Tex. Admin. Code § 170.3 (relating to Guidelines), prior to dispensing or delivering such prescriptions.'').

I have considered and reject Respondent'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. Exceptions, at 7–9, 11–12. In its Exceptions, Respondent claims that PIC Igwe testified that

> when she initially gets a new customer's prescription, she calls the clinic and practitioner to verify the patient is being seen by the practitioner, the clinic is treating the patient, the condition that is treated, and whether the medication prescribed for the patient is appropriate. Upon the verification by the practitioner that the patient is being treated for a condition with the prescribed drugs, the pharmacist will discuss the prescription with the customer, as appropriate. If a different pharmacy is shown on the PMP, the pharmacist will occasionally call that pharmacy to discern that pharmacist's comfort with the previous prescription.

Exceptions, at 7 (citing Tr. 477–80, 492). Respondent argues that through this process it resolved any red flags on the subject prescriptions. *Id.* at 9.

Once again, however, Respondent has partially misrepresented PIC Igwe's testimony. PIC Igwe testified that for new patients presenting a controlled substance prescription, she would always ''call the clinic and make sure that the clinic did write the prescription.'' Tr. 477–481. She did not testify that she asked about the condition being treated or whether the medication prescribed for the patient is appropriate. PIC Igwe did testify that she would check with the prescriber if she had a concern about ''the dose, the interactions or what not,'' but she did not testify that she did this for all patients presenting controlled substance prescriptions for the first time. Tr. 481.

Additionally, as I discussed *supra,* there is no documentary evidence in the administrative record that Respondent followed the protocols she described in her testimony. The Government issued a subpoena to Respondent requesting ''a copy of the complete patient profile record or any other patient record (paper or electronic) that your pharmacy maintained [for the subject patients], pursuant to the requirements of the Texas Administrative Code Title 22 § 291.33(c)(2)(A) & (C) Operational Standards'' and instructed Respondent to include ''the entire patient record that your pharmacy maintained for each individual, including, but not limited to, any and all Pharmacist comments relevant to the individuals drug therapy, including any information peculiar to the specific patient or drug as well as any consultation with the prescribing practitioner . . . .'' GX 9 (Sept. 6, 2016 Subpoena) and 10 (June 14, 2017 Subpoena). There is no documentation in any of the records Respondent provided in response to the Government's subpoenas that Respondent ever contacted a practitioner or other pharmacy regarding the subject patients the first time they visited Respondent. GX 2. In fact, the only pharmacist notes on any of the records was a ''V'' on one prescription, which PIC Igwe testified meant she had verified the prescription, but the marked prescription was not the first time Respondent had dispensed the same controlled substances to the patient. *Id.;* GX 2, at 44–55.

Respondent claims that PIC Igwe made notes in the ''Demographics'' section of the patient profiles when she had discussions with a prescriber regarding ''the dose, the interactions or what not.'' Tr. 481, 546; Exceptions, at 15. PIC Igwe, however, had no explanation for why she did not produce this claimed documentation to the Government in response to the subpoenas other than to say that it ''is not typically printed in the patient profile sheet,'' and she had no explanation for why she did not provide it as an exhibit or otherwise bring it to the administrative hearing. Tr. 481–482, 546–47. PIC Igwe had a similar response when asked why she filled controlled substance prescriptions that lacked the prescriber's DEA number, a requirement for a valid prescription. Tr. 391, 412; 21 CFR 1306.05(a); Tex. Health & Safety Code § 481.074(k). When a prescription lacks the prescriber's DEA number, Dr. Witte testified that the pharmacist should contact the prescriber and annotate the DEA number on the prescription itself or in the patient profile. Tr. 391. PIC Igwe stated that she would have the prescriber fax her a copy of his or her DEA license with the DEA number, but she did not produce those faxes in response to the Government subpoenas or bring them with her to the hearing. Tr. 535–36. In light of the allegations against Respondent and the explicit requests of the Government subpoenas, I find that it strains credulity that Respondent's claimed documentation exists, but that Respondent did not think it was necessary to provide it to the Government or at the hearing. I, therefore, do not credit Respondent's claims that it adequately investigated and resolved the red flags on the subject prescriptions.

Further, this Agency has applied, and I apply here, the ''adverse inference rule.'' *E.g., Pharmacy Doctors Enterprises d/b/a/Zion Clinic Pharmacy,* 83 FR at 10899. 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 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent's decision not to provide records gives rise to an inference that any such evidence is unfavorable to Respondent.

Based on Respondent's failure to adequately investigate and resolve the many red flags on the subject prescriptions before filling them, I find

[N] 22 Tex. Admin Code § 291.29 has subsequently been amended since the time frame relevant to this matter. The citations and quotations to the Texas Administrative Code in this decision reflect the law as it was at the time the subject prescriptions were dispensed.

that Respondent either knew the prescriptions were issued without a legitimate medical purpose or dispensed the prescriptions knowing there was a high probability that the prescriptions were issued without a legitimate medical purpose. Accordingly, I agree with the ALJ's finding in the Recommended Decision that the Government has proven by substantial evidence that Respondent filled prescriptions for controlled substances that it knew were not prescribed for legitimate medical purposes, or was willfully blind to such, in violation of its corresponding responsibility under 21 CFR 1306.04(a). I also agree with the ALJ's finding that by filling the subject prescriptions without resolving the red flags and documenting the resolution, Respondent acted outside the usual course of professional practice in violation of 21 CFR 1306.06.

ALJ's Determination That Respondent Violated 22 Tex. Amin. Code § 291.33(c)(2)

Respondent filed additional exceptions to the ALJ's determination that Respondent violated the Texas State Board of Pharmacy's Operational Standards for Community Pharmacies, 22 Tex. Admin. Code § 291.33(c)(2). The Texas regulation requires that ''a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant: . . . reasonable dose and route of administration; . . . duplication of therapy; . . . and, proper utilization, including overutilization or underutilization.'' *Id.* at § 291.33(c)(2)(A)(i). If a pharmacist identifies one of the listed ''clinically significant conditions [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' *Id.* at § 291.33(c)(2)(A)(ii). The pharmacist must also document the consultation with the prescriber including the date the pharmacist consulted with the prescriber, the name of the person with whom the pharmacist spoke, and any applicable information pertaining to the consultation. *Id.* at § 291.33(c)(2)(C).

The Government alleged, and the ALJ agreed, that Respondent violated 22 Tex. Admin. Code § 291.33(c)(2) by failing to contact prescribers and document the conversations when presented with prescriptions that raised red flags. OSC, at 2–5; *e.g.,* RD, at 77–79, 82, 87. Respondent objects to the Government's and the ALJ's interpretation of the regulation as requiring a pharmacist to consult with prescribers and document the consultation for all red flags raised by a prescription. Exceptions, at 9–10. Respondent argues that the regulation only requires a pharmacist to document the resolution of ''a clinically significant condition or drug regimen review related question'' and that not all red flags, such as geographical distance, are ''a clinically significant condition or drug regimen review question'' that require documentation under the regulation. *Id.* (citing 22 Tex. Admin. Code § 291.33(c)(2)(A)).

Neither the Government nor the Respondent elicited expert testimony or provided other evidence of what conditions or situations qualify as ''clinically significant'' such that a Texas pharmacist is required by the regulation to consult with the prescriber and document the consultation. During the hearing, Dr. Witte was asked by the ALJ if she was ''aware of whether or not Texas law requires the documentation of red flags'' and she replied ''No. I don't believe so. . . . I'm not aware if there's an actual law.'' [O] Tr. 378. Because there is insufficient evidence on the record through expert testimony or other evidence of state law that the red flags raised by the subject prescriptions are ''clinically significant'' and therefore required documentation of their resolution under Texas regulation, I cannot determine, based on the record before me, that Respondent violated 22 Tex. Admin. Code § 291.33(c). Accordingly, I have edited the Recommended Decision, which I am adopting, to remove the findings that Respondent violated 22 Tex. Admin. Code § 291.33(c).

However, my determination regarding 22 Tex. Admin. Code § 291.33(c) has no effect on the ultimate outcome of this matter. The substantial evidence on the record demonstrates that failing to resolve and document the resolution of red flags falls below the minimum standards of practice of pharmacy in the State of Texas and is, therefore, a violation of 21 CFR 1306.06. *See* Tr. 178–82, 261–62.

5. Sanction

In the RD, the ALJ found that Respondent had taken ''no responsibility for its egregious and repeated failure to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances and other responsibilities of a registration'' and ''presented no evidence of mitigation or remediation'' RD, at 94. The ALJ, therefore, recommended that I revoke Respondent's registration and deny any pending application for renewal or modification. *Id.* Respondent filed exceptions to the ALJ's finding that Respondent did not accept responsibility for its misconduct or ''show the requisite remorse for the wrongdoing alleged against [Respondent].'' Exceptions, at 14.

Where, as here, the Government has met its *prima facie* burden of showing that the respondent's continued registration is inconsistent with the public interest due to its violations pertaining to controlled substance dispensing and recordkeeping, the burden shifts to the respondent to show why it can be entrusted with the responsibility carried by its registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (citing *Samuel S. Jackson,* 72 FR 23848, 23853 (2007)). DEA cases have repeatedly found that when a registrant has committed acts inconsistent with the public interest, ''the Respondent is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Holiday CVS,* 77 FR at 62339 (internal quotations omitted). *See, also, Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 FR 78745, 78749, 78754 (2010) (holding that respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

I agree with the ALJ's finding that there is nothing in the Administrative Record that suggests Respondent has accepted responsibility for its actions. At the hearing, PIC Igwe was asked, ''Do you believe you failed to ensure that the prescriptions for controlled substances which you dispensed were issued for a legitimate medical purpose?'' and PIC

[O] Dr. Witte was later asked if she was familiar with the Texas rule that ''mandates that, 'Upon identifying any clinically significant conditions, situation,' the pharmacist shall take appropriate steps to avoid or resolve the problem, including consultation with the prescribing practitioner . . .'' and also mandates that ''Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber, and written documentation of these discussions made and maintained.'' Tr. 411–412. Dr. Witte responded that ''Yes'' the rule sounded familiar. *Id.* Dr. Witte, however, did not provide any testimony regarding which, if any, of the red flags raised by the subject prescriptions were clinically significant conditions or situations that required consultation and documentation under the rule.

Igwe responded, ''I don't believe that I failed.'' Tr. 567. There is also nothing in Respondent's Proposed Findings or Closing Brief accepting responsibility for the controlled substances dispensed outside the usual course of professional practice and in violation of Respondent's corresponding responsibility. Respondent argues that PIC Igwe took responsibility by admitting that she provided DEA investigators with an incomplete inventory printout during the Administrative Inspection. Exceptions, at 14. I acknowledge PIC Igwe's admission to providing inaccurate documents; however, she did not accept her responsibility as a registrant to have a ''readily retrievable'' dispensing log that met the requirements of 21 CFR 1304.22(c)–repeatedly minimizing her conduct by blaming it on her computer software and failing to correct her conduct by providing DEA with an accurate and complete log within a reasonable time following the inspection.[P] *See* 21 CFR 1304.04(g) (requiring registrants to maintain specified records such that the information is readily retrievable); *Edmund Chein, M.D.,* 72 FR 6580, 6593 (2007); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR at 10901, *aff'd Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x 724, 730 (2019) (finding that producing records as an exhibit for the hearing did not comply with the ''readily retrievable'' requirement of the regulation). Accordingly, I agree with the ALJ that Respondent has not rebutted the Government's *prima facie* case and has not accepted responsibility such that I can entrust it with a registration.

Respondent further argues that the ALJ should have weighed sanctions other than revocation, such as temporary suspension. Exceptions, at 15. While the Agency possesses the discretion to order a sanction short of revocation, I conclude that exercising that discretion here would ill-serve the public interest. Respondent has not shown that it can be entrusted with the responsibility carried by its registration—having failed to accept responsibility for its conduct, I have no assurance that Respondent would not repeat the conduct if it were to retain a registration. My predecessors have also revoked the pharmacy registrations for conduct similar to Respondent's. *See, e.g., Morning Star Pharmacy & Medical Supply 1,* 85 FR 51045 (2020); *Heavenly Care Pharmacy,* 85 FR 53402 (2020); *Pharmacy Doctors Enterprises d/b/a/ Zion Clinic Pharmacy,* 83 FR 10876 (2018).

Finally, Respondent has argued that revocation is inappropriate because the ''DEA investigators did not make a finding of Imminent Harm the day they presented the Administrative Inspection Warrant to [Respondent] back in June of 2015.'' Exceptions, at 14. Respondent has provided no citation for its argument, and I reject the claim as it lacks any basis in Agency statute, regulation, or prior decisions.

For the reasons above, I reject Respondent's contention that the ALJ's recommendation is overly broad and adopt the ALJ's recommended sanction.

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 FT4134805 issued to The Pharmacy Place. 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 The Pharmacy Place to renew or modify this registration. This order is effective May 21, 2021.

D. Christopher Evans,

Acting Administrator.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision

Charles Wm. Dorman

Administrative Law Judge

February 13, 2018

Appearances:

Frank W. Mann, Esq. *for the Government*

Lurese A. Terrell, Esq. *for the Respondent*

The Drug Enforcement Administration (''DEA'' or ''Government'') served The Pharmacy Place (''Pharmacy'' or ''Respondent'') with an Order to Show Cause (''OSC''), seeking to revoke DEA Certificate of Registration (''COR''), Number FT4134805. Administrative Law Judge Exhibit (''ALJ-'') 1. In response to the OSC, the Respondent timely requested a hearing before an Administrative Law Judge. ALJ–2. The first two sessions of the hearing in this matter were held in Dallas, Texas, from September 12–13, 2017. The Respondent's expert, however, failed to appear on either of those days. To accommodate the Respondent, the hearing was continued. On November 20, 2017, the hearing reconvened. The November 20, 2017 session of the hearing was conducted by video teleconference from the DEA Hearing Facility in Arlington, Virginia, with the parties and witnesses located at the DEA District Office in San Antonio, Texas.

At the conclusion of the hearing on November 20, 2017, the Parties were directed to submit their post-hearing briefs no later than January 10, 2018. Tr. 767. On January 8, 2018, however, the Government filed a Consent Motion for Enlargement of Time to File Post-Hearing Briefs, requesting a new filing date of January 24, 2018. ALJ–31. That motion was granted. ALJ–32. Then on January 19, 2018, the Respondent filed a similar motion, requesting an extension of time to file post-hearing briefs until February 7, 2018. ALJ–33. That motion was also granted. ALJ–34.

The issue before the Acting Administrator is whether a preponderance of the evidence supports the revocation of the Respondent's DEA Certificate of Registration (''DEA–COR''), No. FT4134805, pursuant to 21 U.S.C. 824(a)(4) and 823(f), and the denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f).

This Recommended Decision is based on my consideration of the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

Allegations

1. Between August 2014 and May 2015, the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). The Pharmacy did so by repeatedly filling controlled substance prescriptions that contained red flags of diversion and/or abuse without addressing or resolving those red flags. The Pharmacy's conduct in doing so violated 21 U.S.C. 823(f)(4); Tex. Health & Safety Code § 481.070-.075; Tex. Health & Safety Code § 481,128; and Tex. Admin. Code § 291.22(c)(2). Additionally, the Pharmacy engaged in conduct that demonstrates negative experience in its dispensing of controlled substances, in violation of 21 U.S.C. 823(f)(2). ALJ–1, at 2–3, para. 3, 6–8.

2. Between August 2014 and May 2015, the Pharmacy's pharmacists filled numerous prescriptions for highly-abused controlled substances that contained one or more of the following red flags, without resolving those red

[P] Although Respondent eventually produced Respondent Exhibit C, which PIC Igwe testified was Respondent's complete dispensing log for the controlled substance audited by DEA investigators, Tr. 467–71, the document does not comply with the requirements of 21 CFR 1304.22(c), RD, at 85–86.

flags: (1) Prescriptions written to individuals traveling long and/or unusual distances to obtain the prescriptions and/or to fill them at the Pharmacy; (2) prescriptions from individuals obtaining the same or similar combinations of controlled substances from the same small number of providers; (3) prescriptions for highly-abused ''drug cocktails'', such as hydrocodone and alprazolam; (4) prescriptions containing inappropriate and/or unusual directions for use; and (5) prescriptions for controlled substances which the customer purchased with cash. The Pharmacy's practice of filling prescriptions for controlled substances, despite unresolved red flags, included, but was not limited to, the following instances:

a. On August 1, 2014, the Pharmacy filled a prescription for 120, 10 mg tablets of hydrocodone presented by an undercover agent. The agent obtained the prescription from a practitioner in a clinic in south Dallas, more than 30 miles from the Pharmacy, which is located north of Dallas. There was no legitimate medical purpose for the prescription and the agent's address on the prescription was fictitious. The agent also sought to purchase the prescription with cash. ALJ–1, at 3–4, para. 10(a).

b. From August 2014 to May 2015, the Pharmacy dispensed prescription cocktails (hydrocodone and alprazolam) to 25 different individuals, all of whom traveled unusual paths and distances to obtain their prescriptions for these controlled substances and to have them filled at the Pharmacy. Six individuals, J.W., H.J., M.H., A.S., K.S., and M.A., traveled more than 100 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. Another 17 individuals, J.S., C.J., SW, J.W.2, S.H., R.E., R.N., R.H., B.B., S.N., I.B., M.W.2, Y.S., R.H.2, C.D., A.K., and S.B., traveled between 70–100 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. Four individuals, R.N., E.H., B.B., and T.H., traveled between 60–70 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. All of these individuals sought to purchase their prescriptions with cash. Additionally, the prescriptions issued to M.W., J.S., J.W., C.J., S.N., J.W.2, S.H., H.J., E.H., A.S., R.E., K.S., S.B., R.H., T.W., I.B., M.W.2, Y.S., M.A., R.H.2, B.B., C.D., A.K., and R.N., were facially invalid and in violation of federal and state law because they lacked the patient's address and the practitioner's DEA number. ALJ–1, at 4, para. 10(b).

c. Many of the individuals mentioned in paragraph (b), above, obtained the prescriptions from physicians who were engaged in ''pattern prescribing,'' *i.e.,* prescribing the same controlled substances in identical or substantially similar quantities. For instance, between August 19, 2014 and October 2, 2014, C.J., SW, J.W.2, S.H., and H.J. all received prescriptions for hydrocodone and alprazolam from the same physician, I.I., and they traveled long and unusual paths to obtain their prescriptions and have them filled at the Pharmacy. Then between November 14, 2014, and May 1, 2015, the Pharmacy filled 12 prescriptions for hydrocodone written by C.V. for patients A.S., R.E., K.S., G.B., M.A., R.H.2, A.K., R.N., and M.H. All of these patients traveled long and unusual paths to obtain their prescriptions and have them filled. The Pharmacy also filled prescription cocktails (hydrocodone and alprazolam), written by C.V. for patients M.A., R.H.2, and A.K. on April 17, 21, and May 1, 2015, respectively. Additionally, between January 13, 2015 and May 11, 2015, the Pharmacy dispensed controlled substances pursuant to ''pattern-style'' prescriptions issued by NE On 14 different occasions, the Pharmacy dispensed 90, 10 mg tablets of hydrocodone to 11 different customers. On 8 different occasions, the Pharmacy filled identical prescription cocktails written by NE consisting of 90, 10 mg tablets of hydrocodone and 60, 2 mg tablets of alprazolam. Identical prescription cocktails were dispensed to both I.B. and T.W. on April 10, 2015, and to B.B. and C.D. on April 23, 2015. ALJ–1, at 4, para. 10(c).

d. On April 17, 2015, the Pharmacy filled a prescription for hydrocodone to G.B., who had traveled an unusual path and distance of more than 75 miles to obtain her prescription and have it filled at the Pharmacy, and then return home. ALJ–1, at 5, para. 10(d).

3. A DEA audit of the Pharmacy's 10 mg hydrocodone, covering the period of September 25, 2013 through June 18, 2015, revealed a shortage of 47,183 dosage units. Because the Controlled Substances Act requires the maintenance of ''complete and accurate'' inventories, as well as a ''complete accurate record of each substance . . . received, sold, delivered or otherwise disposed of,'' this shortage violated 21 U.S.C. 827(a). ALJ–1, at 5, para. 13.

Witnesses

I. The Government's Witnesses

The Government presented its case through the testimony of four witnesses and a sworn declaration. The Government's first witness was retired Diversion Investigator 1 (hereinafter, DI 1). Tr. 25–146. DI 1 served as a DI with the DEA for 14 years and was assigned to the Dallas, Texas office since June 2008. Tr. 26, 78. As a DI, DI 1 conducted scheduled regulatory investigations, all of which required that he conduct an audit of controlled substances. Tr. 78. DI 1 estimated that he had conducted about 70 audits in his career. Tr. 80.

DI 1 was part of a DEA team that conducted an Administrative Inspection Warrant (''AIW'') of the Pharmacy on June 18, 2015. Tr. 26–27, 60, 451. During that inspection, the DEA obtained documents from the Pharmacy, including: Prescriptions; copies of order forms, invoices, and packing forms concerning the Pharmacy's receipt of controlled substances; and the Pharmacy's dispensing history of hydrocodone. Tr. 35–36, 77–78.

While at the Pharmacy on June 18, 2015, DI 1 conducted a closing inventory of the Pharmacy's hydrocodone, during which all of the medication in the Pharmacy was examined. Tr. 47, 130, 132. That inventory revealed that the Pharmacy was short more than 47,000 tablets of hydrocodone. Tr. 87.

The primary purpose of DI 1's testimony was to lay the foundation for the introduction of Government Exhibits 1–12. During his testimony, all of those exhibits were admitted into evidence. Tr. 3–4. DI 1 also testified that he asked the Pharmacy to provide the DEA with a ''complete history'' of its dispensing of hydrocodone, and that in response to that request the Pharmacy provided the DEA with Government Exhibit 6. Tr. 36–37.

DI 1's testimony was presented in a professional, candid and straightforward manner. In addition, DI 1's testimony was sufficiently objective, detailed, plausible, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

The Government next presented the testimony of its expert, Dr. Amy Witte, Pharm.D. (''Dr. Witte''). Tr. 150–345, 355–425, 763. Government Exhibit 13 is a copy of Dr. Witte's curriculum vitae. Tr. 153–55. Dr. Witte holds a Doctor of Pharmacy degree from the University of Texas at Austin. Tr. 152. Dr. Witte has been a licensed pharmacist in Texas since 2004. Tr. 152–53. Dr. Witte is currently employed with the University of the Incarnate Word, Feik School of Pharmacy, Department of Pharmacy Practice, in San Antonio, Texas, as a full professor, where she has taught Federal and Texas pharmacy law. Tr. 150, 157–58. She is currently the main professor in the endocrine module, with a

specialty in diabetes and thyroid disorders. Tr. 151, 163. She is also currently employed as a clinical pharmacist with the Texas Veterans Health Care System. Tr. 150, 156. Dr. Witte worked as a pharmacist for Walgreens from 2004 until 2011. Tr. 157. Dr. Witte testified that she was certified as an expert witness with the DEA in 2013. Tr. 156. After Respondent's counsel conducted voir dire examination of Dr. Witte, Tr. 158–67, she objected to Dr. Witte being accepted as an expert because Dr. Witte's qualifications were ''all academic.'' Tr. 167–69. The Respondent's objection was overruled and Dr. Witte was then accepted as an ''[e]xpert in the field of pharmacy in the state of Texas.'' Tr. 169.

Dr. Witte presented testimony concerning what a pharmacist is required to do before filling a prescription for a controlled substance in Texas. Tr. 169–71, 178–80, 192, 210. In addition, she testified about circumstances that may give rise to a red flag, which a pharmacist would need to resolve before filling a prescription for a controlled substance. Tr. 171–74, 177–80, 189, 191–93, 244, 281, 321, 323. She also provided testimony based upon her review of Government Exhibits 2, 3, and 12, and rendered her opinion as to whether filling various prescriptions in those exhibits fell below the minimal standard of the practice of pharmacy in Texas, whether filling those prescriptions was within the usual course of the practice of pharmacy in Texas, and whether the pharmacist who filled the prescriptions had satisfied the corresponding responsibility to ensure that only prescriptions issued for a legitimate medical purpose were filled. *See, e.g.,* Tr. 211, 217, 227–28, 236–37, 244–45.

Having closely listened to Dr. Witte's testimony, and having closely reviewed the transcript of her testimony, I find that it was sufficiently objective, detailed, plausible, and internally consistent to be considered credible in this Recommended Decision.

The Government's third witness was DI 2. Tr. 426–440. She testified that she has been a DI with the DEA since 2005. Tr. 426. To become a DI, DI 2 received 12 weeks of training at the DEA Training Academy concerning, ''diversion investigations, pharmacology of drugs, regulatory audits, administrative inspection warrants, . . . and criminal cases.'' Tr. 427. DI 2 is currently assigned to DEA's tactical diversion squad in Dallas, Texas, where she primarily focuses on criminal investigations. Tr. 427. Prior to becoming a DI, DI 2 was an adjunct professor in NASA's aerospace education program at Oklahoma State University. Tr. 427.

DI 2 provided testimony concerning her involvement of DEA's investigation of the Pharmacy, indicating that the Pharmacy had come to DEA's attention as part of a larger investigation into pill mills. Tr. 428. DI 2 was the case agent for the larger investigation. Tr. 428. DI 2 noted that the Pharmacy stood out to her because it was located quite a distance from the offices of the pill mill doctors whose prescriptions the Respondent was filling. Tr. 430. DI 2 participated in the execution of the AIW. Tr. 430.

DI 2's testimony was presented in a professional, candid, and straightforward manner. In addition, DI 2's testimony was sufficiently objective, detailed, plausible, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

Pursuant to an agreement with the Respondent, the Government did not call Ms. Ijeoma Igwe, the Pharmacy's manager and pharmacist-in-charge, as a witness so long as the Respondent called her to testify. Thus, an assessment of her credibility is contained under the discussion of the Respondent's witnesses.

The Government also presented the sworn declaration of UC 1. GE–11. UC 1 presented to the Pharmacy as an undercover agent using the name ''M.W.'' Tr. 41; GE–10, at 3; GE–11, at 2. Prior to the hearing, the Respondent filed an objection ''to the affidavit testimony of [UC 1] because it deprives the Respondent of its cross examination of said witness.'' ALJ–15, at 2. The Respondent's objection to the use of the sworn declaration of UC 1 was overruled in a prehearing Order issued on August 29, 2017. ALJ–18, at 1–2. When the Government introduced UC 1's declaration at the hearing, the Respondent again objected, and again that objection was overruled. Tr. 31–32. In admitting the declaration, I noted that it was a hearsay document and Respondent's lack of opportunity to cross examine UC 1 would be considered in determining what weight to give to the Exhibit. Tr. 32; *see* 21 CFR 1316.58(b). Having examined the sworn declaration of UC 1, I find that its contents are consistent with other evidence of record. For example, UC 1's description of the operation of the Redbird Medical Clinic is consistent with the testimony of DI 2. Tr. 120, 428–31, 435–37. Also, the declaration's statements that: UC 1 received a prescription from Nurse L.R. at the Redbird Medical Clinic for 120 tablets of hydrocodone; the prescription was faxed to the Pharmacy; he was waited on by a female employee at the Pharmacy when he arrived; and he paid $150 for the hydrocodone, are consistent with the content of Government Exhibit 2, at 1, and the fact that the prescription was filled by Ms. Igwe. Tr. 577–78. Finally, none of the evidence presented by the Respondent contradicts the content of the sworn declaration of UC 1. Accordingly, I fully credit the sworn declaration of UC 1.

II. The Respondent's Witnesses

The Respondent presented its case through the testimony of two witnesses. The first witness the Respondent called was Ms. Ijeoma Igwe. Tr. 442–607. Ms. Igwe obtained her pharmacy degree at the University of Liverpool in England and she worked as a clinical pharmacist in England. Tr. 445. Ms. Igwe immigrated to the United States in 2005. Tr. 445, 605–06. Ms. Igwe began her pharmacy career in the United States serving an internship for 8 to 10 months with CVS Pharmacies in Texas. Tr. 445, 606. Ms. Igwe then worked as a pharmacist for Target, filling in where needed at different Target stores. Tr. 446. Ms. Igwe then became interested in compounding pharmacy, which entails making custom medications, and worked for a compounding pharmacy for three years until April 2013. Tr. 447–48. Then in September 2013, Ms. Igwe opened The Pharmacy Place. Tr. 448.

Ms. Igwe presented testimony about the character and operation of the Pharmacy. Tr. 448–51. She also testified about being present at the Pharmacy when the DEA executed the AIW on June 18, 2015, and her interaction with the DEA investigators. Tr. 451–54, 456–58, 465–67. Ms. Igwe described herself as being perplexed, surprised, and shocked during the execution of the AIW, and that she did her best to assist the investigators. Tr. 452. Ms. Igwe testified that after the DEA investigators left the Pharmacy she discovered that she had not provided them a complete record of her hydrocodone dispensing history, attributing her error to a lack of familiarity with the software program. Tr. 466–67. Working with her ''software people,'' Ms. Igwe was able to print out another dispensing log, which she sent to her attorney. Tr. 467–71, 548.

Ms. Igwe testified concerning her standard procedures she used when filling prescriptions. Tr. 477–81. Those procedures included calling a prescriber to verify a prescription for a new patient, checking the prescription monitoring program (''PMP''), as well as checking the dosing and normal things a pharmacist looks for. Tr. 477–84, 503, 517, 586, 590, 607. She also testified

that she would sometimes put a ''V'' on prescriptions to indicate that she had verified them. Tr. 482, 557. She also testified that she would make notes in the ''Demographics'' section of the patient profile to resolve a red flag if she had a discussion with a prescriber about a ''clinical'' matter. Tr. 481, 585.

Ms. Igwe testified that the Pharmacy receives prescriptions from other providers similar to the prescriptions at issue in this case. Tr. 518–22. She noted that there was an orthopedist downstairs from the Pharmacy and he prescribes hydrocodone which she fills, and that there is one customer who gets 150 tablets a month and another who gets 180 tablets a month. Tr. 476–77, 518, 522. She further testified that because she gets other similar prescriptions she believed the prescriptions at issue in this case were in line with what other patients were receiving from other clinics. Tr. 522.

Ms. Igwe also testified that she was not concerned about the distance a customer traveled if they lived in the Dallas-Fort Worth metroplex. Tr. 493–94. Later she testified that distance would be a concern if she did not know the source of the prescription. Tr. 578. She also testified that she did not know where Everman, Texas, was located, yet she filled multiple prescriptions for patient A.S., who lived in Everman. Tr. 579; GE–2, at 22–33. Ms. Igwe also testified that she would not fill a prescription if the address on the prescription did not match the address on the customer's driver's license. Tr. 539.

While Ms. Igwe seemed confident while she testified, and her testimony appeared sincere and candid, there are several issues with her testimony that detract from its overall believability. First, she testified that she would call the prescriber the first time a patient presented with a prescription for a controlled substance and that she would sometimes mark the prescription with a ''V'' to indicate that she had verified the prescription. Tr. 477, 482, 557. The documentary evidence, however, does not support that testimony. For example, there are 68 prescriptions contained in Government Exhibit 2, but only one is marked with a ''V.'' [1] GE–2, at 49. Furthermore, the alprazolam prescription marked with a ''V'' for patient K.S. is dated February 26, 2015. *Id.* K.S., however, had filled prescriptions for both alprazolam, as well as hydrocodone, at the Pharmacy six times before Ms. Igwe marked the February 26, 2015 prescription with a ''V.'' GE–2, at 44–46, 53–55. In addition, Government Exhibit 6 establishes that Dr. C.V. wrote many prescriptions for hydrocodone, but in spite of all those prescriptions, Ms. Igwe never had a conversation with Dr. C.V. about a patient. Tr. 561. In fact, the only time Ms. Igwe talked with Dr. C.V. was when he called her about a non-patient matter. Tr. 561.

Second, Ms. Igwe testified that she did not find the prescriptions at issue in this case to be out of line with other prescriptions she filled. Tr. 522. She also testified that she filled prescriptions for an orthopedist, who performed surgery downstairs from the Pharmacy, and that the orthopedist prescribed hydrocodone. Tr. 476, 518. She further testified that she had one customer who took 150 hydrocodone tablets a month and another who took 180. Tr. 518, 522. While the documentary evidence does not necessarily contradict that testimony, the documentary evidence clearly does not support Ms. Igwe's testimony. For example, Government Exhibit 6 details 929 prescriptions that the Pharmacy filled for hydrocodone. All but 25 of those prescriptions were written by the same small group of prescribers, whose prescriptions are identified on the patient profiles contained in Government Exhibit 2. Further examination of Government Exhibit 6 fails to reveal any patient with a prescription for 150 or 180 tablets of hydrocodone. In addition, there is only one prescription written by a prescriber, Dr. V.K., with the same address as the Pharmacy; she wrote a prescription for 30 tablets of hydrocodone. GE–6, at 13.

Third, Ms. Igwe's explanation about why she was not concerned about the delay between the hydrocodone that was prescribed for pain and the date the patient picked it up with respect to Government Exhibit 2, at 1, makes little sense. She explained that a patient with chronic pain might possibly have pain medicine they had received before to tide them over until they could pick up a new prescription. Tr. 564–65. She also testified that she always checked the PMP before filling prescriptions. Tr. 479. The prescription on page 1 of Government Exhibit 2 was for an undercover agent using a fake name. Had Ms. Igwe checked the PMP for that patient, she would not have found any prior prescriptions, eliminating the possibility that the patient had leftover medication to tide him over. Clearly, as Government counsel suggested, Ms. Igwe was simply speculating about reasons for the delay. Tr. 545, 565; *see also* ALJ–35, at 24.

When initially explaining the ''Rx Date'' on the entries in Government Exhibit 6, Ms. Igwe testified that all of the hydrocodone prescriptions identified in Government Exhibit 6 were electronic prescriptions and the ''Rx Date'' was the date the prescriptions were received. Tr. 533, 560, 562. She backtracked from that position when confronted by the fact that the prescription at Government Exhibit 2, at 1, was a handwritten prescription and it was also recorded on page 8 of Government Exhibit 6. Tr. 562, 580. Other handwritten prescriptions contained in Government Exhibit 2 are also recorded in Government Exhibit 6. *Compare* GE–2, at 16 *with* GE–6, at 28; *compare* GE–2, at 28 *with* GE–6, at 65. At the hearing, my impression was that Ms. Igwe was downplaying the significance of the ''Rx Date,'' because to do so decreased the likelihood that she would have observed one prescription after another for hydrocodone coming into the Pharmacy, written by the same doctors and for the same strengths and normally for the same quantity.

Finally, Ms. Igwe testified that when she received faxed prescriptions from medical clinics, the clinics also faxed additional information such as the patient's address and identification on separate pages. Tr. 488–89, 539–40. Ms. Igwe also testified that when she would resolve red flags concerning clinical matters about a prescription she would make notes in the demographics section of the patient profile. Tr. 481, 546. She further explained that these notes did not print out when she printed the patient profile. Tr. 482. When asked why she did not bring copies of the materials the medical clinics had faxed to her, or copies of her notes that showed she had resolved red flags, Ms. Igwe testified that she did not think she needed to or that she did not think it was necessary. Tr. 547. This explanation makes no sense in light of the allegations against her and it is not credible. Ms. Igwe's credibility on this issue is further undermined by the fact that this type of information was sought by the investigators during the execution of the AIW and by the September 6, 2016 subpoena. Tr. 78, 356–57; GE–9.

In light of the aspects of Ms. Igwe's testimony outlined above, and those are but a few of the examples that could be given, I find that her testimony merits only limited belief. Thus, where Ms. Igwe's testimony conflicts with the testimony of other witnesses, or with the documentary evidence of record, I credit that other testimony and those documents over Ms. Igwe's testimony.

[1] None of the prescriptions submitted by the Respondent in Respondent Exhibit H are marked with a ''V.''

The Respondent's second witness was Mr. Robert Litman. Tr. 623–762. His curriculum vitae is contained in Respondent's Exhibit B. Tr. 632. Mr. Litman testified concerning his background education and work history. Tr. 624–631, 652–655. Mr. Litman earned his pharmacy degree from the University of Florida in 1981 and he has worked as a pharmacist since then. Tr. 624. Mr. Litman has managed about a dozen small pharmacies over the past 36 years. Tr. 624. He is currently the Director of Consultant and Management Services with Ultimed Health Advisors, dealing with, among other things, the ''management of retail pharmacy operations.'' Tr. 622; RE–B, at 1. Mr. Litman is also a Clinical Assistant Professor of Pharmacy Practice in geriatric medicine at Nova Southeastern University, Ohio State University, and Palm Beach Atlantic University. Tr. 641, 644; RE–B, at 2. Mr. Litman has previously testified as an expert witness, but only in Florida. Tr. 623, 638–39. Mr. Litman currently works a couple of days per month as a retail pharmacist. Tr. 650, 652. Following voir dire by Government counsel, Mr. Litman was accepted as an expert witness, without objection, in the area of ''retail pharmacy practices.'' Tr. 656.

Mr. Litman presented his testimony in a direct, straightforward, and candid manner. Mr. Litman had a professional demeanor while he testified. During voir dire of Mr. Litman, the Government noted that Mr. Litman's expert testimony was evaluated by another Administrative Law Judge (''ALJ'') in an earlier case before the DEA. Tr. 650–52; *see Howard N. Robinson, M.D.,* 79 FR 19356 (2014). While the ALJ in that case found some portions of a report that Mr. Litman prepared to be ''peculiar,'' the ALJ credited his testimony, describing it as ''sufficiently detailed, authoritative and candid.'' Tr. 652; *Robinson, M.D.,* 79 FR at 19364–65. While I too find portions of Mr. Litman's testimony to be a bit peculiar or inconsistent, in general I find that he presented testimony that was ''sufficiently detailed, authoritative, and candid'' to be generally credited in this decision.

Some portions of Mr. Litman's testimony that were peculiar or inconsistent concerned the following areas: Distance that customers traveled; a lack of concern for pattern prescribing; drug cocktails; and a delay between the date a prescription was written to treat pain and the date the customer picked up the prescription. Mr. Litman was not particularly concerned about the distance a customer traveled to fill a prescription. Tr. 726–30. While he did testify that as a pharmacist working in Miami, he would find it a little leery if a customer traveled from South Carolina to fill a prescription, he also testified that there was no problem if the customers were from in-state. Tr. 730. Mr. Litman's approach seemingly ignores the fact that portions of South Carolina are closer to Miami than is, ''in-state'', Pensacola, Florida. Further, and of greater significance, Mr. Litman was not familiar with DEA case law concerning pharmacy customers driving long distances, or of the Texas requirement for pharmacists to consider distance. Tr. 727. Thus, without an understanding of the law, it is understandable why Mr. Litman has little concern for the distance a customer travels to obtain a prescription and have it filled.

Mr. Litman also testified that he would not be concerned about pattern prescribing when filling 23 successive prescriptions for hydrocodone from the same provider. Tr. 747–49. Nevertheless, Mr. Litman testified that he would call the prescriber every time he was presented with a new prescription for hydrocodone. Tr. 747, 749. Mr. Litman also testified that he would not be concerned about pattern prescribing if he had spoken with the doctor and was comfortable that there was a legitimate doctor-patient relationship. Tr. 748.

Mr. Litman's testimony concerning drug cocktails was difficult to follow. Mr. Litman first acknowledged that a customer presenting prescriptions for hydrocodone and alprazolam would be presenting prescriptions for a drug cocktail. Tr. 740. Mr. Litman further testified that he would only be concerned about filling such prescriptions if the customer was diverting or abusing the controlled substances. Tr. 741. Mr. Litman, however, could not explain how a pharmacist would know if the customer was diverting or abusing the controlled substances. Tr. 741. He later explained that the combination of these two drugs could be a drug cocktail depending on the reason the patient received the prescription. Tr. 741–42. Mr. Litman's explanation ignores the fact that the only way the pharmacist could make an informed decision as to whether the prescriptions had been issued for a legitimate medical purpose would be to call the prescriber. Coming full circle, Mr. Litman then testified that when confronted with prescriptions for hydrocodone and alprazolam he would call the prescriber to ''make sure that [the prescriber] wrote those prescriptions, that they were valid prescriptions for a patient, and there was a doctor-patient relationship.'' Tr. 743.

Mr. Litman was also asked whether he would have any concern where a patient delayed picking up a prescription written for pain, and he said it would not concern him at all. Tr. 749–50. When asked why he would have no concern, not surprisingly he gave the same speculative answer given by Ms. Igwe—he would assume the patient had some medication left over from a prior prescription or the patient had obtained medication samples directly from the prescriber. Tr. 750–52. The answer is not surprising because Mr. Litman was able to read Ms. Igwe's testimony before he testified. Tr. 683. Although this delay would be of no concern to Mr. Litman, he did testify that he would call the doctor to ''let him know that the patient hadn't filled [the prescription] for a week, and [ask] if there was an issue.'' Tr. 751. Mr. Litman's explanation suggests that he would be concerned about a delay in picking up a prescription for pain medication, even though he would not acknowledge it.

These four examples of areas in which Mr. Litman's testimony was peculiar or inconsistent are not all-inclusive. Thus, while I find Mr. Litman's testimony to be generally worthy of belief, where it conflicts with Dr. Witte's testimony, or laws, regulations, or DEA precedent, I give greater weight to her testimony and to legal authority.

The Facts

I. Stipulations of Fact

The parties agree to 45 stipulations (''Stip.''), which are accepted as facts in these proceedings:

1. Respondent Pharmacy Place is registered with DEA as a retail pharmacy authorized to handle controlled substances in Schedules II–V under DEA COR number FT4134805 at 4031 W. Plano Parkway, Suite 211, Plano, Texas 75093. DEA COR FT4134805 expires on November 30, 2019.

2. The pharmacy is owned by HOIC Enterprises, LLC, a Texas limited liability company, and does business as The Pharmacy Place. It is operated and managed by Harrison and Ijeoma Igwe.

3. According to the Texas Office of the Comptroller, Harrison Igwe and Ijeoma Igwe are listed as managers of HOIC Enterprises LLC.

4. According to the Texas Board of Pharmacy, The Pharmacy Place is a licensed community pharmacy in the State of Texas, license no. 28650.

5. According to the Texas Board of Pharmacy, Ijeoma Igwe is a licensed pharmacist (License No. 44785) in the

State of Texas and is the Pharmacist-in-Charge (''PIC'') of The Pharmacy Place.

6. Norco is a brand name of a combination medication containing the Schedule II generic drug hydrocodone.

7. Xanax is the brand name of the Schedule IV generic drug alprazolam.

8. Promethazine with codeine is a Schedule V controlled substance.

9. Government Exhibit (''GE'') 3, pp. 1–5, is a Mapquest printout showing the path and distance from M.A.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) M.A.'s residence. (107 miles total).

10. Government Exhibit (''GE'') 3, pp. 6–10, is a Mapquest printout showing the path and distance from B.B.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE on 201 Billings Street in Arlington, Texas (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) B.B.'s residence. (80 miles total).

11. Government Exhibit (''GE'') 3, pp. 11–15, is a Mapquest printout showing the path and distance from B.B.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE on 2617 Bolton Boone Drive in DeSoto, Texas (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) B.B.'s residence. (66 miles total).

12. Government Exhibit (''GE'') 3, pp. 16–19, is a Mapquest printout showing the path and distance from G.B.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) G.B.'s residence. (55 miles total).

13. Government Exhibit (''GE'') 3, pp. 20–24, is a Mapquest printout showing the path and distance from I.B.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) I.B.'s residence. (79 miles total).

14. Government Exhibit (''GE'') 3, pp. 25–29, is a Mapquest printout showing the path and distance from S.B.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) S.B.'s residence. (79 miles total).

15. Government Exhibit (''GE'') 3, pp. 30–34, is a Mapquest printout showing the path and distance from C.D.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) C.D.'s residence. (81 miles total).

16. Government Exhibit (''GE'') 3, pp. 35–39, is a Mapquest printout showing the path and distance from R.E.'s residence (as listed in Respondent's Patient Profile) to (1) C.Z., S.G., and/or L.R. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.E.'s residence. (86 miles total).

17. Government Exhibit (''GE'') 3, pp. 40–44, is a Mapquest printout showing the path and distance from R.E.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.E.'s residence. (94 miles total).

18. Government Exhibit (''GE'') 3, pp. 45–48, is a Mapquest printout showing the path and distance from E.H's residence (as listed in Respondent's Patient Profile) to (1) I.I. and/or Dr. A.Q. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) E.H's residence. (68 miles total).

19. Government Exhibit (''GE'') 3, pp. 49–53, is a Mapquest printout showing the path and distance from M.H.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) M.H.'s residence. (116 miles total).

20. Government Exhibit (''GE'') 3, pp. 54–58, is a Mapquest printout showing the path and distance from M.H.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) M.H.'s residence. (121 miles total).

21. Government Exhibit (''GE'') 3, pp. 59–63, is a Mapquest printout showing the path and distance from R.H.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. A.Q. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.H.'s residence. (79 miles total).

22. Government Exhibit (''GE'') 3, pp. 64–68, is a Mapquest printout showing the path and distance from R.H.'s residence (as listed in Respondent's Patient Profile) to (1) J.W. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.H.'s residence. (76 miles total).

23. Government Exhibit (''GE'') 3, pp. 69–73, is a Mapquest printout showing the path and distance from R.H.2's residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.H.2's residence. (92 miles total).

24. Government Exhibit (''GE'') 3, pp. 74–78, is a Mapquest printout showing the path and distance from S.H.'s residence (as listed in Respondent's Patient Profile) to (1) I.I. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) S.H.'s residence. (76 miles total).

25. Government Exhibit (''GE'') 3, pp. 79–83, is a Mapquest printout showing the path and distance from C.J.'s residence (as listed in Respondent's Patient Profile) to (1) I.I. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) C.J.'s residence. (81 miles total).

26. Government Exhibit (''GE'') 3, pp. 84–88, is a Mapquest printout showing the path and distance from H.J.'s residence (as listed in Respondent's Patient Profile) to (1) I.I. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) H.J.'s residence. (105 miles total).

27. Government Exhibit (''GE'') 3, pp. 89–93, is a Mapquest printout showing the path and distance from A.K.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) A.K.'s residence. (81 miles total).

28. Government Exhibit (''GE'') 3, pp. 94–98, is a Mapquest printout showing the path and distance from R.N.'s residence (as listed in Respondent's Patient Profile) to (1) the Billings Street address in Arlington, Texas, where C.Z., S.G., Dr. NE and/or L.R. are listed as practicing according to Respondent's Patient Profile) to (2) Respondent's address to (3) R.N.'s residence. (95 miles total).

29. Government Exhibit (''GE'') 3, pp. 99–103, is a Mapquest printout showing the path and distance from R.N.'s residence (as listed in Respondent's Patient Profile) to (1) the Bolton Boone Drive address in DeSoto, Texas, where Dr. NE is listed as practicing according to Respondent's Patient Profile) to (2) Respondent's address to (3) R.N.'s residence. (78 miles total).

30. Government Exhibit (''GE'') 3, pp. 104–108, is a Mapquest printout showing the path and distance from R.N.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) R.N.'s residence. (64 miles total).

31. Government Exhibit (''GE'') 3, pp.109–112, is a Mapquest printout showing the path and distance from S.N.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) S.N.'s residence. (81 miles total).

32. Government Exhibit (''GE'') 3, pp.113–117, is a Mapquest printout showing the path and distance from A.S.'s residence (as listed in Respondent's Patient Profile) to (1) C.Z., Dr. NE, L.R., and/or S.G. (as listed in

Respondent's Patient Profile) to (2) Respondent's address to (3) A.S's residence. (104 miles total).

33. Government Exhibit (''GE'') 3, pp.118–122, is a Mapquest printout showing the path and distance from A.S.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) A.S.'s residence. (111 miles total).

34. Government Exhibit (''GE'') 3, pp.123–127, is a Mapquest printout showing the path and distance from J.S.'s residence (as listed in Respondent's Patient Profile) to (1) L.R. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) J.S.'s residence. (80 miles total).

35. Government Exhibit (''GE'') 3, pp.128–133, is a Mapquest printout showing the path and distance from K.S.'s residence (as listed in Respondent's Patient Profile) to (1) C.Z., Dr. NE, S.G., and/or L.R. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) K.S.'s residence. (101 miles total).

36. Government Exhibit (''GE'') 3, pp.134–139, is a Mapquest printout showing the path and distance from K.S.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. C.V. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) K.S.'s residence. (109 miles total).

37. Government Exhibit (''GE'') 3, pp.140–144, is a Mapquest printout showing the path and distance from Y.S.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE on Billings Street in Arlington, Texas, (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) Y.S.'s residence. (97 miles total).

38. Government Exhibit (''GE'') 3, pp.145–150, is a Mapquest printout showing the path and distance from Y.S.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE on Bolton Boone Drive in DeSoto, Texas (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) Y.S.'s residence. (79 miles total).

39. Government Exhibit (''GE'') 3, pp.151–156, is a Mapquest printout showing the path and distance from J.W.'s residence (as listed in Respondent's Patient Profile) to (1) S.G. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) J.W.'s residence. (108 miles total).

40. Government Exhibit (''GE'') 3, pp.157–161, is a Mapquest printout showing the path and distance from J.W.2's residence (as listed in Respondent's Patient Profile) to (1) I.I. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) J.W.2's residence. (98 miles total).

41. Government Exhibit (''GE'') 3, pp.162–166, is a Mapquest printout showing the path and distance from M.W.2's residence (as listed in Respondent's Patient Profile) to (1) L.R. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) M.W.2's residence. (97 miles total).

42. Government Exhibit (''GE'') 3, pp.167–171, is a Mapquest printout showing the path and distance from M.W.2's residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) M.W.2's residence. (79 miles total).

43. Government Exhibit (''GE'') 3, pp.172–176, is a Mapquest printout showing the path and distance from SW's residence (as listed in Respondent's Patient Profile) to (1) I.I. (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) SW2's residence. (99 miles total).

44. Government Exhibit (''GE'') 3, pp.177–181, is a Mapquest printout showing the path and distance from T.W.'s residence (as listed in Respondent's Patient Profile) to (1) Dr. NE (as listed in Respondent's Patient Profile) to (2) Respondent's address to (3) T.W.'s residence. (66 miles total).

45. Government Exhibit (''GE'') 12, pp.1–5, is a Mapquest printout showing the path and distance from 5944 Callaston Lane, Ft. Worth, Texas to (1) Redbird Medical Clinic (3107 Camp Wisdom Road, Dallas, Texas) to (2) Respondent's location to (3) 5944 Callaston Lane, Ft. Worth, Texas.

II. Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

The Pharmacy

1. Ms. Ijeoma Igwe (''Ms. Igwe'') graduated from pharmacy school at the University of Liverpool in England in 1989. Tr. 445, 605–06. After graduating, she worked as a clinical pharmacist in England until she relocated to the United States in 2005. *Id.* at 445.

2. Ms. Igwe began practicing pharmacy in Texas in 2006 by working as a pharmacy intern with CVS for 8–10 months. *Id.* at 445–46, 606. She then worked as a full-time floater pharmacist at various Target stores. *Id.* at 446–47. She eventually left Target and worked for a rehabilitation hospital for three months. *Id.* at 447. She then worked as a pharmacist at Albertson's. *Id.* at 447.

3. Ms. Igwe is a licensed Texas pharmacist. *Id.* at 516.

4. While working at Albertson's, Ms. Igwe developed an interest in compounding pharmacy. Tr. 447. She then worked at a compounding pharmacy for approximately three years until April 2013. *Id.* at 447.

5. Ms. Igwe opened the Pharmacy in September 2013. *Id.* at 448.

6. The Pharmacy is owned by HOIC Enterprises, LLC, and Ms. Igwe is the pharmacist-in-charge of the Pharmacy. *Id.* at 35.

7. The Pharmacy is a small pharmacy. *Id.* at 433, 449. When the DEA inspected the Pharmacy, the Pharmacy was filling approximately 60–100 prescriptions a day. *Id.* at 474, 696–97.

8. Ms. Igwe is the only pharmacist who works at the Pharmacy. *Id.* at 449, 481–82, 577.

9. Because Ms. Igwe is the only pharmacist at the Pharmacy, she filled all the prescriptions in Government Exhibit 2. *Id.* at 577–78.

10. Most of the Pharmacy's prescriptions are electronically received through ''e-script.'' *Id.* at 487–88. Some prescriptions are sent by fax. *Id.* at 488.

11. The Pharmacy began seeing prescriptions from Redbird Medical Clinic, and other clinics under investigation, around January or February 2014. *Id.* at 475.

The Inspection

12. The Pharmacy came to DEA's attention during a larger investigation of ''pill mill'' clinics in the Dallas area in 2013. *Id.* at 428. The DEA went to the Pharmacy because it had been identified as a pharmacy that was filling prescriptions issued by ''pill mill'' clinics. *Id.* at 63–64, 430.

13. The DEA suspected that some prescriptions the Pharmacy filled were not issued for legitimate medical purposes because they were issued from a ''pill mill'' clinic. *Id.* at 120. The suspected ''pill mill'' clinic had a security guard in the parking lot who ushered people into the clinic. *Id.* at 120.

14. At least two doctors and four nurse practitioners involved in the DEA's investigation of Dallas-area pill mills were indicted. *Id.* at 437–38. One of the doctors pled guilty and was sentenced. *Id.* at 437. Additionally, two pharmacists were indicted, pled guilty, and sentenced. *Id.* at 438.

15. On June 18, 2015, Diversion Investigators, DI 1and DI 2 were part of the DEA investigative team that executed an Administrative Inspection

Warrant (''AIW'' or ''Inspection'') at the Pharmacy. *Id.* at 27, 60, 431, 451.

16. During the inspection, Ms. Igwe was the only employee working at the Pharmacy. *Id.* at 141–42.

17. During the inspection, DEA investigators discussed their concerns about the Pharmacy with Ms. Igwe. *Id.* at 431–32.

18. During the inspection, DEA asked Ms. Igwe for any documentation she had to show that the Pharmacy had verified the prescriptions it had filled. *Id.* at 78, 431–32.

19. DEA investigators also requested that the Pharmacy turn over all of the notes it had concerning the resolution of red flags. *Id.* at 356–57, 431–32; GE–9.

20. Ms. Igwe told investigators that she did not verify the legitimacy of every prescription the Pharmacy filled. Tr. 432.

21. During the inspection, DI 1 and DI 2 asked Ms. Igwe if she believed the prescriptions were genuine, and Ms. Igwe stated that she believed they were. *Id.* at 457.

22. The Pharmacy was asked to provide DEA with a complete history of its dispensing of hydrocodone [2] from the date the Pharmacy opened to the date of the inspection, June 18, 2015. *Id.* at 36, 431–32.

23. During the inspection, when DEA investigators asked Ms. Igwe for documentation concerning the Pharmacy, Ms. Igwe pointed to where the documentation was located. *Id.* at 66, 431–32. At the time of the inspection, the Pharmacy was in disarray. *Id.* at 66. Investigators also seized invoices, 222 Forms, hard-copy prescriptions, and the Pharmacy's dispensing history for hydrocodone. *Id.* at 35–36, 77–78, 434, 456.

24. Government Exhibit 6 is the hydrocodone dispensing log Ms. Igwe printed from the Pharmacy's computer and provided to DI 2 and DI 1 when they executed the AIW at the Pharmacy. *Id.* at 37, 67, 135, 456, 553.

25. The date range printed at the top of Government Exhibit 6 runs from October 23, 2013, to June 18, 2015. *Id.* at 553.

26. Ms. Igwe later realized that the dispensing log she gave to the investigators was incomplete. *Id.* at 466. She had never printed an inventory report before. *Id.* at 466.

27. Sometime after the inspection, Ms. Igwe contacted the manufacturer of the software the Pharmacy used, and the manufacturer showed her how to run the complete hydrocodone dispensing report. *Id.* at 467. She then gave this report, contained in Respondent Exhibit C, to an attorney to forward to the DEA. *Id.* at 468–69, 470–71, 549.

28. There are no dates or date range on any of the documents in Respondent Exhibit C. *Id.* at 551.

29. Pages 5–133 of Government Exhibit 2 contain prescriptions obtained from the Pharmacy during the administrative inspection on June 18, 2015, and patient profiles the Pharmacy provided to the DEA in response to an administrative subpoena. *Id.* at 44–45; GE–2.

30. The Pharmacy's computer system automatically assigns a date, time, and prescription number to the prescription when it is received. Tr. 533–34, 562, 580.

31. Government Exhibit 8 contains invoices showing the quantity of hydrocodone shipped to the Pharmacy. *Id.* at 49–50. The invoices in Government Exhibit 8 are some of the invoice documents DI 1 reviewed in conducting an audit of the Pharmacy's hydrocodone during the inspection. *Id.* at 52–54. DI 1 conducted the inspection at DI 2's direction. *Id.* at 64–65.

32. During the inspection, Ms. Igwe informed DEA investigators that they had all the documentation they had requested. *Id.* at 77.

33. During the inspection, Ms. Igwe was ''pretty upset'' and ''a little freaked out.'' *Id.* at 95, 97, 452.

34. During the inspection, Ms. Igwe had no response when asked if she found it suspicious that customers were traveling from a clinic 30 miles away to get their prescriptions filled at the Pharmacy. *Id.* at 76–77, 101–02.

35. During the inspection, Ms. Igwe told DEA investigators that she had spoken to one of the prescribers, Dr. C.V., on one occasion. *Id.* at 106.

36. After the administrative inspection, DI 1 conducted an audit of the Pharmacy's inventory of hydrocodone 10/325 mg. *Id.* at 45–46.

37. In conducting the audit, the Pharmacy's initial inventory showed zero hydrocodone. *Id.* at 46–47. DI 1 reviewed the Pharmacy's receiving documents for controlled substances and he took a closing inventory for hydrocodone on June 18, 2015. *Id.* at 47. The audit revealed that the Pharmacy was short 47,183 tablets of hydrocodone 10/325 mg. *Id.* at 56–58; GE–7.

38. DI 1 looked at all medications in the Pharmacy when he conducted the closing inventory of hydrocodone on June 18, 2015. Tr. 130, 132.

39. During the inspection, Ms. Igwe signed the closing inventory. *Id.* at 141.

40. In all of the audits that DI 1 has conducted in his career, he has never identified a shortage as large as the shortage he identified at the Pharmacy. *Id.* at 90. Even a shortage of 2500 tablets of hydrocodone is a substantial shortage. *Id.* at 88–89.

41. The Texas Prescription Monitoring Program (''PMP'') did not match up with the Pharmacy's dispensing records. *Id.* at 60. The dispensing records showed that the first dispensing took place on July 7, 2014, but the PMP showed that the Pharmacy filled prescriptions for hydrocodone between January and June 2014. *Id.* at 60. Those prescriptions are not contained in the Pharmacy's dispensing record for hydrocodone. *Id.;* GE–6. The shortage that DI 1 found when auditing the Pharmacy's hydrocodone would be reduced if the information contained in the PMP concerning the prescriptions the Pharmacy filled prior to July 7, 2014, were considered. Tr. 76.

42. The PMP is not a Pharmacy record. *Id.* at 123–24.

43. The DEA did not receive any explanation from the Pharmacy concerning why its distribution report, Government Exhibit 6, did not report a distribution of hydrocodone until July 7, 2014. *Id.* at 138.

44. DI 1 was never informed that the Pharmacy had additional information to provide him concerning the audit he conducted. *Id.* at 85.

Controlled Substances

45. Hydrocodone has been a schedule II controlled substance since October 6, 2014. *Id.* at 132–33.

46. The highest strength of hydrocodone is 10/325 mg. *Id.* at 176.

47. A prescription for 90 tablets of hydrocodone would be a large quantity of tablets. *Id.* at 366–67, 394.

48. Hydrocodone is usually prescribed to be taken once every 4 to 6 hours, as needed for moderate to severe pain, not to exceed 6 tablets in 24 hours. *Id.* at 176, 283, 366, 680. Normally a patient would have another medication for moderate to severe pain. *Id.* at 176–77, 681.

49. The highest strength for alprazolam is 2 mg. *Id.* at 177, 723.

50. A prescription for 60 tablets of alprazolam would be a large quantity of tablets. *Id.* at 394–95.

51. Prescriptions for the highest strength of a controlled substance raise a concern that the patient could exceed the maximum daily dose. *Id.* at 230.

52. The maximum dose of acetaminophen is 4 grams per day. *Id.* at 531, 680. A pharmacist's concern with the dose of hydrocodone would lie with the acetaminophen component of

[2] All of the hydrocodone dispensed by the Pharmacy in this case was hydrocodone/APAP 10/325 mg. This Recommended Decision will simply refer to it as ''hydrocodone.'' ''APAP'' is the abbreviation for acetaminophen. Tr. 398.

the drug. *Id.* at 531, 662. Ten tablets of hydrocodone contain 3.25 grams, which is below the maximum per day. *Id.* at 531, 680. According to the standard instruction of one tablet every four to six hours, a patient would take no more than six tablets of hydrocodone per day, which would be less than the maximum daily dose of acetaminophen. *Id.* at 531, 680.

53. Alprazolam, hydrocodone, and promethazine with codeine are high-alert drugs. *Id.* at 269.

54. Any combination of alprazolam, hydrocodone, promethazine with codeine, and carisoprodol constitutes a drug cocktail of high-alert drugs. *Id.* at 178, 270–71, 710, 740.

55. When taken together, alprazolam and hydrocodone can produce a euphoric and addictive effect very similar to that of a heroin high. *Id.* at 178, 269, 711.

56. Alprazolam and hydrocodone are among the top 10 most frequently prescribed controlled substances in the United States. *Id.* at 271, 273, 668.

Red Flags

57. The term ''red flag'' is not contained in any DEA regulation. *Id.* at 256, 657.

58. Pharmacists use the term ''red flag'' to denote a potential issue with a prescription. *Id.* at 170–71, 569, 657. The minimum standard of the practice of pharmacy in Texas requires a pharmacist to look for red flags. *Id.* at 171.

59. A red flag can be indicative of drug abuse or diversion. *Id.* at 172, 741.

60. Ms. Igwe did not learn the term ''red flag'' during her pharmacist training in England, but she now understands what it means. *Id.* at 521.

61. Pattern prescribing is a red flag because it indicates no individualization of therapy. *Id.* at 171, 244, 745. An example of pattern prescribing would be multiple prescriptions from the same prescriber or medical group for the same medications, in the same quantities, dosages, and strengths, written for different patients. *Id.* at 171.

62. When a medical provider only prescribes the maximum strength of a controlled substance, the prescriptions suggest that the provider is engaged in pattern prescribing. *Id.* at 231–32.

63. The distance a person travels, or the route a person travels, to fill a prescription can be a red flag because it is likely there are multiple pharmacies along the same route. *Id.* at 172, 174–75.

64. When a patient travels all over a metropolitan area to get to a doctor and then to a pharmacy to fill a prescription, that behavior raises a red flag because there would be multiple pharmacies along the way where the patient could fill the prescription.[3] *Id.* at 281, 321, 323.

65. Paying cash for a prescription can be a red flag. *Id.* at 172, 692.

66. Most patients have some sort of third-party payer, such as health insurance, to pay for their prescriptions. *Id.* at 358.

67. Hydrocodone and alprazolam are normally covered by insurance. *Id.* at 399.

68. The lack of a patient's address and/or the prescriber's DEA registration number on a prescription is a red flag. *Id.* at 179, 391, 412, 693–94.

69. Prescriptions for high-alert drugs such as alprazolam, hydrocodone, and promethazine with codeine, have the potential for abuse and diversion, and thus can be a red flag. *Id.* at 172–74, 720.

70. A drug cocktail is a red flag. *Id.* at 178.

71. Dosing instructions for hydrocodone that require the patient to take one tablet twice a day for moderate to severe pain would be a red flag, because it is less than the normal dosage for hydrocodone. *Id.* at 177.

72. Many of the prescriptions for hydrocodone contained in Government Exhibit 2 had dosing instructions to take one tablet every four to six hours, which is the normal dosing for hydrocodone, and not a red flag. *Id.* at 343–44

73. Dosing instructions for alprazolam that require the patient to take one tablet twice a day for anxiety raises a red flag because alprazolam is typically dosed more frequently than twice per day when it is prescribed for anxiety. *Id.* at 177.

74. Alprazolam can be prescribed to treat pain. *Id.* at 665–66.

75. A delay between the date that a prescription is written for moderate to severe pain and the date the prescription is filled can be a red flag. *Id.* at 396–97.

Standards of Pharmacy Practice

76. When a customer presents a prescription to a pharmacy, the pharmacist should examine the prescription, looking at the date of the prescription, the patient's name and address, the medication and its strength and quantity, as well as its directions for use, and the signature of the provider. *Id.* at 169–70.

77. If the prescription does not contain the patient's address or the prescriber's DEA number, the prescription is invalid and the pharmacist should not fill the prescription. Tr. 179, 391, 412; *see also* 21 CFR 1306.05(a); Tex. Health & Safety Code § 481.074(k). When the prescription lacks a patient address, the pharmacist could resolve that red flag by speaking with the patient, checking the patient's driver's license, or checking the patient's profile, and then documenting the action the pharmacist took to resolve the red flag. Tr. 179–80. When the prescription lacks the prescriber's DEA number, the pharmacist should contact the prescriber and annotate the DEA number on the prescription itself and in the patient profile. *Id.* at 391.

78. Information contained on a cover sheet of a faxed prescription could resolve a red flag, but that information still must be documented. *Id.* at 302–03. That information must be documented so that when the customer returns with an identical prescription there would be no need to call the provider. *Id.* at 319–20. The Respondent has produced no cover sheets. *Id.* at 547.

79. When a pharmacist is presented with a prescription that contains one or more red flags, the pharmacist should call the prescriber to try to resolve the red flag or flags and then document the information that resolves the red flag on the prescription itself or in the patient's profile. *Id.* at 178–79.

80. A reasonably prudent pharmacist would investigate prescriptions after seeing several prescriptions written by the same doctor or medical practice for the same drugs and the same quantity, and with the same dosing instructions. *Id.* at 210.

81. The first time a patient presents prescriptions for hydrocodone and alprazolam to a pharmacy, the pharmacist might fill the prescriptions. *Id.* at 239–40. But when the patient keeps returning with the same prescriptions, the pharmacist should contact the provider. *Id.* at 239–40.

82. When presented with the first prescription of the day for hydrocodone and alprazolam, a pharmacist might not think much about filling the prescription, but after seeing a handful of prescriptions written for the same drug, the same dose, the same strength, and by the same providers, the pharmacist should identify and resolve those red flags. *Id.* at 333.

83. Evidence of pattern prescribing raises the concern of diversion and/or the abuse of high-alert drugs. *Id.* at 257.

84. After seeing a handful of prescriptions for the same controlled substances with the same strengths and instructions for use, the prescriptions become suspicious. *Id.* at 358–59.

[3] In this case, the term ''round-trip distance'' refers to the distance from a patient's residence to the prescriber, continuing to the Pharmacy, and then returning home. Tr. 176.

85. A pharmacist concerned about pattern prescribing should call the prescriber to ask about the medical purpose and dosing, and then document the discussion the pharmacist had with the prescriber. *Id.* at 261.

86. A pharmacist cannot resolve problems concerning the medication, directions for use, or medical purpose by talking to the patient. *Id.* at 179.

87. The patient profile should contain the correct address for the prescriber. *Id.* at 361–62.

88. A prudent pharmacist would question the distance a patient traveled if a patient lives in Fort Worth but sees a doctor in Dallas. *Id.* at 192.

89. A pharmacist could resolve a red flag concerning the distance a patient traveled by talking with the patient and documenting the conversation. *Id.* at 402–05.

90. The failure to document the resolution of a red flag is below the minimum standard of the practice of pharmacy in Texas. *Id.* at 180.

91. A pharmacist can use the PMP to determine whether a patient is filling prescriptions at another pharmacy. *Id.* at 398. Most pharmacies have access to the PMP. *Id.* at 398.

92. The PMP shows the names of the doctors and pharmacies a patient has been using. *Id.* at 479–82.

93. Information regarding a patient is only in the PMP if a pharmacy inputs the information into the system. *Id.* at 484.

The Pharmacy's Practices

94. Ms. Igwe is familiar with a Texas regulation that [she testified requires a pharmacist to document conversations with practitioners regarding clinical matters about a particular prescription.] [*A] *Id.* at 585.

95. There are no pharmacist notes in the record that resolve the red flags in Government Exhibit 2. *Id.* at 566–67.

96. Sometimes Ms. Igwe would write a ''V'' indicating ''verified'' on the hard-copy prescription, but she did not do this for every prescription. *Id.* at 482, 557.

97. Ms. Igwe testified that when she verified a prescription, she would make a note on the ''demographics'' page of the patient's profile that the provider confirmed the prescription. Tr. 481, 585. This information does not print out along with the patient profile. *Id.* at 482.

98. When a customer came to the Pharmacy for the first time to fill a prescription for a controlled substance, she would call the prescriber's office to confirm that the doctor wrote the prescription and that the patient was actually seen at the clinic. *Id.* at 477–78, 503, 517, 586, 590, 607.

99. Ms. Igwe has never verified whether Redbird, AC Medical, or Arlington Oaks was registered with the State of Texas as a pain management clinic. *Id.* at 537–38.

100. There were no notes in the Pharmacy's records concerning specialty clinics or other pharmacies refusing to fill prescriptions filled by the Pharmacy. *Id.* at 360–61.

101. If the doctor confirmed that he or she wrote the prescription, Ms. Igwe would look up the patient in the PMP to make sure the patient was not doctor or pharmacy shopping. *Id.* at 478, 484, 573.

102. Ms. Igwe does not consider it doctor shopping if a patient obtains prescriptions from multiple providers in the same practice. *Id.* at 556. She only considers it doctor shopping if the patient obtains prescriptions from ''totally different'' clinics with which she was unfamiliar. *Id.* at 556.

103. Ms. Igwe testified that before filling a prescription for a controlled substance, she would search the patient's name in the PMP, verify the dosage was correct, and check for any potential drug interactions. *Id.* at 478, 554.

104. Ms. Igwe testified that if she received multiple prescriptions from the same provider, she would not check with the provider for subsequent prescriptions because she did not ''see the point of doing it'' again when she already contacted the provider about the first prescription the patient presented to the Pharmacy. *Id.* at 478–79, 517. She would only contact the provider again if the prescription changed. *Id.* at 482.

105. Ms. Igwe testified that she checked the PMP each time a customer came back to the Pharmacy to make sure that customer had not been obtaining controlled substances from other doctors. *Id.* at 479, 504, 517.

106. Ms. Igwe testified that the first page of a faxed prescription would be a cover sheet with the patient's identification (typically a driver's license) and home address. *Id.* at 489.

107. Ms. Igwe testified that when a patient picked up a controlled substance at the Pharmacy, she would ask the patient for his or her driver's license and check it against the copy of the driver's license faxed by the provider. *Id.* at 490. She would then scan the patient's identification card into the Pharmacy's computer database. *Id.* at 490.

108. Ms. Igwe testified that if the identification card presented by the patient at the Pharmacy did not match the information faxed with the prescription, then she would not fill the prescription. *Id.* at 491, 539.

109. There were no notes in the Pharmacy's records concerning the distances customers traveled to get their prescriptions filled at the Pharmacy. *Id.* at 360–61.

110. The Pharmacy's records do not make a distinction between cash payments and insurance payments. *Id.* at 522. Ms. Igwe testified that approximately half of the prescriptions the Pharmacy fills are paid for using insurance. *Id.* at 496–97, 522. The remaining prescriptions are paid for in cash. *Id.* at 497.

111. The ''co-pay'' information on the Pharmacy's fill stickers indicates the amount the customer paid for the prescription. *Id.* at 499–500. On Government Exhibit 6, the information under ''billed'' is the amount the Pharmacy billed to the customer or insurance. *Id.* at 498. On Government Exhibit 6, ''margin'' represents the Pharmacy's profit on a particular sale. *Id.*

112. On the Pharmacy's fill stickers, the number underneath the patient's name is the prescription, or ''Rx'', number, which is assigned when the prescription is entered into the pharmacy's computer system. *Id.* at 184–85, 583; GE–2, at 1. The Rx numbers are assigned sequentially; the higher the number the more recent the prescription was filled. *Id.* at 185–86. For example, the Rx number ending in 6330 would have been filled prior to Rx number 6331. *Id.* at 185–86.

113. The fill sticker also shows the date the prescription was filled, but not the date it was written. *Id.* at 186. The date the prescription was written is recorded on the prescription itself. *Id.*

114. On the fill stickers, the abbreviation ''Cpy'' stands for copay. *Id.* at 499.

115. Ms. Igwe spoke to Dr. C.V. on only one occasion. *Id.* at 500, 561, 587. Dr. C.V. called the Pharmacy to ask for the Pharmacy's fax number to send a statement that he was leaving Redbird Clinic. *Id.* at 500, 561. During that phone call, Ms. Igwe did not talk to Dr. C.V. about any prescriptions. *Id.* at 561–62.

116. Ms. Igwe would sometimes ask her customers if the medications they were prescribed were still working for them. *Id.* at 527.

117. Ms. Igwe did not always fill a bottle with medication on the same day that she printed its label. *Id.* at 560, 575.

[*A] Text adjusted in response to Respondent's Exceptions.

The Prescribers [4]

118. The prescription pad for Redbird Medical clinic (''Redbird'') contains the names of the following medical providers: C.V., M.D.; L.R., ACNS–BC; I.I., DNP–FNP; L.O., FNP–C; and J.W., ANP–BC, with an address on West Camp Wisdom Road in Dallas, Texas. *Id.* at 207–08; GE–2, at 12, 67. Although a prescriber identified as Dr. A.Q. was not listed on the prescription pad for Redbird, he had the same address on West Camp Wisdom Road. GE–2, at 70.

119. On October 2, 2014, the prescription pad for AC Medical clinic (''AC Medical'') contained the names of the following medical providers: C.V., M.D.; I.I., DNP–FMP; L.R., ACNS–BC; S.G., FNP; and C.Z., PA, with an address on Billing Street in Arlington, Texas. GE–2, at 16.

120. On January 13, 2015, the prescription pad for AC Medical contained the names of the following medical providers: C.V., M.D.; NE, M.D.; L.R., ACNS–BC; S.G., FNP; and C.Z., PA, with an address on East Arkansas Lane in Arlington, Texas. Tr. 207; GE–2, at 132.

121. The prescription pad for Arlington Oaks medical clinic (''Arlington Oaks'') contains the names of the following medical providers: C.V., M.D.; S.G., FNP; L.R., ACNS–BC; and C.Z., PA, with an address on Billing Street in Arlington, Texas. Tr. 206; GE–2, at 5.

The M.W. Prescription

122. DI 1 identified Government Exhibit 11 as the declaration of UC 1, an agent of the Texas Department of Public Safety. Tr. 30. In the declaration, UC 1 describes an undercover operation in which he obtained a prescription from the Redbird Clinic and filled the prescription at the Pharmacy. *Id.* at 30.

123. DI 1 knew UC 1 from his work on the investigation of the Pharmacy, but he did not know that UC 1 was going undercover. *Id.* at 68–69, 140. DI 1 reviewed UC 1's declaration and discussed it with him. *Id.* at 31–32.

124. During the undercover operation, UC 1 used the name M.W., and he used a driver's license with that name. Tr. 41; GE–10, at 3. The driver's license had a fictitious Fort Worth address. Tr. 189, 541; GE–11, at 2. The Pharmacy maintained a copy of the prescription it filled for M.W. and a copy of M.W.'s patient profile. Tr. 41; GE–10, at 4–5.[5]

125. At 6:55 a.m. on July 29, 2014, undercover agent UC 1 was in a car in the Redbird parking lot. GE–11, at 2. There were about 15 other occupied vehicles in the parking lot at that time. *Id.* An individual came out of the clinic and asked the drivers to inform him how many people were in each vehicle, and the drivers indicated between two and five persons were in each car. *Id.* The individual then began directing traffic and controlling the flow of traffic into the clinic. *Id.*

126. When UC 1 entered the Redbird clinic he was searched by an armed security guard and was seated in the order that he had entered the clinic. GE–11, at 2. When called to the receptionist's counter, UC 1 paid a fee of $170.00, and filled out a questionnaire, using the ''M.W.'' alias. *Id.* He provided the fictitious address of 5944 Callaston Lane, Fort Worth, Texas.[6] *Id.* UC 1 indicated that he was experiencing back pain due to sleeping on an old mattress. GE–11, at 3.

127. At 10:40 a.m. UC 1 met with L.R., ACNS–BC, who checked his heart, looked at his back, and an old scar on his knee. GE–11, at 3. L.R. then issued ''M.W.'' three prescriptions, to include 120 tablets of hydrocodone 10 mg. *Id.* Redbird informed ''M.W.'' that the prescription would be sent to the Pharmacy and UC 1 confirmed that the Pharmacy received it on August 1, 2014. *Id.;* Tr. 190.

128. The M.W. prescription was written on July 29, 2014, and received by the Pharmacy on August 1, 2014. Tr. 543, 562–63; GE–2, at 1; GE–11, at 3; RE–G, at 8.

129. The M.W. prescription was written to treat pain. Tr. 543; GE–2, at 1.

130. The M.W. prescription was faxed by Redbird to the Pharmacy. Tr. 192, 430, 571–72, 592; GE–2, at 1; GE–11, at 3; RE–G, at 8.

131. A copy of the prescription that undercover agent UC 1 received from Redbird, under the name of ''M.W.,'' as well as the Pharmacy's fill sticker for that prescription, are both contained on page 1 of Government Exhibit 2. Tr. 183–84.

132. On August 4, UC 1 presented to the Pharmacy as ''M.W.,'' and purchased the prescriptions, paying $150.00 for the hydrocodone. Tr. 576, 591; GE–2, at 1; GE–11, at 3.

133. The fact that the M.W. prescription was written on July 29, 2014, and not picked up until August 4, 2014, did not cause Ms. Igwe any concern. Tr. 577.

134. Ms. Igwe did not look up the address on M.W.'s driver's license to verify whether it was a real or fictitious address. Tr. 541; GE–11, at 3.

135. The prescription that L.R. wrote for M.W. raises the following red flags: No patient address; no provider DEA number; [ ] [*B] the prescription was written on July 29, 2014, but not faxed to the Pharmacy until August 1, 2014, and not picked up until August 4, 2014; and an unusual path and distance to obtain the prescription and get it filled.[7] Tr. 188–94.

136. There are no notes on the M.W. prescription or in the Pharmacy's patient profile for M.W. indicating that any of the red flags were resolved prior to filling the prescription. Tr. 194–95; GE–2, at 1; GE–10, at 4–5.

137. Based on the information provided to the Pharmacy, M.W., more likely than not, would have passed many pharmacies as he traveled the 99 miles from his purported residence in Fort Worth, to Redbird south of Dallas, to the Pharmacy, north of Dallas, and then return to his purported Fort Worth home. Tr. 193–94, 364–65; GE–12.

138. Ms. Igwe had no concern about the distance between M.W.'s fictitious address in Fort Worth and the Pharmacy in Plano. Tr. 542–43.

139. There is transmission data printed along the top of the page that contains the M.W. prescription and fill sticker indicating that the page was ''4 of 4'' of the pages Redbird faxed to the Pharmacy. GE–2, at 1. Dr. Witte was not provided pages one through three to review, nor are those pages contained in the Administrative Record. Tr. 255; GE–2, at 1.

The Other Prescriptions

140. Government Exhibit 2 contains 77 prescriptions for 27 of the Pharmacy's customers. Tr. 254; GE–2. Government Exhibit 2 also contains patient profiles for 26 of the Pharmacy's customers. GE–2. Several of the patient profiles contained in Government Exhibit 2 reveal prescriptions the Pharmacy filled for hydrocodone and

[4] The medical professionals mentioned in Findings of Fact 118–121, and 155, when referred to as a group, will be referred to as ''the Prescribers'' in this Recommended Decision. This group is comprised of C.V., L.R., I.I., L.O., A.Q., J.W., S.G., C.Z., and NE

[5] Government Exhibit 2, page 1, is another copy of the prescription issued to ''M.W.'' Tr. 40. Government Exhibit 2, page 2, is a photo of the prescription bottle of hydrocodone filled by the Pharmacy for ''M.W.'' Tr. 43.

[6] I find that the fact that M.W. used a fictitious address to be irrelevant. *See* Tr. 191; *infra* note 40.

[*B] Text adjusted in response to Respondent's Exceptions.

[7] Dr. Witte testified that the delay in picking up this prescription raises the question of whether the patient actually needed the prescription for pain and whether the prescription was written for a legitimate medical purpose. Tr. 193. That concern is exacerbated by the fact that the patient waited an additional three days to pick up the prescription after Redbird faxed it to the Pharmacy. Tr. 193; GE–2, at 1; GE–11, at 3. [Dr. Witte also testified that M.W. received a ''large quantity'' of a high-alert drug, which could be a red flag. Tr. 189.]*

alprazolam prior to August 2014, for which the actual prescriptions are not contained in the Administrative Record. *Id.* at 32–33, 42–43, 54–55, 82.

141. On several occasions, prescription cocktails of hydrocodone and alprazolam, contained in Government Exhibit 2, were written or filled on different days. Tr. 311; GE–2, at 28–30, 34–36, 50–52, 94–96, 109–11, 117–19.

142. The patient profile for A.S. raises a red flag of pattern prescribing: The same controlled substances; the same strength and dosages (90 hydrocodone 10/325 mg, 60 alprazolam 2 mg); the same small group of providers; and cash payments. Tr. 241, 408–09; GE–2, at 22–33. Between February 24, 2014 and March 30, 2015, A.S. filled six prescriptions for hydrocodone and six prescriptions for alprazolam at the Pharmacy. GE–2, at 31–33. On February 24, 2014, the Pharmacy filled prescriptions of 120, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for A.S., written by S.G., a family nurse practitioner at AC Medical and Arlington Oaks. *Id.* at 32–33; *see also id.* at 5, 16 (displaying S.G.'s name on prescription pads of those two practices). On May 1, 2014, the Pharmacy filled prescriptions of 90, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for A.S., written by S.G. *Id.* at 32. The round-trip distance [8] for A.S. to obtain her prescriptions and have them filled at the Pharmacy was 104 miles. Stip. 32.

143. The patient profile for R.E. raises a red flag of pattern prescribing: The same controlled substances; the same strength and dosages (90 hydrocodone 10/325 mg, 60 alprazolam 2 mg); the same small group of providers; and cash payments. Tr. 237–39; GE–2, at 34–43. Between April 3, 2014 and March 23, 2015, R.E. filled five prescriptions for hydrocodone and five prescriptions for alprazolam at the Pharmacy. GE–2, at 42–43. On April 3, 2014, the Pharmacy filled prescriptions of 90, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for R.E., written by S.G. *Id.* at 43. On May 30, 2014, the Pharmacy filled prescriptions of 90, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for R.E., written by C.Z., a physician's assistant at AC Medical and Arlington Oaks. *Id.* at 42–43; *see also Id.* at 5, 16 (displaying C.Z.'s name on prescription pads of those two practices). The round-trip distance for R.E. to obtain his prescriptions and have them filled at the Pharmacy was 86 miles. GE–3, at 35–40.

144. On March 18, 2014, the Pharmacy filled prescriptions of 120, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for K.S., written by L.R., a nurse practitioner at Redbird, AC Medical, and Arlington Oaks. GE–2, at 55; *see also id.* at 5, 12, 16 (displaying L.R.'s name on prescription pads of those three practices). On April 15, 2014, the Pharmacy filled prescriptions of 90, 10 mg tablets of hydrocodone and 60 tablets of Alprazolam for K.S., written by S.G. *Id.* at 55. On May 27, 2014, the Pharmacy filled prescriptions of 90, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for K.S., written by S.G. *Id.* at 54–55. Then on June 26, 2014, the Pharmacy filled prescriptions of 120, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for K.S., written by S.G. *Id.* at 54. The round-trip distance for K.S. to obtain her prescriptions and have them filled at the Pharmacy was 101 miles. Stip. 35

145. On June 19, 2014, the Pharmacy filled prescriptions of 120, 10 mg tablets of hydrocodone and 60 tablets of alprazolam for M.W.2, written by L.R. *Id.* at 82. The round-trip distance for M.W.2 to obtain her prescriptions and have them filled at the Pharmacy was 97 miles. Stip. 41.

146. The patient profile for R.N. raises a red flag of pattern prescribing: The same controlled substances; the same strength and dosages (90 hydrocodone 10/325 mg, 60 alprazolam 2 mg); the same small group of providers; and cash payments. Tr. 239–41; GE–2, at 117–29. Between November 17, 2014 and May 11, 2015, R.N. filled five prescriptions for hydrocodone and five prescriptions for alprazolam at the Pharmacy. GE–2, at 128–29.

147. On August 6, 2014, L.R. wrote prescriptions for 120 tablets of hydrocodone and 60 tablets of alprazolam for patient J.S. GE–2, at 3–4. The prescriptions were filled the same day at the Pharmacy where the customer paid $59.99 for the alprazolam and $150.00 for the hydrocodone. *Id.* at 3. To obtain the prescription and have it filled, J.S. would have traveled 80 miles. Stip. 34.

148. On August 8, 2014, S.G. wrote prescriptions for a drug cocktail of 90 hydrocodone and 60 alprazolam for patient J.W. Tr. 197–98, 399; GE–2, at 5. The prescriptions were filled at the Pharmacy on August 11, 2014, where the customer paid $59.99 for the alprazolam and $125.00 for the hydrocodone. GE–2, at 5. To obtain the prescription and have it filled, J.W. would have traveled 108 miles. Stip. 39.

149. On August 29, 2014, S.G. wrote prescriptions for 120 hydrocodone and 60 alprazolam for patient J.W. GE–2, at 6. The prescriptions were filled at the Pharmacy on September 12, 2014, where the customer paid $59.99 for the alprazolam and $160.00 for the hydrocodone. *Id.* To obtain the prescription and have it filled, J.W. would have traveled 108 miles. Stip. 39. The patient picked up the prescription at the Pharmacy 14 days after the prescription was written. GE–2, at 6. Neither the prescriptions for J.W. nor his patient profile, maintained by the Pharmacy, contain any notes resolving the red flags presented by these prescriptions. Tr. 208–10.

150. The January 16, 2015 prescription for R.H. for alprazolam raises a red flag. Tr. 242. The prescription indicates that the alprazolam was to be taken once every eight hours, but the prescription label has instructions indicating that it was to be taken one tablet twice per day.[9] Tr. 242, 753–54; GE–2, at 66.

151. The January 16, 2015 prescription for R.H. for hydrocodone raises several red flags. Tr. 242. The prescription indicates that the hydrocodone was to be taken once every 8 to 12 hours for moderate to severe pain. *Id.* at 396; GE–2, at 64–65. If the patient had moderate to severe pain, the patient would be taking the medication once every four to six hours. Tr. 396, 681, 686. In addition, while the prescription was written for moderate to severe pain on January 16, 2015, the prescription was not filled until January 20, 2015. Tr. 396; GE–2, at 64–65. Filling a prescription for moderate to severe pain four days after it was written raises a red flag. Tr. 193, 396–97. Further, R.H. paid cash for his hydrocodone and alprazolam prescriptions, paying a total of $212.98 on January 20, 2015. GE–2, at 65–66. Finally, to obtain his prescriptions and have them filled, R.H. would have traveled more than 75 miles. Stips. 21, 22.

152. The April 6, 2015 prescription for R.H. for hydrocodone indicates that it was to be taken 1 to 2 tablets every 8 to 12 hours for moderate to severe pain. Tr. 241; GE–2 at 68. These dosing

[8] The ''round-trip distance'' is the distance, as measured by MapQuest, from the patient's address as recorded in the Pharmacy's records, to the prescriber's office, as reflected in the patient's profile maintained by the Pharmacy, then to the Pharmacy, and returning to the patient's home. *See, e.g.,* GE–3, at 1–5. There is no evidence that any patient traveled this round-trip distance, as a continuous or single trip, upon leaving the patient's home. Nevertheless, the three addresses used to calculate the distances are taken from the Pharmacy's records.

[9] Litman testified that a pharmacist should document in the pharmacy's computer system if he or she was dispensing a medication with dosing instructions different than prescribed. Tr. 753–54. There is no such documentation in this Administrative Record.

instructions are a red flag because for moderate to severe pain the patient should be taking the medication more frequently. Tr. 241, 395–96; GE–2, at 64–65, 68–69.

153. R.H. was receiving two different controlled substances from two different doctors, hydrocodone from Dr. A.Q. and promethazine with codeine from Nurse J.W. Tr. 242–43, 341; GE–2, at 70. Dr. A.Q. and Nurse J.W. had different addresses. Tr. 243, 362–64; GE–2, at 70. A pharmacist would want to determine why a patient was obtaining controlled substances from two different doctors from different locations. Tr. 243, 362–64.

154. There are no pharmacist's notes or remarks written on R.H's prescriptions or in his patient profile that resolves the red flags raised by his controlled substance prescriptions. Tr. 243.

155. Government Exhibit 6 contains the Pharmacy's hydrocodone dispensing history between July 7, 2014 and May 21, 2015. Tr. 37, 138, 168; GE–6, at 1, 85. Government Exhibit 6 documents 927 prescriptions that the Pharmacy filled for hydrocodone. GE–6. All but 25 of those prescriptions were written by the same small group of prescribers, who wrote the prescriptions identified on the patient profiles contained in Government Exhibit 2: Dr. C.V., Dr. NE, ANP J.W., Dr. A.Q., PA C.Z., NP L.O., DNP I.I., NP S.G., and ACNS L.R.[10] The Pharmacy filled 104 prescriptions for hydrocodone before it filled the hydrocodone prescription for J.S. on August 6, 2014. GE–2, at 3; GE–6, at 1–10.

156. Between October 10–23, 2014, the Pharmacy received 26 consecutive prescriptions for 90 tablets of hydrocodone written by Dr. C.V. GE–6, at 29–31. Between November 7–12, 2014, the Pharmacy filled 17 consecutive prescriptions for 90 tablets of hydrocodone written by Dr. C.V. GE–6, at 33–35.

157. Between November 12–20, 2014, the Pharmacy received 20 consecutive prescriptions for hydrocodone written by Dr. C.V., all but one of which were for 90 tablets. GE–6, at 35–37.

158. The Pharmacy received 9 prescriptions for 90 tablets of hydrocodone 10/325 mg on December 31, 2014. Tr. 424–25, 560; RE–G, at 44–45; GE–6, at 44–45. Eight of the nine prescriptions were written by Dr. C.V. Tr. 424–25; RE–G, at 44–45; GE–6, at 44–45. Receiving these nine prescriptions on the same date did not cause Ms. Igwe any concern. Tr. 561.

159. Between April 9 and May 8, 2015, the Pharmacy received 105 consecutive prescriptions for hydrocodone written by either Dr. C.V. or Dr. NE, all but six of which were for 90 tablets. GE–6, at 69–79. Finally, between May 18–21, 2015, the Pharmacy filled 23 consecutive prescriptions for hydrocodone 10/325 mg written by Dr. NE, all but one of which were for 90 tablets. Tr. 594–95; GE–6, at 83–85.

160. The prescriptions identified in Findings of Fact 155–159 are examples of pattern prescribing. Tr. 171, 231, 388.

161. All the prescriptions in Government Exhibit 6 were filled by Ms. Igwe. Tr. 390; *see also* 22 Tex. Admin. Code § 291.33(c)(7)(A)(iv) (requiring the dispensing pharmacist to write his or her initials on the prescription label).

162. *Prescriptions Written by Nurse Practitioner I.I.:*

Patient	Date prescription written; filled	Controlled substance(s); quantity	Round-trip distance (miles)	Cost	Record citations
J.W.2	8/18/14; 8/20/14	Hydrocodone (120); Alprazolam (60).	98	$150.00; $59.99	Tr. 234; GE–2, at 12; Stip. 40.
C.J	8/18/14; 8/19/14	Hydrocodone (90); Alprazolam (60).	81	$125.00; $59.99	Tr. 233; GE–2, at 8; Stip. 25.
S.W	8/19/14; 8/19/14	Hydrocodone (120); Alprazolam (60).	99	$150.00; $59.99	Tr. 234; GE–2, at 10; Stip. 43.
S.H	9/4/14; 9/4/14	Hydrocodone (90); Alprazolam (60).	76	$120.00; $59.99	Tr. 234–35; GE–2, at 14; Stip. 24.
H.J	10/2/14; 10/2/14	Hydrocodone (120); Alprazolam (60).	105	$160.00; $59.99	Tr. 235; GE–2, at 16; Stip. 26.

[10] *See* GE–6, at 13, 17, 41, 43, 47, 53, 56, 58, 64, 65, and 85 for prescriptions written by eight other prescribers.

163. These prescriptions written by Nurse Practitioner I.I. are indicative of pattern prescribing: Same controlled substances; same quantity; same dosages; same prescriber; same drug cocktails. Tr. 236. This pattern indicates a lack of individualization of therapy. *Id.* at 209. In addition, these patients took unusual paths and distances to obtain and fill their prescriptions. *Id.* at 236. The similarities would make a pharmacist wonder why multiple patients from this medical provider were being prescribed the same quantity of hydrocodone, and in the same strength and dosing. *Id.* at 258.

164. The unusual path and distance that I.I.'s patients traveled to obtain their prescriptions and get them filled is a red flag. *Id.* at 236.

165. The fill stickers for all of I.I.'s patients indicate that they paid $120 to $160 for their prescriptions for hydrocodone, which is much higher than the usual cost of hydrocodone. *Id.* at 222–23. The cash price for 90 tablets of hydrocodone is about $70, and the cash price for 60 tablets of alprazolam is about $35. *Id.* at 223.

166. There are no notes on I.I.'s prescriptions or the patient profiles documenting the Pharmacy's resolution of any red flag or consultation with I.I. regarding the red flags. *Id.* at 236; GE–2, at 4, 7, 9, 11, 13, 15, 17, 21, 31–33, 42–43, 53–55, 59, 63, 70, 74, 78, 82, 85, 92–93, 97, 102, 104–05, 107–08, 112, 116, 128–29, 133.

167. *Prescriptions Written by Dr. C.V.:*

Patient	Date prescription written; filled	Controlled substance(s); quantity	Round-trip distance (miles)	Cost	Record citations
R.E	11/14/14; 11/14/14	Hydrocodone (90) [11]	94	$180	Tr. 218, 226, 238–39; GE–2, at 35–36; Stip. 17.
R.N	11/15/2014; 11/17/2014	Hydrocodone (90) [12]	64	$180	Tr. 221, 226; GE–2, at 117–118; Stip. 30.
R.N	Filled: 12/19/14	Hydrocodone (90) [13]	64	Unknown	Tr. 222; GE–2, at 129; Stip. 30.
A.S	Filled: 12/22/14	Hydrocodone (90) [14]	111	Unknown	Tr. 217–18, 226, 241; GE–2, at 32; Stip. 33.
M.H	1/13/15; 1/13/15	Hydrocodone (90) [15]	121	$179.99	Tr. 222, 226; GE–2, at 130–31; Stip. 20.
K.S	1/27/15; 1/27/15	Hydrocodone (90) [16]	109	$179.99; $59.99	Tr. 204, 219, 226; GE–2, at 44–46; Stip. 36.
K.S	2/26/15; 2/26/15	Hydrocodone (90) [17]	109	$179.99	Tr. 205, 219, 226; GE–2, at 47–48; Stip. 36.
R.E	3/23/15; 3/23/15	Hydrocodone (90) [18]	94	$179.99; $59.99	Tr. 218, 226; GE–2, at 39–42; Stip. 17.
K.S	3/26/15; 3/26/15	Hydrocodone (90) [19]	109	$179.99	GE–2, at 50–52; Stip. 36.
A.S	3/28/15; 3/30/15	Hydrocodone (90) [20]	111	$179.99	Tr. 217, 226; GE–2, at 28–30; Stip. 33.
G.B	4/16/15; 4/17/15	Hydrocodone (90)	55	$179.99	Tr. 219–20, 226; GE–2, at 83–84; Stip. 12.
M.A	4/17/15; 4/17/15	Hydrocodone (90) [21]	107	$179.99	Tr. 205–06, 220, 226; GE–2, at 94–95; Stip. 9.
R.H.2	4/20/15; 4/21/15	Hydrocodone (90) [22]	92	$179.99 $59.99	Tr. 220, 226; GE–2, at 98–100; Stip. 23.
A.K	5/1/15; 5/1/15	Hydrocodone (90) [23]	81	$179.99 $59.99	Tr. 221, 226; GE–2, at 113–115; Stip. 27.

168. Theprescription that Dr. C.V. wrote for G.B. on April 16, 2015, contained unusual dosing instructions for hydrocodone, of one tablet three times per day. Tr. 383; GE–2, at 83. Faced with these dosing instructions, the pharmacist should have called the prescriber to confirm the dosing instructions before filling the prescription. Tr. 383.

169. The prescriptions written by Dr. C.V. are indicative of pattern prescribing: Same controlled substances; same quantity; same dosages; same prescriber; same drug cocktails. *Id.* at 215. This pattern indicates a lack of individualization of therapy. *Id.* at 209. In addition, these patients took unusual paths and distances to obtain and fill their prescriptions. *Id.* at 226–27. The similarities would make a pharmacist wonder why multiple patients from this doctor/medical practice were being prescribed the same quantity of hydrocodone, and in the same strength and dosing. *Id.* at 258.

170. The unusual path and distance that Dr. C.V.'s patients traveled to obtain their prescriptions and get them filled is a red flag. *Id.* at 236.

171. The fill stickers for all of these patients indicate that they paid $179.99 for their prescriptions for hydrocodone, which is much higher than the usual cost of 90 tablets of hydrocodone. *Id.* at 222–23. The cash price for 90 tablets of hydrocodone is about $70, and the cash price for 60 tablets of alprazolam is about $35. *Id.* at 223.

172. There are no notes on Dr. C.V.'s prescriptions or the patient profiles documenting that the Pharmacy resolved any red flag or consulted with Dr. C.V., or other prescribers. Tr. 227,

[11] The day before Dr. C.V. wrote R.E. a prescription for hydrocodone, S.G. FNP, of the same medical practice as Dr. C.V., wrote R.E. a prescription for 60 tablets of alprazolam 2 mg. The Pharmacy filled this prescription the same day it was written, November 13, 2014. GE–2, at 34–36. Although Dr. C.V. and FNP S.G. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and FNP S.G. being located at 201 Billings Street, Arlington, Texas. GE–2, at 42.

[12] The day before Dr. C.V. wrote R.N. a prescription for hydrocodone, L.R., ACNS–BC, of the same medical practice as Dr. C.V., wrote R.N. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 119. The Pharmacy filled both prescriptions the same day, November 17, 2014. GE–2, at 117–19. Although Dr. C.V. and ACNS L.R. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and ACNS L.R. being located at 202 Billings Street, Arlington, Texas. GE–2, at 119, 129.

[13] The same day the Pharmacy filled the prescription for hydrocodone, written by Dr. C.V. for R.N., it also filled a prescription for 60 tablets of alprazolam 2 mg, written by L.R., ACNS–BC, for R.N. GE–2, at 129. Although Dr. C.V. and ACNS L.R. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and ACNS L.R. being located at 202 Billings Street, Arlington, Texas. GE–2, at 119, 129.

[14] The same day the Pharmacy filled the prescription for hydrocodone, written by Dr. C.V., for A.S., it also filled a prescription for 60 tablets of alprazolam 2 mg, written by L.R., ACNS–BC, for A.S. GE–2, at 32. Although Dr. C.V. and ACNS L.R. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and ACNS L.R. being located at 202 Billings Street, Arlington, Texas. GE–2, at 30, 32.

[15] On the same day that Dr. C.V. wrote M.H. a prescription for hydrocodone, Dr. NE, of the same medical practice as Dr. C.V., wrote M.H. a prescription for 60 tablets of alprazolam 2 mg. Both prescriptions were filled by the Pharmacy on the same day, January 13, 2015. GE–2, at 130–32. Although Dr. C.V. and Dr. NE were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and Dr. NE being located at 201 Billings Street, Arlington, Texas. GE–2, at 132–33. Further, the address for Dr. NE in the patient profile is different from her address listed on the prescription, 2596 East Arkansas Lane, Arlington, Texas. *Id.*

[16] On the same day that Dr. C.V. wrote K.S. a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. C.V., wrote K.S. a prescription for 60 tablets of alprazolam 2 mg. *Cf.* GE–2, at 46. Both prescriptions were filled by the Pharmacy on the same day, January 27, 2015. GE–2, at 44–46. The Pharmacy fill sticker for the alprazolam prescription inaccurately lists Dr. C.V. as the prescriber. *Compare* GE–2, at 46 *with* known signatures of C.Z. at GE–2, at 30, 52, 122–23. Although Dr. C.V. and C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and C.Z. being located at 201 Billings Street, Arlington, Texas. GE–2, at 53. Further, the address for C.Z. in the patient profile is different from his address listed on the prescription for alprazolam, 2596 East Arkansas Lane, Arlington, Texas. *Compare* GE–2, at 46 *with* GE–2, at 53.

[17] On the same day that Dr. C.V. wrote K.S. a prescription for hydrocodone, Dr. NE, of the same medical practice as Dr. C.V., wrote K.S. a prescription for 60 alprazolam 2 mg. GE–2, at 49. Both prescriptions were filled by the Pharmacy on the same day, February 26, 2015. GE–2, at 47–49. Although Dr. C.V. and Dr. NE were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, and Dr. NE being located at 201 Billings Street, Arlington, Texas. GE–2, at 49, 53. Further, the address for Dr. NE in the patient profile is different from her address listed on the prescription, 2596 East Arkansas Lane, Arlington, Texas. *Id.*

[18] Two days before Dr. C.V. wrote R.E. a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. C.V., wrote R.E. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 41. Both prescriptions were filled by the Pharmacy on the same day, March 23, 2015. GE–2, at 39–41. The Pharmacy fill sticker for the prescription for alprazolam inaccurately lists Dr. C.V. as the prescriber. *Compare* GE–2, at 41 *with* known signatures of C.Z. at GE–2, at 30, 52, 122–23. Although Dr. C.V. and C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and C.Z. being located at 201 Billings Street, Arlington, Texas. GE–2, at 42. Further, the address for C.Z. in the patient profile is different from his address listed on the prescription for alprazolam, 2596 East Arkansas Lane, Arlington, Texas. *Compare* GE–2, at 41 *with* GE–2, at 42.

[19] The day before Dr. C.V. wrote K.S. a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. C.V., wrote K.S. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 52. Both prescriptions were filled by the Pharmacy the next day, March 26, 2015. GE–2, at 50–52. Although Dr. C.V. and PA C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, and PA C.Z. being located at 201 Billings Street, Arlington, Texas. GE–2, at 49, 53. Further, the address for PA C.Z. in the patient profile is different from his address listed on the prescription, 2596 East Arkansas Lane, Arlington, Texas. *Id.*

[20] The day after Dr. C.V. wrote A.S. a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. C.V., wrote A.S. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 30. Both prescriptions were filled by the Pharmacy the next day, March 30, 2015. GE–2, at 28–30. Although Dr. C.V. and PA C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, and PA C.Z. being located at 201 Billings Street, Arlington, Texas. GE–2, at 30–31. Further, the address for Dr. C.V. in the patient profile is different from his address listed on the prescription, 8222 Douglas Avenue, Dallas, Texas, and the address for PA C.Z. in the patient profile is different from his address listed on the prescription, 2596 East Arkansas Lane, Arlington, Texas. GE–2, at 28, 30–31.

[21] The day before Dr. C.V. wrote M.A. a prescription for hydrocodone, L.R., ACNS–BC, of the same medical practice as Dr. C.V., wrote M.A. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 96. Both prescriptions were filled by the Pharmacy the next day, April 17, 2015. GE–2, at 94–96. Although Dr. C.V. and ACNS L.R. were with the same medical practice, Dr. C.V.'s prescription lists an address of 201 Billing Street, Arlington, Texas, and the prescription that L.R. wrote shows her address as being, 2596 East Arkansas Lane, Arlington, Texas. GE–2, at 94, 96. In addition, while the prescription for alprazolam clearly bears the signature of ACNS L.R., the fill sticker indicates that Dr. C.V. wrote the prescription. GE–2, at 96.

[22] Three days before Dr. C.V. wrote R.H.2 a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. C.V., wrote R.H.2 a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 100. Both prescriptions were filled by the Pharmacy on April 21, 2015. GE–2, at 98–100. The Pharmacy fill sticker for the prescription for alprazolam inaccurately lists Dr. C.V. as the prescriber. *Compare* GE–2, at 100 *with* known signatures of C.Z. at GE–2, at 30, 52, 122–23. Although Dr. C.V. and C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, yet the prescription for hydrocodone lists his address as 201 Billings Street, Arlington, Texas. GE–2, at 101. The prescription pad that C.Z. used to write the prescription for alprazolam lists his address as 2596 East Arkansas Lane, Arlington, Texas. GE–2, at 100.

[23] On the same day that Dr. C.V. wrote A.K. a prescription for hydrocodone, C.Z. wrote A.K. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 115. Both prescriptions were filled by the Pharmacy on the same day, May 1, 2015. GE–2, at 113–15. The Pharmacy fill sticker for the prescription for alprazolam inaccurately lists Dr. C.V. as the prescriber. *Compare* GE–2, at 115 *with* known signatures of C.Z. at GE–2, at 30, 52, 122–23. Although Dr. C.V. and C.Z. were with the same medical practice, the patient profile shows Dr. C.V. being located at 916 Wynnewood Shopping Center, Dallas, Texas, yet the prescription for hydrocodone lists his address as 201 Billings Street, Arlington, Texas. GE–2, at 113. The prescription pad that C.Z. used to write the prescription for alprazolam lists his address as 2596 East Arkansas Lane, Arlington, Texas. GE–2, at 115.

404–05; GE–2, at 4, 7, 9, 11, 13, 15, 17, 21, 31–33, 42–43, 53–55, 59, 63, 70, 74, 78, 82, 85, 92–93, 97, 102, 104–05, 107–08, 112, 116, 128–29, 133.

173. *Prescriptions written by Dr. NE:*

Patient	Date prescription written; filled	Controlled substance(s); quantity	Round-trip distance (miles)	Cost	Record citations
A.S	1/24/15; 1/26/15	Hydrocodone (90) [24]	104	$179.99	Tr. 200–01; GE–2, at 22–23; Stip. 32.
R.N	2/2/2015; 2/3/2015	Hydrocodone (90) [25]	95	$179.99	Tr. 239–41; GE–2, at 120–21; Stip. 28.
R.E	2/2/2015; 2/2/2015	Hydrocodone (90) [26]	86	$179.99	GE–2, at 38, 42; GE–3, at 35–40.
A.S	2/27/2015; 2/27/2015	Hydrocodone (90)[27]	104	$179.99	GE–2, at 26–27, 31; Stip. 32.
B.B	3/20/2015; 3/20/2015	Hydrocodone (90); Alprazolam (60).	80	$179.99; $59.99	Tr. 214; GE–2, at 102–04; Stip. 10.
S.B	3/26/2015; 3/27/2015	Hydrocodone (90); Alprazolam (60).	79	$179.99; $59.99	Tr. 212; GE–2, at 56–58; Stip. 14.
S.N	4/2/2015; 4/2/2015	Hydrocodone (90); Alprazolam (60).	81	$179.99; $59.99	Tr. 214, 214–15; GE–2, at 60–62; Stip. 31.
T.W	4/10/2015; 4/10/2015	Hydrocodone (90); Alprazolam (60).	66	$179.99; $59.99	Tr. 212–13, 215; GE–2, at 71–73; Stip. 44.
I.B	4/10/2015; 4/10/2015	Hydrocodone (90) [28]	79	$179.99; $59.99	Tr. 213, 215; GE–2, at 75–77; Stip. 13.
M.W.2	4/13/2015; 4/13/2015	Hydrocodone (90) [29]	79	$179.99; $59.99	Tr. 214, 215; GE–2, at 79–81; Stip. 42.
Y.S	4/17/2015; 4/17/2015	Hydrocodone (90); Alprazolam (60).	78	$179.99; $59.99	Tr. 214–15; GE–2, at 86–88; Stip. 38.
B.B	4/22/2015; 4/23/2015	Hydrocodone (90); Alprazolam (60).	66	$179.99; $59.99	GE–2, at 105–107; Stip. 11.
C.D	4/23/2015; 4/23/2015	Hydrocodone (90) [30]	81	$179.99; $59.99	Tr. 214–15; GE–2, at 109–111; Stip. 15.
R.N	5/11/2015; 5/11/2015	Hydrocodone (90); Alprazolam (60).	78	$179.99; $59.99	Tr. 214–15; GE–2, at 125–27; Stip. 29.
Y.S	5/18/2015; 5/18/2015	Hydrocodone (90) [31]	78	$179.99; $59.99	GE–2, at 89–91.

174. The prescriptions written by Dr. NE are indicative of pattern prescribing: same controlled substances; same quantity; same dosages; same prescriber; same drug cocktails. Tr. 215. This pattern indicates a lack of individualization of therapy. *Id.* at 209. In addition, these patients took unusual paths and distances to obtain and fill their prescriptions. *Id.* at 215–16.

175. The unusual paths and distances that Dr. NE's patients traveled to obtain their prescriptions and get them filled is a red flag. *Id.*

176. The fill stickers for all of Dr. NE's patients indicate that they paid $179.99 for their prescriptions for hydrocodone, which is much higher than the usual cost of 90 tablets of hydrocodone. *Id.* at 222–23. The average cash price at other pharmacies for 90 tablets of hydrocodone is about $70, and the cash price for 60 tablets of alprazolam is about $35. *Id.* at 223.

177. There are no notes on the hard-copies of Dr. NE's prescriptions or the patient profiles documenting that the Pharmacy resolved any of the red flags, or consulted with Dr. NE or any other prescriber regarding the red flags. *Id.* at 216–17; GE–2, at 4, 7, 9, 11, 13, 15, 17, 21, 31–33, 42–43, 53–55, 59, 63, 70, 74, 78, 82, 85, 92–93, 97, 102, 104–05, 107–08, 112, 116, 128–29, 133.

Additional facts required to resolve the issues in this case are included in the Analysis section of this Recommended Decision.

[24] The day before Dr. NE wrote A.S. a prescription for hydrocodone, L.R., ACNS–BC, also with the AC Medical practice, wrote A.S. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 24. Both prescriptions were filled by the Pharmacy on January 26, 2015. GE–2, at 22–24. The fill sticker, however, erroneously lists Dr. NE as the prescriber. The prescription pad for AC Medical shows an address on East Arkansas Lane, but Dr. NE's electronic prescription for A.C. shows an address of 201 Billings Street, and the patient profile for A.S. shows L.R's address as 202 Billing Street. *Id.* at 22, 31.

[25] On the same day that Dr. NE wrote R.N. a prescription for hydrocodone, C.Z., PA, of the same medical practice as Dr. NE, wrote R.N. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 122–23. Both prescriptions were filled by the Pharmacy on the following day, February 3, 2015. *Id.* at 120–23.

[26] The Administrative Record contains the Pharmacy's fill sticker for this prescription, but not the actual prescription. GE–2, at 38, 42. On the same day that the Pharmacy filled this prescription it also filled a prescription for 60, 2 mg tablets of alprazolam, which was written by L.R., ACNS–BC, on the same day. GE–2, at 37. Dr. NE's address is listed on R.E.'s patient profile as being at Billings Street in Arlington, Texas, while the office address on the prescription pad that L.R. used to write the prescription for alprazolam is East Arkansas Lane, Arlington, Texas. *Id.* at 37, 42.

[27] The day before Dr. NE wrote A.S. a prescription for hydrocodone, C.Z., PA, also with the AC Medical practice, wrote A.S. a prescription for 60, 2 mg tablets of alprazolam. GE–2, at 25. The Pharmacy also filled that prescription for alprazolam the day before it filled the prescription that Dr. NE wrote for hydrocodone. *Id.* at 25. The prescription pad for AC Medical shows an address on East Arkansas Lane for both Dr. NE, and C.Z., but Dr. NE's electronic prescription for A.C. shows an address of 201 Billings Street, Arlington, Texas. *Id.* at 22–26.

[28] On the same day that Dr. NE wrote I.B. a prescription for hydrocodone, S.G., FNP, of the same medical practice as Dr. NE, wrote I.B. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 77. Both prescriptions were filled by the Pharmacy on the same day, April 10, 2015. *Id.* at 75–77. The fill sticker for the alprazolam, however, erroneously lists Dr. NE as the prescriber. *Id.* at 77.

[29] On the same day that Dr. NE wrote M.W.2 a prescription for hydrocodone, S.G., FNP, of the same medical practice as Dr. NE, wrote M.W.2 a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 81. Both prescriptions were filled by the Pharmacy on the same day, April 13, 2015. *Id.* at 79–81. The fill sticker for the alprazolam, however, erroneously lists Dr. NE as the prescriber. *Id.* at 81.

[30] The day before Dr. NE wrote C.D. a prescription for hydrocodone, S.G., FNP, of the same medical practice as Dr. NE, wrote C.D. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 111. Both prescriptions were filled by the Pharmacy on April 23, 2015. *Id.* at 109–11. The fill sticker for the alprazolam, however, erroneously lists Dr. NE as the prescriber. *Id.* at 111.

[31] On the same day that Dr. NE wrote Y.S. a prescription for hydrocodone, S.G., FNP, of the same medical practice as Dr. NE, wrote Y.S. a prescription for 60 tablets of alprazolam 2 mg. GE–2, at 91. Both prescriptions were filled by the Pharmacy on the same day, May 18, 2015. *Id.* at 89–91. The fill sticker for the alprazolam, however, erroneously lists Dr. NE as the prescriber. *Id.* at 91.

Analysis

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR 1301.44(e). Under 21 U.S.C. 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration ''inconsistent with the public interest.'' The DEA considers the following five factors to determine whether continued registration is in the public interest:

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

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.[32]

21 U.S.C. 823(f).

These public interest factors are considered separately. *See Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76–77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009).

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the evidence. *Steadman,* 450 U.S. at 100–03. If the Government makes a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate. *Med. Shoppe—Jonesborough,* 73 FR 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (citations omitted). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38385 (2013).

Here, the Government's allegations focus on the manner in which the Pharmacy, through its agents, dispensed controlled substances. In addition, the Government has alleged recordkeeping violations.

I. The Government's Position

The Government submitted its Proposed Findings of Fact, Conclusions of Law, and Argument (''Government's Brief'') on February 7, 2018.[33] In its brief, the Government addressed: Numerous instances of the Pharmacy dispensing controlled substances in violation of its corresponding responsibility to ensure that the prescribing and dispensing of controlled substances was done only for legitimate medical purposes. ALJ–35, at 9–21. The Government also addressed the Pharmacy's recordkeeping violations, and as a result of those recordkeeping violations, the Pharmacy's inability to account for over 47,000 tablets of hydrocodone. ALJ–35, at 21.

With respect to the Pharmacy dispensing in violation of its corresponding responsibility, the Government pointed out the testimony of its expert witness, Dr. Witte. ALJ–35, at 6–21. Dr. Witte's testimony touched upon virtually each prescription contained in Government Exhibit 2. ALJ–35, at 9–21. The Government noted that Dr. Witte identified numerous red flags concerning the prescriptions the Pharmacy filled, to include: Pattern prescribing; long and unusual distances traveled to obtain and fill prescriptions; delay in filling prescriptions; cash payments for prescriptions; prescriptions for high-alert drugs, such as hydrocodone, alprazolam, and promethazine with codeine; prescriptions for high dosage strengths of the controlled substance; prescription cocktails, such as hydrocodone and alprazolam prescribed together; and prescriptions containing atypical directions for use. ALJ–35, at 7–9. In addition, Dr. Witte testified that to resolve a red flag, a pharmacist in Texas should call the prescriber and then document the prescriber's explanation either on the prescription itself, or in the patient's profile maintained by the pharmacy. ALJ–35, at 8. Failing to document the resolution of a red flag falls below the minimum standards of the practice of pharmacy in Texas. *Id.*

With respect to recordkeeping violations, the Government's Brief detailed that during execution of the Administrative Inspection Warrant in June 2015, the Pharmacy was asked for its inventories and its dispensing history for hydrocodone. ALJ–35, at 21. The dispensing records provided by the Pharmacy did not account for any dispensing prior to July 7, 2014, while other non-Pharmacy records showed dispensing prior to that date, and the Pharmacy had opened in September 2013. ALJ–35, at 21–22. As a result of the documentation provided by the Pharmacy, the Pharmacy could not account for over 47,000 tablets of hydrocodone. *Id*

Based upon the allegation contained in the OSC, and the evidence produced by the Government, the Government argues that Factors 2 and 4 of the five factors listed in 21 U.S.C. 823(f), are the relevant factors to consider in this case, specifically the registrant's experience in dispensing controlled substances and its compliance with applicable state, federal, or local laws relating to controlled substances. ALJ–35, at 27.

The Government argues that the Pharmacy violated 21 CFR 1306.04(a) and 1306.06 when it failed to meet its corresponding responsibility by filling prescriptions outside the usual course of professional practice. ALJ–35, at 27–34. Specifically, the Government alleges that the Pharmacy ''repeatedly distributed controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion.'' *Id.* at 29. The Government notes that all of the prescriptions in Government Exhibit 2 gave rise to one or more of the above mentioned red flags. *Id.* Significantly, the Government notes there is no evidence that the Pharmacy documented the resolution of any of the red flags concerning the prescriptions presented in this case. *Id.* at 30. The Government also notes that the Respondent was served with a subpoena that specifically requested any and all documentation concerning the resolution of red flags, yet no such documentation has been produced. *Id.*

The Government noted that the Pharmacy also had recordkeeping shortcomings, and an audit revealed a substantial shortage of hydrocodone. *Id.* at 34–36. While recognizing that the Respondent produced records, Respondent Exhibit C, claiming they

[32] The Government has not made any Factor Five allegations against the Respondent. ALJ–35, at 27.

[33] The Government's Brief has been marked as ALJ–35.

represent all of the Respondent's dispensing of hydrocodone, the Government further argues that there is ''no record of any dispensing prior to July 7, 2014.'' [34] ALJ–35, at 34. Citing *Alexander Drug Co.,* 66 FR 18299, 18303 (2001), the Government noted that recordkeeping violations alone can serve as a sufficient bases to revoke a registration. *Id.* at 35. In addition, the Government cites to *Paul H. Volkman,* 73 FR 30630, 30644 (2008), for the proposition that failing to maintain dispensing logs with respect to an extraordinary quantity of controlled substances provides sufficient reason by itself to revoke a registration as being inconsistent with the public interest. *Id.* at 35.

In conclusion, the Government argued that the Pharmacy's COR should be revoked because a preponderance of the evidence establishes that allowing the Pharmacy to keep its registration would be contrary to the public interest. *Id.* at 39. In support of this argument, the Government noted that the Pharmacy had not accepted any responsibility for its actions and it had not indicated what actions it would take to ensure future compliance with laws and regulations governing the handling of controlled substances. *Id.*

II. The Respondent's Position

The Respondent submitted its Proposed Findings of Fact and Conclusions of Law (''Respondent's Proposed Findings'') on February 7, 2018.[35] The Respondent also submitted the Respondent's Closing Brief (''Respondent's Brief'') on February 7, 2018.[36] I have read and considered both documents in preparing this Recommended Decision.

In the Respondent's Proposed Findings, the Respondent highlighted the policies and procedures the Pharmacy has in place to confirm the legitimacy of new prescriptions for controlled substances. ALJ–36, at 4–7. Some of those policies and procedures include: verifying a prescriber's authorization to prescribe; checking the PMP for doctor shopping; entering prescription and patient information into the Pharmacy's computer system; contacting the prescriber's office when new patients present to the Pharmacy to ensure there is a doctor-patient relationship; questioning the patient about the need for the medication; and marking prescriptions with a ''V'' once the prescription has been verified.[37] *Id.* at 5–7. The Respondent also highlights testimony suggesting that it saw nothing unusual with the prescriptions contained in Government Exhibit 2. *Id.* at 8. For example, the Respondent notes that: It considered the prescriptions to be therapeutic and commonly prescribed; other physicians prescribe in similar patterns; the Prescribers only wrote 10% of the prescriptions the Pharmacy filled; the patients were not filling their prescriptions early or doctor shopping; and the patients did not show up in groups. *Id.* at 8.

Based upon the Respondent's proposed findings of fact,[38] the Respondent also offers several conclusions of law. Significantly, the Respondent concludes that the Government failed to meet its burden of proof to show that the Pharmacy had filled prescriptions for controlled substances that contained red flags without resolving those red flags. *Id.* at 15. The Respondent also concludes that the Pharmacy was never asked to provide the DEA with evidence of its documentation.[39] *Id.* at 15–16. Citing *Superior Pharmacy I & Superior Pharmacy II,* 81 FR 31310, 31335 (2016), the Respondent also concludes that the Government presented no proof of willful indifference, and that ''a reasonable suspicion is not enough to establish that a pharmacist acted with the requisite scienter.'' *Id.* at 15. Further, citing *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28667 n.2 (2015), the Respondent concludes that there is no evidence of willful blindness. *Id.* at 16.

In the Respondent's Brief, the Respondent minimally summarizes some of the testimony.[40] The Respondent then sets out the standards that must be met to prove that a Pharmacy violated its corresponding responsibility, once again relying on *Superior Pharmacy I & Superior Pharmacy II,* 81 FR at 31335 and *JM Pharmacy,* 80 FR at 28667 n.2. In conclusion, the Respondent argues:

> Taking the admitted evidence and testimony as a whole, there is no evidence the pharmacist isn't completely committed to her duties as a pharmacist. She verifies early and checks the PMP every prescription. There was no evidence of diversion based on the surveillance by the DEA, and the 47000 doses of hydrocodone is probably wrong pursuant to the testimony of the man who wrote the report. Further, there is no evidence of willful blindness or willful indifference by the pharmacist. The

[34] This argument is an overstatement. The Respondent did produce evidence of dispensing prior to July 7, 2014, though it takes some digging to find it. The lowest RX number for a prescription for hydrocodone dispensed by the Pharmacy on July 7, 2014, is 105254. GE–6, at 1. The Respondent demonstrated that it dispensed more than 300 prescriptions for hydrocodone with prescription numbers lower than 10525. *See* RE–C, at 31–42. Based on the RX numbers of those prescriptions, and the manner in which those numbers are assigned to prescriptions, those 300 prescriptions were filled prior to July 7, 2014. Those records, however, were not produced until long after the Pharmacy was required to produce them.

[35] The Respondent's Proposed Findings has been marked as ALJ–36.

[36] The Respondent's Brief has been marked as ALJ–37.

[37] There is only one prescription in Government Exhibit 2 that is marked with a ''V''. *See* GE–2, at 49.

[38] Some of the Respondent's Proposed Findings of Fact (''PFF'') are not supported by the Administrative Record. Representative examples follow. In PFF 7 the Respondent states that the Pharmacy was under visual surveillance by DEA. ALJ–36, at 3. At best the Administrative Record would support a finding that DI 1 thinks that the ''tactical diversion squad was going out there and watching it.'' Tr. 93. This ''fact,'' whether accurate or not, is not relevant to the issues in this case. In PFF 38 the Respondent cites Government Exhibit 6 for its position that not more than 10% of the prescriptions issued each day were issued by one of the medical clinics under investigation. ALJ–36, at 7. Government Exhibit 7, however, only concerns hydrocodone. The Administrative Record makes abundantly clear that the ''Prescribers wrote far more prescriptions than just hydrocodone.'' PFF 32 has little resemblance to the actual testimony cited in support of the PFF. ALJ–36, at 6. In PFF 44 the Respondent states that distance and route traveled by the patients who obtained prescriptions from one of the Prescribers ''was often based on convenience to work, or proximity to the clinic rather than convenience to home.'' ALJ–36, at 8. There is no evidence to support this assertion. Rather, the citation to the record provided by the Respondent of Tr. 494–95, provides more reasonable support for the conclusion that Ms. Igwe did not find it uncommon for patients to be coming from different locations around the Dallas-Fort Worth area, and because it was not uncommon she did not question it. Further, the investigation of the Pharmacy began because the ''Pharmacy Place was so far from these clinics.'' Tr. 430. The Respondent also states that Mr. Litman testified that the only way to determine a physician was prescribing non-controlled substances to mask the illegitimate prescribing of controlled substances was to find another red flag in the prescription. *See* PFF 77, ALJ–36, at 13. That, however, is not Mr. Litman's testimony. He begins his answer by saying, ''the only thing to do is call the physician . . . .'' Tr. 683.

[39] This conclusion seemingly ignores Government Exhibit 9. *See also* Tr. 357.

[40] On at least two instances, the Respondent significantly mischaracterizes the testimony. The Respondent states that the ''DEA undercover agent did not divert the drugs . . . . nor was the Pharmacy Place related to any diversion activity by the Agent.'' ALJ–37, at 3. This statement reflects a total misunderstanding of diversion by the Respondent. Diversion occurs whenever anyone received a controlled substance they should not have received. Then the Respondent states that Dr. Witte testified ''she would probably not check the distance travelled by the customer.'' ALJ–37, at 5. Actually when the transcript is examined, what Dr. Witte said was that she would ''probably not'' check to see if an address was legitimate. Tr. 191. This issue is also not relevant to the issues in this case. What is relevant is the fact that the Pharmacy's own records indicate the patient in question traveled from Fort Worth to a clinic south of Dallas, then to the Pharmacy north of Dallas, and then back to Fort Worth in order to obtain a prescription and have it filled, yet the Pharmacy asked no questions about that distance the patient traveled or the unusual route the patient would have taken.

pharmacy is a neighborhood pharmacy that compounds medication and caters to children . . . . The Pharmacy Place is minority owned and operated by the owner. It compounds medications. Based on the pharmacist (sic) testimony in the trial, pharmacists' (sic) differ in approach and protocol based on experience, knowledge and background. The continued operation of the pharmacy is consistent with the public interest.

ALJ–37, at 7.

Factor One & Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority, and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid state pharmacy license in Texas. The record contains no evidence of a recommendation regarding the Respondent's privilege to operate as a pharmacy by a relevant state licensing board or professional disciplinary authority. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20011, 20018 (2011). It is well established that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008).

Agency precedent establishes 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 Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011) (''The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'') Accordingly, Factor One does not weigh for or against revocation in this matter.

As to Factor Three, there is no evidence that Respondent, or any of its agents, have been convicted of an offense under either federal or Texas law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011). Therefore, the DEA has held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is not dispositive. *Id.* Accordingly, Factor Three weighs neither for nor against revocation in this case.

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

Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, M.D.,* 79 FR 18698, 18709 (2014); *John V. Scalera, M.D.,* 78 FR 12092, 12098 (2013). Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). Factor Two analysis focuses on a registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate [dispensing] over the course of [the registrant's] professional career'') (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state laws concerning controlled substances. 21 U.S.C. 823(f)(4). Factor Four analysis also focuses on violations of state and federal regulations. *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009) (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.,* 74 FR 10083, 10090–91 (2009).

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

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

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

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28667, 28670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are

aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

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 29. *See also* OSC, at 5 (''Pharmacy Place's pharmacists were willfully blind to or deliberately ignorant of the high probability that the [subject prescriptions] lacked a legitimate medical purpose. Pharmacy Place pharmacists were willfully blind to the fact that large numbers of customers seeking controlled substance prescriptions, often prescription cocktails, and residing long distances from Pharmacy Place's location and/or their respective physicians created a suspicious situation requiring increased scrutiny.'').] [*C]

Because the Pharmacy is located in Texas, it is important to review the requirements of Texas law as it relates to pharmacists. To begin, Texas law provides that ''[a] pharmacist may not: (1) dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code § 481.074(a)(1). Texas law further provides that ''[a] pharmacist may not: (2) dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.'' *Id.* at § 481.074(a)(2). It is also unlawful in Texas for any ''registrant or dispenser'' to deliver a controlled substance in violation of section 481.074 of the Texas Health and Safety Code. *Id.* at § 481.128. Additionally, the Texas Health and Safety Code mandates that a ''prescription for a controlled substance'' must show ''the name, address, and date of birth or age of the patient'' as well as the ''Federal Drug Enforcement Administration number'' of the practitioner issuing the prescription. *Id.* at § 481.074(k)(3), (7).

In addition to Texas statutes, the Texas State Board of Pharmacy has issued rules for the operational standards that Texas pharmacists are expected to follow when filling a new or refill prescription. Those operational standards dictate that

> [f]or the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant: . . . (III) reasonable dose and route of administration; (IV) reasonable directions for use; (V) duplication of therapy; (VI) drug-drug interactions; . . . [and] (X) proper utilization, including overutilization or underutilization.

See 22 Tex. Admin. Code § 291.33(c)(2)(A)(i).

The operational standards also mandate that ''[u]pon identifying any clinically significant conditions, [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' *Id.* at § 291.33(c)(2)(A)(ii). Furthermore, ''[p]rior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained.'' *Id.* at § 291.33(c)(2)(A)(iv). [ ] [*D] Texas operational standards require at a minimum that such documentation be

> on the prescription or in the pharmacy's data processing system associated with the prescription . . . and shall include . . . (1) date the prescriber was consulted; (ii) name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) initials for the purpose of identifying the pharmacist who performed the consultation.

Id. at § 291.33(c)(2)(C). [ ] [*E]

The Texas State Board of Pharmacy has also issued rules concerning the labels that a pharmacist puts on the bottles of controlled substances being dispensed by a pharmacy. Those standards require that

> [a]t the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information: (i) name, address and phone number of the pharmacy; (ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman; (iii) date the prescription is dispensed; (iv) initials or an identification code of the dispensing pharmacist; (v) name of the prescribing practitioner; . . .

Id. at § 291.33(c)(7)(A). While this particular section of the operational standards was not cited in the OSC, it is relevant in this case because the Pharmacy should have been following these requirements when filling prescriptions.[41]

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341 (citing *Med. Shoppe—Jonesborough,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50397, 50407–08 (2007); *EZRX, L.L.C.,* 69 FR 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61613, 61617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64921, 64924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR at 63,181; *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341.

In support of its allegations that the Pharmacy violated its corresponding responsibility, the Government convincingly argues that the Pharmacy filled prescriptions to customers without documenting the resolution of numerous red flags. Regarding the documentation of red flags in Texas, [Dr. Witte credibly testified that it would be below the minimum standards of practice and outside the usual course of professional practice for a Texas pharmacist to fail to document the resolution of red flags on a prescription before dispensing it. Tr. 178–82, 209–211 244–47]; [*F] *see also The Medicine Shoppe,* 79 FR 59,504, 59,509 n.14, 59,516 (2014) (concluding a Texas pharmacy violated its corresponding

[*C] I am omitting some language from the RD and adding the above to clarify the analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

[*D] Text adjusted in response to Respondent's Exceptions.

[*E] Text removed in response to Respondent's Exceptions.

[41] [The ALJ used this footnote to take official notice under the Administrative Procedure Act of 22 Tex. Admin. Code § 291.33(c)(7)(A). In the section on Respondent's Exceptions, *supra,* I addressed Respondent's response and found that the ALJ properly applied the regulation.]*

[*F] Text adjusted to add reference and citation to Dr. Witte's testimony.

duty by failing to document the resolution of red flags on hard-copy prescriptions and that the record as a whole lacked evidence that red flags were resolved).

Pattern Prescribing

[Both expert witnesses in this matter testified that pattern prescribing is a red flag that can be indicative of drug abuse or diversion. FF 58–59, 61; Tr. 171–72.] [*G] ''`Pattern prescribing' occurs when a physician prescribes the same drug and the same dosage to every patient the physician sees.'' *The Medicine Shoppe,* 79 FR 59504, 59512 (2014); *see also Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR 79188, 79215 (2016) (noting expert's definition of pattern prescribing as ''`patients going to the same doctor for the same ailments, receiving the same prescriptions in the same quantity without any difference in the treatment.' '). Pattern prescribing raises a red flag because a ''prescription should be tailored to each patient's individual needs based on their chronic conditions.'' *The Medicine Shoppe,* 79 FR at 59,512; *see also United States* v. *Hammond,* 781 F.2d 1536, 1538 (11th Cir. 1986) (accepting expert testimony that ''the lack of individualized dosing'' is indicative of diversion). When a doctor prescribes the same controlled substances to different patients with similar doses for everybody, it suggests the doctor is simply churning out controlled substance prescriptions indiscriminately rather than conducting legitimate medical treatment. [*See* FF 61;] [*H] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR at 79195; 21 CFR 1306.04(a) (requiring controlled substances to be prescribed only for ''legitimate medical purpose[s]''). Ultimately, the concern with pattern prescribing is that it indicates a lack of individualization of therapy. [FF 61.] [*I]

Agency [cases involving similar factual scenarios and credible expert testimony] [*J] demonstrate that pattern prescribing manifests itself in one of two forms. One form of pattern prescribing occurs where one physician or clinic prescribes the same controlled substances to different patients over an extended time period. *See Holiday CVS, L.L.C.,* 77 FR 62316, 62323 (2012) (determining that a doctor was clearly ''engaged in pattern prescribing'' where the doctor repeatedly prescribed ''oxycodone and alprazolam based on nearly uniform diagnoses'' over the course of six months). Another form of pattern prescribing occurs where one doctor or clinic writes the same prescription to different patients on the same day. *See Superior Pharmacy I & Superior Pharmacy II,* 81 FR 31310, 31322 (2016) (describing instance where various doctors of same clinic wrote 16 prescriptions for oxycodone 30 mg on the same date to different patients). The Respondent's expert witness, Mr. Litman, however, was only concerned about the second category of pattern prescribing—seeing the same prescription 20 times in one day. Tr. 659–60.

Some red flags, such as prescription cocktails, suboptimal dosing, and cash payment, should capture a pharmacist's attention early on, if not immediately. In contrast, with respect to the first variety of pattern prescribing—and to a lesser extent the second variety—the problem manifests itself over an extended period of time and is not immediately recognizable. FF 67, 92. Quite literally, pattern prescribing occurs when a single provider's or group of providers' prescriptions all share common characteristics and over time create a pattern of the same substances, doses, and strengths. Tr. 228–29, 232–33, 250, 264–65, 279, 289, 353.

In *East Main Street Pharmacy,* the respondent repeatedly dispensed similar prescription cocktails to different patients that were written by the same provider. 75 FR at 66163. The Deputy Administrator's decision in *East Main Street Pharmacy* observed that the prescriptions for hydrocodone and alprazolam were always prescribed at the maximum strength, and that the cocktails always contained some combination of the same substances. *Id.* Examples can be found in this case with the prescriptions issued to J.W., H.J., M.H., A.S., K.S., and M.A., where each patient received prescriptions for 90 to 120 tablets of 10 mg hydrocodone and 60 tablets of 2 mg alprazolam. Tr. 208–09. Dr. Witte noted that these prescriptions constituted a drug cocktail, and were indicative of pattern prescribing, with the ''same medications, the same directions, [and] the same quantity for different patients.'' *Id.* at 209. Dr. Witte further testified that upon receipt of such prescriptions ''a reasonably prudent pharmacist'' should investigate the red flag presented by the prescriptions. *Id.* at 210. [She further testified that a pharmacist acting in the usual course of professional practice and following the minimum standard of practice in Texas would not fill the prescriptions without resolving the red flag and documenting the resolution. Tr. 210–211.] [*K] There is no documentation in the Administrative Record, however, showing that the Pharmacy resolved any of the red flags. *Id.* at 210. Additional examples of unresolved pattern prescribing can also be seen in the prescriptions issued by I.I., C.V., and NE *See* FF 163, 169, 174.

Repeat prescriptions for the same handful of drug cocktails issued by the same providers for different patients should ''create[ ] an obvious and compelling level of suspicion that the prescriptions lacked a legitimate medical purpose.'' *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR at 79199. Such is the case with the prescriptions filled by the Pharmacy. FF 162–177. Based upon her review of Government Exhibit 2, Dr. Witte credibly testified that while the prescriptions presented numerous red flags, the issue of pattern prescribing stood out and was suspicious. Tr. 171, 244, 296, 335, 358–59.

Varying the substances and doses, however, would weigh against a finding of pattern prescribing. In *Hills Pharmacy,* for example, the Administrator rejected the Government's claim of pattern prescribing because the dosages ranged from 140 to 240 tablets. 81 FR at 49841 n.46. Additionally, out of a set of 20 prescriptions provided by the Government, there were 3 different controlled substances prescribed in various strengths. *Id.*

In this case, Dr. Witte identified pattern prescribing as a recurring issue with the prescriptions she reviewed that had been filled by the Pharmacy [and testified that a pharmacist dispensing prescriptions within the minimum standard of practice in Texas would have recognized the pattern prescribing in the subject prescriptions as a red flag].[*L] Tr. 171, 244, 296, 335, 358–59; FF 61–62. Her testimony and analysis concerning those prescriptions is consistent with the DEA cases discussed above. FF 61–62. Furthermore, when examining the prescriptions filled by the Pharmacy beginning in August 2014 and running through May 2015, the pattern prescribing becomes more and more apparent with each prescription filled. Because Ms. Igwe filled all of these prescriptions, the pattern should have become obvious to her. Tr. 578.

Distance

The distance a patient is willing to travel to obtain a prescription and fill it is one factor a pharmacist must consider when discharging his or her

[*G] Text and citations added for clarity.

[*H] Citation added.

[*I] Citation replaced and text removed for brevity.

[*J] Text adjusted for clarity.

[*K] Text added for clarity.

[*L] Text adjusted for clarity.

corresponding responsibility. [Tr. 172;] [*M] *see also Hills Pharmacy, L.L.C.,* 81 FR at 49841 n.45; *Samuel Mintlow, M.D.,* 80 FR 3630, 3650 (2015) (applying the distance factor to a physician case and reasoning that a doctor should be suspicious when a patient travels a long distance and ''bypass[es] numerous other potential treating physicians''). This is not a new consideration. Medical and pharmacy experts have testified in DEA cases for at least the past eight years that traveling long distances to obtain or fill controlled substance prescriptions is a red flag indicative of diversion and abuse.[42] Although there is no ''categorical rule'' dictating the precise number of miles that raise a red flag, a pharmacist must nevertheless take the distance traveled into account when deciding whether to dispense controlled substances. *Hills Pharmacy,* 81 FR at 49841 n.45. [] [*N]

Additionally, Texas regulations include the distance a patient traveled as one factor pharmacists should be aware of before dispensing a controlled substance. The Texas State Board of Pharmacy, echoing the federal standard, requires pharmacists to ''exercise sound professional judgment with respect to'' the legitimacy of a prescription. 22 Tex. Admin. Code § 291.29(a); *see also* 21 CFR 1306.04(a), 1306.06. The Board then goes on to provide a non-exhaustive list of circumstances a pharmacist should weigh when evaluating a prescription's legitimacy, including ''the geographical distance between the practitioner and the patient or between the pharmacy and the patient.'' 22 Tex. Admin. Code § 291.29(c)(4).

As Dr. Witte noted, seeing a doctor in south Dallas and filling a prescription in Plano (north of Dallas) when the patient lives in Fort Worth raises a concern Tr. 189–93, 281, 321. While testifying, Dr. Witte asked an appropriate rhetorical question, ''Why did these patients feel the need to drive clear across Dallas, all the way up to Plano, north of the city, to fill these prescriptions?'' *Id.* at 281. Nothing in the Administrative Record provides an answer to that question. Dr. Witte further opined that, ''more than likely, there are many pharmacies located between . . . where the patient lives and where the clinic is.'' [43] *Id.* at 263; *see also id.* at 323. Certainly there could have been valid reasons for the distances and routes traveled, but the minimum standards in Texas obligate a pharmacist to at least raise this concern with the provider to determine the prescription's legitimacy, and then document the explanation. [FF 63–64, 79, 90].[*O] This was not done here. FF 79, 88, 90; GE–2; RE–E. Dr. Witte's testimony is consistent with DEA precedent and Texas law. Further, while Ms. Igwe did not seem to have the slightest concern about the distance her customers were traveling to obtain their prescriptions and get them filled, she also apparently had not the slightest curiosity as to why this small group of prescribers had referred so many patients to her relatively small and out of the way Pharmacy. While nothing in the Administrative Record directly answers that question, that facts alone should have raised a question about the legitimacy of the prescriptions.

The Respondent's expert witness, Mr. Litman, however, minimized the significance of distance, noting that we live ''in a very mobile society now, and people are on the go all the time.'' Tr. 730. Mr. Litman added that on some days he commutes 80 miles. *Id.* As a pharmacist, who at times works in a retail pharmacy in Miami, Florida, Mr. Litman would be concerned with a patient traveling from South Carolina to fill a prescription. *Id.* at 695. Mr. Litman, however, was not aware of DEA cases that deal with pharmacy customers who had driven long distances to obtain their prescriptions and have them filled. *Id.* at 727. And as previously noted, the DEA has considered distance to be a red flag of diversion for at least the past 8 years. *See supra* note 42 and accompanying text. Further, Mr. Litman was apparently unaware of the Texas requirement to at least consider the distance a customer has traveled to fill a prescription. Tr. 739; *see* 22 Tex. Admin. Code § 291.29(c)(4). [His testimony concerning distance contradicts cases based on credible expert testimony that distance is a red flag under the usual course of professional practice of pharmacy. *Morning Star Pharmacy and Medical Supply 1,* 85 FR at 51052; *Hills Pharmacy, L.L.C.,* 81 FR at 49841 n.45 (2016); *Jones Total Health Care Pharmacy, L.L.C. & SND Healthcare, L.L.C.,* 81 FR at 79194–95; 21 CFR 1306.04(a) (creating the pharmacist's corresponding responsibility). It also contradicts Dr. Witte's credible testimony that the distances the patients traveled to fill the subject prescriptions were red flags that a pharmacist following the minimum standards of practice in Texas should have investigated, resolved, and documented before filling the prescriptions. *E.g.,* Tr. 401–404.] [*P] Accordingly, I give no weight to Mr. Litman's testimony that distance is not a red flag. Tr. 726–27.

Cash Payments

Dr. Witte testified that paying cash for prescriptions was a red flag. *See, e.g.,* Tr. 172–73, 229–30, 263. She also testified that the average cash price for 90 tablets of hydrocodone was about $70.00 and the average price for 60 tablets of alprazolam was about $35.00 *Id.* at 223, 229. Here, the Pharmacy's customers were routinely paying $179.99 and $59.99, respectively. FF 167, 173. When a customer purchased prescriptions for both hydrocodone and alprazolam at the same visit to the Pharmacy, the customer would pay $239.98. *Id.* Even Mr. Litman expressed concern for cash payments in excess of $200.00. Tr. 692, 753. Mr. Litman also downplayed the significance of cash payments because many individuals do not have medical insurance and ''cash payments are much more common these days.'' *Id.* Ms. Igwe testified, however, that a majority of customers used insurance to pay for their prescriptions. *Id.* at 496. If that is the case, it is more concerning that all of the customers from Government Exhibit 2 paid cash when filling prescriptions for hydrocodone and/or alprazolam. FF 111, 165, 171, 176.

Paying cash for controlled substances, rather than billing insurance, is a red flag that the patient is seeking the substances for illicit purposes. '''[A]ny reasonable pharmacist knows that a patient that (sic) wants to pay cash for a large quantity of controlled substances is immediately suspect.'" *Jones Total Health Care Pharmacy,* 81 FR at 79194 (quoting *E. Main St. Pharmacy,* 75 FR at 66158). Paying for a prescription in cash is ''the preferred payment method for

[*M] Citation added.

[42] *Marcia L. Sills, M.D.,* 82 FR 36423, 36434 (2017); *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79188, 79188 (2016); *Edge Pharmacy,* 81 FR 72092, 72103 (2016); *Hills Pharmacy, L.L.C.,* 81 FR 49816, 49820, 49822 (2016); *Superior Pharmacy I & Superior Pharmacy II,* 81 FR 31310, 31323 (2016); *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44083 (2012), *Holiday CVS, L.L.C.,* 77 FR 62316, 62319 (2012); *Jacobo Dreszer, M.D.,* 76 FR 19836, 19393 (2011); *E. Main St. Pharmacy,* 75 FR 66149, 66150 (2010); *George C. Aycock, M.D.,* 71 FR 17529, 17539 (2009).

[*N] Text removed for brevity.

[43] Dr. Witte was accepted as an expert in the field of pharmacy in the state of Texas, not geography. Tr. 169. Thus, I do not credit her testimony concerning distances, routes, and general availability of pharmacies as that of an expert. I do credit it, however, as a reasonable observation based upon common experience. Certainly one is more likely to pass by a location to fill prescriptions in an urban area than a rural one. Common experience also suggests that, in general, it is more time consuming to travel even a short distance in an urban area than a rural one.

[*O] Text removed and citation corrected.

[*P] Text adjusted for clarity and additional citations.

illegitimate prescriptions,'' because it is not traceable. *Masters Pharmaceutical, Inc.* v. *DEA,* 861 F.3d 206, 220 (DC Cir. 2017). Like all red flags, paying in cash for controlled substances, or cash equivalent, such as credit card or check, is viewed in combination with other evidence of diversion. *See Edge Pharmacy, L.L.C.,* 81 FR 72092, 72103, 72111–12 (2016) (concluding substantial distances, large quantities of highly-abused controlled substances, and cash payments indicated the prescriptions lacked a legitimate medical purpose).

In the absence of other signs of diversion, prices in the range of $25 to $220 may be insufficient to prove that a pharmacist violated his or her corresponding responsibility. *Hills Pharmacy, L.L.C.,* 81 FR at 49839 n.39. DEA cases relying on expert testimony instruct, however, that not all red flags ''have the same hue.'' *Superior Pharmacy I & Superior Pharmacy II,* 81 FR at 31335 n.54. ''[W]here there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose.'' *Id.* Thus, as in this case, cash payments, combined with other red flags, can be enough to find a pharmacist violated 21 CFR 1306.04(a). *Edge Pharmacy, L.L.C.,* 81 FR at 72111–12; *Superior Pharmacy I & Superior Pharmacy II,* 81 FR at 31335 n.54.

The Allegations

The Prescriptions

1. Initially, the Government alleged that between August 2014 and May 2015 the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). ALJ–1, at 2, para. 3. The Pharmacy did so by repeatedly filling controlled substance prescriptions that contained red flags of diversion and/or abuse without addressing or resolving those red flags. The Pharmacy's conduct in doing so violated 21 U.S.C. 823(f)(4); Tex. Health & Safety Code § 481.070-.075; Tex. Health & Safety Code § 481.128; 22 Tex. Admin. Code § 291.22(c)(2); and 22 Tex. Admin. Code § 291.33. Additionally, the Pharmacy engaged in conduct that demonstrated negative experience in its dispensing of controlled substances, in violation of 21 U.S.C. 823(f)(2). ALJ–1, at 2–3, para. 3, 6–8.

The regulation concerning the usual course of pharmacy practice provides that, ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . . .'' 21 CFR 1306.06. The DEA has also promulgated regulations concerning a pharmacist's corresponding responsibility. That regulation provides:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning of section 309 of the [Controlled Substances] Act (21 U.S.C. 829) and the person knowingly filling such 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.

21 CFR 1306.04(a). Texas regulations require that ''[u]pon identifying any clinically significant conditions, [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' 22 Tex. Admin. Code § 291.33(c)(2)(A)(ii). That resolution must be documented [on the prescription itself or ''in the pharmacy's data processing system associated with the prescription.'' *Id.* at §§ 291.33(c)(2)(A)(iv) and 291.33(c)(2)(C). The minimum documentation requirements include] [*Q] recording the date the pharmacist discussed the matter with the prescriber, recording the name of the person with whom the pharmacist discussed the matter, and any applicable information pertaining to the discussion. *Id.* [ ] [*R]

The Government's first allegation asserts that the Pharmacy violated its corresponding responsibility in filling the prescriptions contained in Government Exhibit 2, which were all filled between August 2014 and May 2015. ALJ–1, at 2, para. 3. The testimony of Dr. Witte, supported by DEA cases, makes clear that pattern prescribing cannot be established by only a few prescriptions. Tr. 332–33. At first blush, the allegation seems inconsistent with DEA precedent and Dr. Witte's testimony that pattern prescribing cannot be established by only a few prescriptions.[44] The Pharmacy, however, did not start filling prescriptions for the ''Prescribers'' in August 2014.

The Pharmacy started receiving prescriptions from Redbird in January or February 2014. FF 11; Tr. 475. In fact, prior to filling the cocktail prescriptions for J.S. on August 6, 2014, the Pharmacy had filled at least 104 prescriptions for hydrocodone written by the same small group of prescribers.[45] FF 155. In addition, the Pharmacy had filled at least 11 prescriptions written by this small group of prescribers for cocktails of hydrocodone and alprazolam prior to August 2014, for patients who had to travel a significant distance to fill those prescriptions. FF 140, 142–45. In each case the prescriptions raised numerous red flags: The patient was receiving a large quantity of controlled substances; the controlled substances constituted a drug cocktail; the prescription was written by one of a small number of prescribers of hydrocodone and alprazolam whose prescriptions the Pharmacy filled for those controlled

[*Q] Text adjusted in response to Respondent's Exceptions.

[*R] Text removed in response to Respondent's Exceptions.

[44] The inconsistency results because the number of prescriptions issued by each individual prescriber in Government Exhibit 2 might be insufficient by itself to establish a pattern that the Pharmacy should have been reasonably expected to notice. Looking solely at the hard-copy prescriptions in Government Exhibit 2, and not the patient profiles, reveals the following breakdown of the number of prescriptions issued by each practitioner. Nurse J.W. issued 1 prescription. GE–2, at 67. Dr. A.Q. issued 5 prescriptions. *Id.* at 18, 20, 64, 66, 68. Nurse L.R. issued 7 prescriptions. *Id.* at 1, 3, 24, 37, 96, 119. Nurse Practitioner I.I. issued 10 prescriptions. *Id.* at 8, 10, 12, 14, 16. Nurse S.G. issued 10 prescriptions. *Id.* at 5, 6, 34, 77, 81, 91, 111, 124. C.Z., PA, issued 8 prescriptions. *Id.* at 25, 30, 41, 46, 52, 100, 115, 122. Dr. C.V. issued 12 prescriptions. *Id.* at 28, 35, 39, 44, 47, 50, 83, 94, 98, 113, 117, 130. Dr. NE issued 23 prescriptions. *Id.* at 22, 26, 49, 56, 58, 60, 62, 71, 73, 75, 79, 86, 88, 89, 102, 104, 105, 107, 109, 120, 125, 127, 132. When written over the course of 10 months, from August 2014 to May 2015, the volume of prescriptions issued by each practitioner might not be suspicious. Thus, in determining whether the Pharmacy filled pattern-style prescriptions, consideration is also given to additional documentary evidence in the Administrative Record beyond the 10 month period in the allegation. For example, consideration has been given to Government Exhibit 6 and Respondent Exhibit C. Consideration is also given to the fact that all the prescribers were associated with the same medical clinics.

[45] Actually, if Respondent's Exhibit C is taken into consideration, the Pharmacy filled far more than 104 prescriptions for hydrocodone written by the same small group of Prescribers prior to filling the hydrocodone prescription for J.S. in August 2014. The 104 figure only takes into account those prescriptions documented by Government Exhibit 6. A review of Respondent's Exhibit C, which the Pharmacy claims to be its complete dispensing history of hydrocodone from the date the Pharmacy opened until the date of the DEA inspection, Tr. 470–71, reveals that the overwhelming majority of prescriptions the Pharmacy filled for hydrocodone were written by one of the Prescribers identified in Findings of Fact 118–121, 155.

substances; the prescriber was located a significant distance from the Pharmacy; and the round-trip distance for the patient to obtain the prescription and have it filled at the Pharmacy was also significant. *Id.*[*S]

Here, Government Exhibit 2 documents that the Pharmacy filled more than 75 controlled substance prescriptions between August 2014 and May 2015 for 27 different customers. FF 140. Those prescriptions contain many of the same red flags as are contained in the prescriptions the Pharmacy filled prior to August 2014 that were written by the same small group of Prescribers.[46] Furthermore, there is no credible evidence that the Pharmacy ever took any steps to resolve any of these red flags, either before or after August 2014. Tr. 216–17, 227, 236.

Accordingly, the allegations contained in paragraphs [3, 6, and 8] [*T] of the OSC asserting that between August 2014 and May 2015 the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a), as well as 21 U.S.C.§ 823(f)(2) and (4); Tex. Health & Safety Code § 481.070-.075; Tex. Health & Safety Code § 481.128; 22 Tex. Admin. Code § 291.22(c)(2) [ ],[*U] are sustained, and weigh in favor of revoking the Pharmacy's DEA registration.

2. The Government next alleged four situations in which the Pharmacy filled prescriptions that contained one or more red flags that the Pharmacy did not resolve prior to filling the prescriptions. The Government listed the following as examples of red flags the Pharmacy did not resolve: (a) Prescriptions for highly-abused controlled substances such as hydrocodone, alprazolam, and promethazine with codeine; (b) prescriptions written to individuals traveling long and/or unusual distances to obtain their prescriptions and/or fill their prescriptions at the Pharmacy; (c) prescriptions for individuals obtaining the same or similar combinations of controlled substances from the same small number of providers; (d) prescriptions for highly-abused drug cocktails, such as hydrocodone and alprazolam; (e) prescriptions containing inappropriate and/or unusual directions for use; and (f) prescriptions for controlled substances purchased with cash. ALJ–1, at 3–5, paras. 10, 10(a)-(d).

Ms. Igwe testified that she did not see any red flags in the prescriptions introduced by the Government because they came from clinics with which she was familiar.[47] Tr. 512–13. Also, the types of controlled substances in these prescriptions were consistent with the clinics' specialty, chronic pain management. *Id.* at 512. Additionally, some of the controlled substances were prescribed with appropriate non-controlled substances. *Id.* at 514, 663–65. For example, some of the prescriptions, such as the M.W. prescription, contained Mobic, an anti-inflammatory that can reduce the need for an opioid. *Id.* at 513, 663–64; GE–2, at 1. Some prescriptions, as in the case of M.W. prescription, also contained Robaxin, which is a muscle relaxant. Tr. 513, 664–65; GE–2, at 1. Mobic and Robaxin are relevant treatment options involving non-scheduled drugs for a patient suffering from chronic pain. Tr. 513, 663–65. Ms. Igwe found it common that different doctors practicing in the same specialty prescribed the same or similar types of controlled substances. *Id.* at 519; *see also id.* at 658.

Ms. Igwe also testified that customers would come into the Pharmacy wearing braces or other ''mobilization'' (sic) devices, consistent with the patient needing a controlled substance to treat pain. *Id.* at 516. Sometimes a customer would say something that indicated to Ms. Igwe the customer needed the medications to treat pain. *Id.* at 516.

In addition, Ms. Igwe was not concerned with patients coming from Fort Worth. FF 138. Ms. Igwe testified that it was not unusual to see patients with a Fort Worth address.[48] *Id.* at 494. The Pharmacy had patients from towns surrounding the Plano area, such as Lavon, Princeton, Farmersville, Gladewater, DeSoto, and Lancaster. *Id.* at 494, 584. The Pharmacy had patients who came from throughout the Dallas-Fort Worth metroplex. *Id.* at 495, 584.

Although Ms. Igwe testified that she was not concerned about red flags, in part, because she was familiar with the clinics the customers were coming from, Ms. Igwe also testified that she never checked to see if the Prescribers' clinics were registered with the State of Texas as pain management clinics. FF 99. Thus, her belief that she was receiving prescriptions from pain management specialists was, at best, uninformed. While it is true that many of the prescriptions in Government Exhibit 6 also included non-controlled substances that could also be used to treat pain symptoms, it is possible that the Prescribers were simply ''masking'' the fact that they were issuing prescriptions for illegitimate reasons. Even the Respondent's own expert, Mr. Litman, concluded that he thought the Prescribers were engaged in masking. Tr. 713. Mr. Litman further testified that the only way to sniff out masking, or at least to ''reduce the suspicions,'' is to ''call the physician.'' *Id.* at 687, 727. The Administrative Record contains no evidence documenting such calls being made to the Prescribers.

With respect to distance, Ms. Igwe, as well as Mr. Litman, apparently had no concerns about the distances the Pharmacy's customers were driving to obtain their prescriptions and have them filled at the Pharmacy. *Id.* at 492–95, 542–43, 695–96, 727. Contributing to Ms. Igwe's lack of concern about distance was the fact that she believed the customers were coming from pain management clinics. *Id.* at 512–13. Further, both Ms. Igwe and Mr. Litman seemed oblivious to the Texas requirement that a pharmacist should consider ''the geographical distance between the practitioner and the patient or between the pharmacy and the patient'' when evaluating a

[*S] The OSC did not allege that Respondent unlawfully dispensed any prescriptions prior to August 2014. Accordingly, while Respondent's dispensing history prior to August 2014 is relevant to establishing patterns in the subject prescriptions, any deficiencies in Respondent's prescription dispensing practices outside of the subject prescriptions do not weigh for or against Respondent retaining its registration.

[46] Government Exhibit 6 is the Pharmacy's dispensing log for hydrocodone. FF 24. The stated date range on Government Exhibit 6 is October 23, 2013 to June 18, 2015. FF 25. The earliest date recorded on Government Exhibit 6, however, is July 7, 2014. GE–6, at 1. The actual hard-copy prescriptions for most of the prescriptions recorded on the dispensing log are not contained in the Administrative Record. Nevertheless, the dispensing log identifies the prescriber, the prescriber's address, the patient, the patient's address, the quantity of hydrocodone tablets dispensed, and amount the customer paid for the prescription. Thus, Government Exhibit 6 documents that most of the prescriptions would have contained the following red flags: Pattern prescribing; a highly abused controlled substance; unusual routes of travel and/or long distances to obtain the prescriptions and have them filled at the Pharmacy; and cash payments.

[*T] Text adjusted in response to Respondent's Exceptions.

[*U] Text adjusted in response to Respondent's Exceptions.

[47] A former Administrator overruled a similar argument in the past. *See Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4729–4730 (1990) (deciding that the ''sheer quantity and frequency of [Preludin] prescriptions'' should have tipped off the pharmacy that the prescriptions lacked a legitimate medical purpose even though the pharmacy argued that the prescriptions were ''not surprising'' given the provider's medical specialty).

[48] In fact, there are numerous Fort Worth addresses for the Pharmacy's customers listed in Government Exhibit 6. Most of those customers, however, also received their prescriptions for hydrocodone from the same small group of Prescribers.

prescription's legitimacy. 22 Tex. Admin. Code § 291.29(c)(4).

Finally, there is no documentation in the Administrative Record of the Pharmacy ever: Resolving any red flags; consulting with providers about red flags; checking the Texas PMP; or having discussions with customers to resolve missing addresses on prescriptions. Tr. 216–17, 227, 236. In fact, although Ms. Igwe testified that she had such documentation, she did not believe she needed to present it.[49] *Id.* at 547. This belief is unreasonable given the allegations contained in the OSC and because Ms. Igwe was asked to produce any notes she had concerning the resolution of red flags during the AIW. FF 18–19.

A. The M.W. Prescription

The Government alleged that on August 1, 2014, the Pharmacy filed a prescription for 120, 10 mg tablets of hydrocodone presented by an undercover agent without resolving the red flags presented by the prescription. The agent obtained the prescription from a practitioner in a clinic in south Dallas, more than 30 miles from the Pharmacy, which is located north of Dallas. There was no legitimate medical purpose for the prescription and the agent used a fictitious address. The agent also sought to purchase the prescription with cash. ALJ–1, at 3–4, paras. 10, 10(a).

The basic facts that support this allegation are contained in the sworn declaration of the undercover investigator, UC 1. GE–11. During his undercover investigation, UC 1 used the name M.W. FF 124. On July 29, 2014, M.W. went to the Redbird Medical Clinic, where Nurse Practitioner L.R. conducted a cursory examination. FF 126–27. L.R. then issued M.W. a prescription for 120, 10 mg tablets of hydrocodone, as well as prescriptions for Robaxin (methocarbamol) and Mobic (meloxicam). FF 127; GE–2, at 1; GE–10, at 5. Instead of simply giving M.W. his prescription so that he could have it filled at the pharmacy of his choice, Redbird informed M.W. that they were sending his prescription to the Pharmacy. FF 127. The Pharmacy, however, did not receive the prescription until August 1, 2014. FF 129. In spite of the fact that the prescription was written for pain, M.W. did not pick up his prescriptions until August 4, 2014. FF 132. Based on the addresses contained in the Pharmacy's records, M.W. would have needed to travel almost 100 miles to obtain his prescriptions from Redbird, have them filled at the Pharmacy, and return to his recorded, though fictitious, address. GE–12. M.W. paid the Pharmacy $206.00 for his three prescriptions, to include $150.00 for the hydrocodone. GE–2, at 1; GE–11, at 3.

In the three weeks before the Pharmacy filled M.W.'s prescription for hydrocodone on August 1, 2014,[50] the Pharmacy had already filled 83 prescriptions for hydrocodone, and L.R. had written 27 of those prescriptions. GE–6, at 1–8. In addition, every one of those prescriptions had been written by one of the Prescribers. *Id., see also* FF 118–21.

The prescription that L.R. wrote for M.W. raises the following red flags: No patient address; no provider DEA number; [ ] *[V] the prescription was written on July 29, 2014, but not faxed to the Pharmacy until August 1, 2014, and not picked up until August 4, 2014; [51] and an unusual path and distance to obtain the prescription and get it filled. FF 47, 63, 69, 75, 135. In addition, M.W. paid over $200 cash to pick up his three prescriptions.[52] FF 65; GE–2, at 1; GE–11, at 3.

There are no notations on the M.W. prescription or on M.W.'s patient profile, maintained by the Pharmacy, to suggest that any of the above noted red flags were resolved either before or after Ms. Igwe filled the prescription for hydrocodone. Tr. 194–95; GE–2, at 1; GE–10, at 4–5. Accordingly, the M.W. prescription for hydrocodone was not dispensed in the usual course of pharmacy practice. Tr. 195. In addition, the pharmacist who filled these prescriptions did not follow the minimum standard of the practice of pharmacy in the State of Texas, and did not satisfy the pharmacist's corresponding responsibility to ensure that prescriptions are issued for legitimate medical purposes. *Id.*

The allegation concerning the M.W. prescription is also included in the allegation contained in paragraphs 3–7 of the OSC that between August 2014 and May 2015 the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice and in contravention of the Pharmacy's corresponding responsibility to ensure that prescriptions are dispensed for legitimate medical purposes. ALJ–1, at 2–3, paras. 3–7. The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Therefore, the allegations contained in paragraphs 10 and 10(a) of the OSC, that the Pharmacy filled the M.W. prescription for 120, 10 mg tablets of hydrocodone on August 1, 2014, without resolving red flags presented by the prescription, are sustained, and weighs in favor of revoking the Respondent's DEA registration. The substance of these allegations, however, will only be considered once.

B. Prescription Cocktails, Distance, Cash Payments, and Facially Invalid Prescriptions

(i.) Next, the Government alleged that from August 2014 to May 2015, the Pharmacy dispensed prescription cocktails (hydrocodone and alprazolam) to 25 different individuals, all of whom traveled unusual paths and distances to obtain their prescriptions for these controlled substances and to have them filled at the Pharmacy. ALJ–1, at 3–4, paras. 10, 10(b).

Government Exhibit 2 reveals that between August 8, 2014, and May 18, 2015, the Pharmacy filled prescriptions for hydrocodone and alprazolam on the same day for 25 different customers. GE–2, at 3–81, 86–132. Of the 27 customers identified in Government Exhibit 2, only patients M.W. and G.B. did not have prescriptions for both hydrocodone and alprazolam filled by the Pharmacy on the same day. *See id.* at 1, and 83–84.

(ii.) The Government also alleged that six individuals, J.W., H.J., M.H., A.S., K.S., and M.A., traveled more than 100 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. ALJ–1, at 3–4, para. 10, 10(b).

Based upon round-trip distance calculations, each of these Pharmacy customers, J.W., H.J., M.H., A.S., K.S., and M.A., traveled more than 100 miles to obtain their prescriptions and have them filled at the Pharmacy. FF 162, 167, 173. Of these six customers, K.S.

[49] In this regard the Respondent is like the student who neglected to turn in his homework. They both get no credit.

[50] The allegation alleges that this prescription was filled on August 1, 2014, which corresponds to the date on the fill sticker. *See* GE–2, at 1. Ms. Igwe acknowledged that the date on the fill sticker is not necessarily the date the customer picked up his or her prescription. FF 117. Ms. Igwe also testified that she had no reason to dispute that M.W. prescription was picked up on August 4, 2014. Tr. 576.

[*V] Text adjusted in response to Respondent's Exceptions.

[51] While Ms. Igwe was not concerned about the delay between the date M.W.'s prescription was written for pain and when it was picked up six days later, her reasoning was based on pure speculation that M.W. could have had other medication left over. Tr. 564–65. Had Ms. Igwe checked the PMP she would have learned that not to be the case. Further, Dr. Witte credibly testified that such a delay would call into question whether the patient needed pain medication and whether the prescription was for a legitimate medical purpose. *Id.* 192–93, 397.

[52] Even the Respondent's expert expressed some concern for cash payments in excess of $200. Tr. 692, 753.

had the shortest round trip of 101 miles, which would have taken 1 hour and 51 minutes to travel during light traffic. GE–3, at 128. Customer M.H. had the longest round-trip distance of 121 miles, which would have taken 2 hours and 19 minutes to travel with heavy traffic. GE–3, at 54.

(iii.) The Government next alleged that 17 individuals, J.S., C.J., SW, J.W.2, S.H., R.E., R.N., R.H., B.B., S.N., I.B., M.W.2, Y.S., R.H.2, C.D., A.K., and S.B., traveled between 70–100 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. ALJ–1, at 3–4, para. 10, 10(b).

Based upon round-trip distance calculations, each of these Pharmacy customers, J.S., C.J., SW, J.W.2, S.H., R.E., R.N., R.H., B.B., S.N., I.B., M.W.2, Y.S., R.H.2, C.D., A.K., and S.B., traveled between 70 to 100 miles to obtain their prescriptions and have them filled at the Pharmacy. FF 47, 151, 162, 167, 173. Of these 17 customers, K.S. had the shortest round trip of 76.6 miles, which would have taken 1 hour and 27 minutes to travel during light traffic. GE–3, at 74. Customer SW had the longest round-trip distance of 99.7 miles, which would have taken 1 hour and 54 minutes to travel in moderate traffic. GE–3, at 167.

(iv.) The Government alleged that four individuals, R.N., E.H., B.B., and T.H.,[53] traveled between 60–70 miles to obtain their prescriptions, have them filled at the Pharmacy, and return home. ALJ–1, at 3–4, para 10, 10(b).

Based upon round-trip distance calculations for Pharmacy customers R.N., E.H., B.B., and T.W., they each traveled between 60 to 70 miles to obtain their prescriptions and have them filled at the Pharmacy. FF 167, 173; GE–2, at 71–73; GE–3, at 45–48, 177–181. Of these four customers, R.N. had the shortest round trip of 64.8 miles, which would have taken 1 hour and 33 minutes to travel during heavy traffic. GE–3, at 104. Customer E.H. had the longest round-trip distance of 68.1 miles, which would have taken 1 hour and 22 minutes to travel in moderate traffic. GE–3, at 45.

(v.) Next, the Government alleged that all of the above customers sought to purchase their prescriptions with cash. ALJ–1, at 3–4, para. 10, 10(b).

Each of the Pharmacy's fill stickers shows a dollar amount preceded by the abbreviation ''Cpy''. *See, e.g.,* GE–2, at 1. That dollar amount is the amount the customer paid the Pharmacy for the prescription. FF 111. Thus, each prescription in Government Exhibit 2 was purchased with cash. In addition, when prescriptions of hydrocodone and alprazolam were purchased on the same day, as they frequently were, a customer would normally pay $179.99 for the hydrocodone and $59.99 for the alprazolam, for a total of $239.98 for the two prescriptions. FF 167, 173, 176; *see, e.g.,* GE–2, at 80–81.

(vi.) The Government also alleged that the prescriptions issued to M.W., J.S., J.W., C.J., S.N., J.W.2, S.H., H.J., E.H., A.S., R.E., K.S., S.B., R.H., T.W., I.B., M.W.2, Y.S., M.A., R.H.2, B.B., C.D., A.K., and R.N., were facially invalid and in violation of federal and state law because they lacked the patient's address and the practitioner's DEA number. ALJ–1, at 3–4, para. 10, 10(b).

Federal regulations require that, among other information, a prescription must contain the patient's address and the registration number of the prescriber. FF 68, 77; 21 CFR 1306.05(a). Texas law also requires that prescriptions contain the patient's address and the prescriber's DEA number. FF 68, 77; Tex. Health & Safety Code § 481.074(k). The prescriptions issued to M.W., J.S., J.W., C.J., S.N., J.W.2, S.H., H.J., E.H., A.S., R.E., K.S., S.B., R.H., T.W., I.B., M.W.2, Y.S., M.A., R.H.2, B.B., C.D., A.K., and R.N., did not contain the patient's address. GE–2, at 1, 3, 5, 6, 8, 12, 14, 16, 20, 24, 25, 30, 34, 37, 41, 46, 49, 52, 58, 62, 66, 67, 73, 77, 81, 88, 91, 96, 100, 104, 107, 111, 115, 119, 122, 124, 127. In addition, all of these prescriptions, except those issued to S.N. and S.B., and one of the prescriptions issued to B.B., did not contain the prescriber's DEA registration number. *See* GE–2, at 58, 62, 104. Therefore, all of these prescriptions were facially invalid under federal and Texas law.

It is also noted that Nurse Practitioner S.G. wrote cocktail prescriptions of hydrocodone and alprazolam for J.W. on August 29, 2014. *Id.* at 6. The prescription for alprazolam indicated that J.W. was to take one tablet twice a day. *Id.* Alprazolam, however, is normally taken more frequently than twice a day. Tr. 177. In addition, J.W. waited 14 days before filling these prescriptions. GE–2, at 6. Such a delay raises a question of whether the prescription is legitimate. Tr. 193. In addition to these two red flags, the two prescriptions combined constituted a drug cocktail. FF 54. The prescription was also written by one of the Prescribers, calling into question pattern prescribing, and J.W. paid $219.99 for the two prescriptions. GE–2, at 6. The Administrative Record does not document that Ms. Igwe resolved any of these issues before filling these two prescriptions for J.W. on September 12, 2014. FF 177.

The allegations addressed in subparagraphs (i.)–(vi.), discussed above, concern: Dispensing drug cocktails; the long and unusual routes that the Pharmacy customers traveled to obtain their prescriptions and have them filled; paying cash for prescriptions; and prescriptions that were facially invalid. Each of these concerns is a red flag. FF 63, 65, 68, 69, 70, 77; Tr. 391–92. When a prescription presents a red flag, a Texas pharmacist must resolve that red flag [and document the resolution] *W prior to filling the prescription. FF 77, 79. [ ] *X Neither the hard-copy prescriptions nor the patient profiles maintained by the Pharmacy contain any documentation showing that the Pharmacy resolved the above-noted red flags. GE–2; *see also* Tr. 216–17, 227, 236. Accordingly, the prescriptions addressed in subparagraph (i.)–(vi.) above were not dispensed in the usual course of the professional practice of pharmacy in the State of Texas. *Id.* at 217, 227, 236. Furthermore, the pharmacist who filled these prescriptions did not follow the minimum standard of the practice of pharmacy in the State of Texas, and did not satisfy the pharmacist's corresponding responsibility to ensure that prescriptions are issued for legitimate medical purposes. Tr. 217, 227–28, 236–37; *see* 21 CFR 1306.04(a).

The allegations contained in paragraphs 10 and 10(b) of the OSC are also included in the allegation that between August 2014 and May 2015 the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice and in contravention of the pharmacist's corresponding responsibility to ensure that prescriptions are dispensed for legitimate medical purposes. ALJ–1, at 2–3, paras. 3–7. The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Therefore, the allegations contained in paragraphs 10 and 10(b) of the OSC, that the Pharmacy filled numerous prescriptions without resolving red flags concerning drug cocktails, distance traveled, cash payments, and facially invalid prescriptions, are sustained, and weigh in favor of revoking the Respondent's

[53] The OSC alleged that ''T.H.'' had a round-trip distance of between 60–70 miles. ALJ–1, at 4, para. 10(b). There is no patient T.H. in Government Exhibit 2. There is, however, a patient T.W. addressed in Government Exhibit 2. GE–2, at 71–74. The round-trip distance for T.W. was 66.9 miles. GE–3, at 177.

*W Text adjusted in response to Respondent's Exceptions.

*X Text removed in response to Respondent's Exceptions.

registration. The substance of these allegations, however, will only be considered once.

C. Pattern Prescribing

The Government next alleged that many of the individuals mentioned in paragraph B, above, obtained their prescriptions from physicians who were engaged in pattern prescribing. ALJ–1, at 3–4, paras. 10, 10(c).

(i.) The Government alleged that between August 19, 2014 [54] and October 2, 2014, patients C.J., SW, J.W.2, S.H., and H.J. all received prescriptions for hydrocodone and alprazolam from Nurse Practitioner I.I., and they traveled long and unusual paths to obtain their prescriptions and have them filled at the Pharmacy. ALJ–1, at 3–4, paras. 10, 10(c).

In the month and a half between August 19, 2014, and October 2, 2014, the Pharmacy filled five identical cocktail prescriptions for customers, C.J., SW, J.W.2, S.H., and H.J. FF 162. The Pharmacy provided each of these customers with 90, 10 mg tablets of hydrocodone, and 60, 2 mg tablets of alprazolam based upon prescriptions they had received from I.I. FF 162. Of the 5 customers, S.H. traveled the shortest round-trip distance of 76 miles, taking 1 hour and 27 minutes in light traffic. GE–3, at 74. H.J. had the longest round trip of 105 miles, taking 1 hour and 56 minutes in light traffic. GE–3, at 84.

Further, by the time the Pharmacy filled the first of I.I.'s prescriptions for hydrocodone for 1 of these 5 customers, the Pharmacy had already filled 149 prescriptions for hydrocodone since July 7, 2014, and I.I. had written 43 of those prescriptions. GE–6, at 1–14. In addition, every one of those prescriptions had been written by one of the Prescribers. *Id.; see also* FF 118–21. Thus, by the time Ms. Igwe filled the prescription for hydrocodone for C.J. on August 19, 2014, a prescription written by I.I., Ms. Igwe would have had ample time to have identified the pattern of I.I.'s prescribing, and that of I.I.'s fellow Prescribers. FF 80–82, 84. Pattern prescribing is a red flag. FF 61. When presented with evidence of pattern prescribing, a Texas pharmacist should contact the prescriber, ask about the prescription's medical purpose, and then document that discussion. FF 80, 85 [ ].[*Y] While Ms. Igwe testified that she had discussions with providers whenever a new patient presented a prescription, those discussions are not documented as required by [the minimum standards of professional practice in Texas].[*Z]

In addition, prescribing hydrocodone and alprazolam together constitutes a cocktail of high-alert drugs. FF 55. When taken together, these two controlled substances can create a euphoric and addictive effect similar to a heroin high. FF 55. A drug cocktail is a red flag. FF 70. Here, on August 19, 2014, the Pharmacy was filling drug cocktail prescriptions written by I.I., but as noted earlier in this Recommended Decision, the Pharmacy had already been filling drug cocktails of hydrocodone and alprazolam, written by the same small group of Prescribers to which I.I. belonged. *See* FF 130, 140, 142–45, 155.

This allegation is also included in the allegation that between August 2014 and May 2015, the Pharmacy filled prescription cocktails of hydrocodone and alprazolam to 25 different individuals. ALJ–1, at 4, para. 10(b). The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Thus, while this allegation is *sustained,* and weighs in favor of revoking the Respondent's registration, its substance will only be considered once.

(ii.) The Government alleged that between November 14, 2014, and May 1, 2015, the Pharmacy filled 12 prescriptions for hydrocodone written by Dr. C.V. for patients A.S., R.E., K.S., G.B., R.H.2, A.K., R.N., and M.H.[55] All of these patients traveled long and unusual paths to obtain their prescriptions and have them filled. ALJ–1, at 3–4, paras. 10, 10(c).

The Pharmacy filled prescriptions for customers A.S., R.E., K.S., G.B., R.H.2, A.K., R.N., and M.H., all written by Dr. C.V. for 90, 10 mg tablets of hydrocodone. FF 167. Significantly, at the same time the Pharmacy filled these prescriptions, it also filled a prescription for 60, 2 mg tablets of alprazolam for each of these customers, written by one of the Prescribers other than Dr. C.V. FF 167. Of these 8 customers, G.B. traveled the shortest round-trip distance of 55.8 miles, taking 1 hour and 31 minutes in heavy traffic. GE–3, at 16. A.S. had the longest round trip of 111 miles, taking 2 hours in light traffic. GE–3, at 118.

Further, by the time the Pharmacy filled the first of Dr. C.V.'s prescriptions for hydrocodone for 1 of these 8 customers on November 14, 2014, the Pharmacy had already filled 379 prescriptions for hydrocodone since July 7, 2014, and Dr. C.V. had written 60 of those prescriptions. GE–6, at 1–14. Of the prescriptions Dr. C.V. wrote, the Pharmacy received 28 consecutive prescriptions from Dr. C.V. for hydrocodone between October 9 and October 23, 2014, and it had received 19 in the week before it received the prescription for patient R.E. on November 14, 2014. GE–6, at 29–31, 33–35. In addition, all but 11 of the 379 prescriptions had been written by one of the Prescribers. GE–6, at 1–35; *see also* FF 118–21. Thus, by the time Ms. Igwe filled the prescription for hydrocodone for R.E. on November 14, 2014, a prescription written by Dr. C.V., Ms. Igwe would have had ample time to identify the pattern of Dr. C.V.'s prescribing, and that of his fellow Prescribers. FF 80–82, 84. Pattern prescribing is a red flag. FF 61. When presented with evidence of pattern prescribing, a Texas pharmacist should contact the prescriber, ask about the prescription's medical purpose, and then document that discussion. FF 80, 85. While Ms. Igwe testified that she had discussions with providers whenever a new patient presented a prescription, those discussions are not documented as required by [the minimum standards of practice in Texas].[*AA]

With the exception of G.B.'s hydrocodone prescription,[56] filled by the Pharmacy on April 17, 2015, this allegation is included in the allegation that between August 2014 and May 2015 the Pharmacy filled prescription cocktails of hydrocodone and alprazolam to 25 different individuals who had to travel long and/or unusual routes to obtain and fill their prescriptions. ALJ–1, at 4, para. 10(b). It is also included in the allegation that the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). ALJ–1, at 2, para. 3. The Government has not advanced any theory as to why this same allegation should be considered three times. *See* ALJ–35. Thus, while this allegation is *sustained,* and weighs in favor of

[54] The first two prescriptions written by Nurse Practitioner I.I. were written on August 18, 2014, rather than August 19. GE–2, at 8, 12.

[*Y] Text removed in response to Respondent's Exceptions.

[*Z] Text adjusted in response to Respondent's Exceptions.

[55] Actually, the Pharmacy filled 13 prescriptions for these 8 customers, plus a prescription for an additional customer, M.A., all of which were written by Dr. C.V. FF 167.

[*AA] Text adjusted in response to Respondent's Exceptions.

[56] G.B. is not mentioned in paragraph 10(b) of the OSC. ALJ–1, at 4.

revoking the Respondent's registration, its substance will only be considered once. The portion of this allegation that alleges that the Pharmacy filled a hydrocodone prescription for G.B., written by Dr. C.V., is included in the allegation that the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). ALJ–1, at 2, para. 3. The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Thus, while the allegation concerning the hydrocodone prescription for G.B. is *sustained,* and weighs in favor of revoking the Respondent's registration, its substance will only be considered once.

(iii.) Next, the Government alleged that the Pharmacy also filled prescription cocktails (hydrocodone and alprazolam), written by Dr. C.V., for patients M.A., R.H.2, and A.K. on April 17, 2015, and May 1, 2015, respectively. ALJ–1, at 3–4, paras. 10, 10(c).

As noted above, Dr. C.V. wrote prescriptions for 90, 10 mg tablets of hydrocodone for M.A., R.H.2, and A.K. FF 167. The Pharmacy also filled prescriptions of 60, 2 mg tablets of alprazolam for these three customers. *See supra* notes 21–23. Dr. C.V., however, did not write prescriptions for alprazolam for those three customers. While the Pharmacy's fill stickers for the alprazolam that those three customers received indicates that Dr. C.V. was the prescribing doctor, the prescriptions themselves clearly show that Dr. C.V. did not write those prescriptions. FF 167; *see supra* notes 21–23; GE–2, at 96, 100, 115. Nurse Practitioner L.R. wrote the prescription for alprazolam for M.A. GE–2, at 96. Physician's Assistant C.Z. wrote the prescriptions for alprazolam for R.H.2 and A.K.[57]

The significance of the alprazolam prescriptions, however, does not depend on the prescriber. Rather, the significance is that the Pharmacy filled the alprazolam prescriptions for M.A., R.H.2, and A.K., as well as for all the other customers who received prescriptions for hydrocodone from Dr. C.V., at the same time that it also filled hydrocodone prescriptions for them. In addition, the Pharmacy filled all of these prescriptions even though the customers presented prescriptions for hydrocodone written by Dr. C.V. at the same time that they presented prescriptions for alprazolam written by another one of the other Prescribers. FF 167.

This allegation is included in the allegation that between August 2014 and May 2015, the Pharmacy filled prescription cocktails of hydrocodone and alprazolam to 25 different individuals. ALJ–1, at 4, para. 10(b). The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Thus, to the extent that this allegation asserts that the Pharmacy filled prescription cocktails for these three identified patients, though the hydrocodone was written by Dr. C.V. and the alprazolam was written by another Prescriber, it is *sustained,* and weighs in favor of revoking the Respondent's registration. The allegation's substance, however, will only be considered once.

(iv.) The Government alleged that between January 13, 2015, and May 11, 2015, the Pharmacy dispensed controlled substances pursuant to ''pattern-style'' prescriptions issued by Dr. NE On 14 different occasions, the Pharmacy dispensed 90, 10 mg tablets of hydrocodone to 11 different customers. ALJ–1, at 3–4, para 10, 10(c).

The Pharmacy filled 15 prescriptions for 11 customers, A.S., R.N., R.E., B.B., S.B., S.N., T.W., I.B., M.W.2, Y.S., and C.D., between January 24, 2015 and May 18, 2015. FF 173; GE–2, at 22–23, 89–90. These prescriptions were written by Dr. NE for 90, 10 mg tablets of hydrocodone. FF 173. Significantly, at the same time the Pharmacy filled these prescriptions, it also filled a prescription for 60, 2 mg tablets of alprazolam for each of these customers, written by either Dr. NE or one of the other Prescribers. FF 173. Of the 11 customers, T.W. traveled the shortest round-trip distance of 66.9 miles, taking 1 hour and 23 minutes in moderate traffic. GE–3, at 177. A.S. had the longest round trip of 104 miles, taking 1 hour and 54 minutes in light traffic. GE–3, at 113. Every prescription was purchased with cash. FF 173. The price for hydrocodone and alprazolam together totaled $239.98. *Id.*

Further, by the time the Pharmacy filled the first of Dr. NE's prescriptions for hydrocodone for 1 of these 11 customers, which was A.S. on January 26, 2015, GE–6, at 52, the Pharmacy had already filled 563 prescriptions for hydrocodone since July 7, 2014, and Dr. NE had written 60 of those prescriptions. GE–6, at 1–52. Of the prescriptions Dr. NE wrote, the Pharmacy received seven consecutive prescriptions from Dr. NE for hydrocodone on November 5, 2014, four consecutive prescriptions from Dr. NE for hydrocodone on November 23, 2014, and six consecutive prescriptions from Dr. NE for hydrocodone on December 30, 2014. GE–6, at 32–33, 37, 44. In addition, all but 18 of the 563 prescriptions had been written by one of the Prescribers. GE–6, at 1–52; *see also* FF 118–21. Thus, by the time Ms. Igwe filled the prescription for hydrocodone for A.S. on January 26, 2015, a prescription written by Dr. NE, Ms. Igwe would have had ample time to identify the pattern of Dr. NE's prescribing, and that of her fellow Prescribers. FF 80–82, 84. Pattern prescribing is a red flag. FF 61. When presented with evidence of pattern prescribing, a Texas pharmacist should contact the prescriber, ask about the prescription's medical purpose, and then document that discussion. FF 80, 85. While Ms. Igwe testified that she had discussions with providers whenever a new patient presented a prescription, those discussions are not documented as required by [the minimum standards of practice in Texas.] [*BB]

This allegation is included in the allegation that between August 2014 and May 2015 the Pharmacy filled prescription cocktails of hydrocodone and alprazolam to 25 different individuals. ALJ–1, at 4, para. 10(b). The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Thus, while this allegation is *sustained,* and weighs in favor of revoking the Respondent's registration, its substance will only be considered once.

(v.) The Government next alleged that on 8 different occasions, the Pharmacy filled identical prescription cocktails written by Dr. NE consisting of 90, 10 mg tablets of hydrocodone and 60, 2 mg tablets of alprazolam. Identical prescription cocktails were dispensed to both I.B. and T.W. on April 10, 2015, and to B.B. and C.D. on April 23, 2015. ALJ–1, at 3–4, para. 10, 10(c).

The Pharmacy filled drug cocktail prescriptions of 90, 10 mg tablets of hydrocodone and 60, 2 mg tablets of alprazolam written by Dr. NE seven different times. FF 173. These prescriptions were filled for customers B.B., S.B., S.N., T.W., Y.S., R.N., and again for B.B. FF 173; GE–2, at 56–58, 60–62, 71–73, 86–88, 102–04, 105–07, 125–27. While the Pharmacy also filled identical cocktail prescriptions for I.B. and T.W. on April 10, 2015, and again for B.B. and C.D. on April 23, 2015, Dr.

[57] *Compare* known C.Z. signatures at GE–2, at 52, 122–23, *with* signatures on the R.H.2 and A.K. prescriptions at GE–2, at 100, 115.

[*BB] Text adjusted in response to Respondent's Exceptions.

NE did not write all of the prescriptions for alprazolam. Nurse Practitioner S.G. wrote the prescriptions for alprazolam for I.B. and C.D. GE–2, at 77, 111. The Pharmacy fill labels for those prescriptions improperly indicate, however, that those prescriptions were written by Dr. NE *Id.*

As noted earlier, the significance of the Pharmacy filling prescriptions for alprazolam, however, does not depend on the prescriber. Rather, the significance is that the Pharmacy filled a prescription cocktail of alprazolam and hydrocodone for I.B., T.W., B.B., and C.D., as well as for all the other customers above who received prescriptions for hydrocodone from Dr. NE In addition, the Pharmacy filled all of these prescriptions even though the customers presented prescriptions for hydrocodone written by Dr. NE, while the prescriptions for alprazolam were written by a different one of the Prescribers. Further, as noted above, all of these prescriptions exhibited the red flags of pattern prescribing, the customers all traveled long or unusual routes to obtain their prescriptions and have them filled, and all of the prescriptions were purchased with cash.

This allegation is included in the allegation that between August 2014 and May 2015, the Pharmacy filled prescription cocktails of hydrocodone and alprazolam to 25 different individuals. ALJ–1, at 4, para. 10(b). The Government has not advanced any theory as to why this same allegation should be considered twice. *See* ALJ–35. Thus, to the extent that Dr. NE only wrote seven prescription cocktails of hydrocodone and alprazolam, and wrote only one such cocktail prescription on April 10, 2015, and one on April 23, 2015, this allegation is *sustained,* and weighs in favor of revoking the Respondent's registration. The substance of the allegation, however, will only be considered once.

Therefore, the allegations contained in paragraphs 10 and 10(c) of the OSC, that the Pharmacy filled numerous prescriptions without resolving red flags concerning drug cocktails, distance traveled, cash payments, and facially invalid prescriptions, are *sustained,* and weigh in favor of revoking the Respondent's registration. With one exception, these sustained allegations are all included in the allegations contained in paragraphs 10 and 10(b) of the OSC, and with that one exception will not be considered as separate allegations in determining whether the Respondent's registration should be revoked. The portion of this allegation that alleged, in paragraph 10(c) of the OSC, that the Pharmacy filled a prescription for G.B. for hydrocodone, written by Dr. C.V., is *sustained,* but it is included in the allegation that the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a), ALJ–1, at 2, para. 3, and it will not be considered twice.

(vi.) The Government's next allegation is that on April 17, 2015, the Pharmacy filled a hydrocodone prescription for G.B., who had traveled an unusual path and distance of more than 75 miles to obtain her prescription and have it filled at the Pharmacy, and then return home. ALJ–1, at 5, para. 10, 10(d).

Government Exhibit 2 documents that the Pharmacy filled a prescription for G.B. for 90, 10 mg tablets of hydrocodone on April 17, 2015. GE–2, at 84. The prescription was written by Dr. C.V. one day earlier. GE–2, at 83. This allegation is included in the allegation that the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). ALJ–1, at 2, para. 3. It is also included in the allegation that between November 14, 2014 and May 1, 2015, the Pharmacy filled 12 [58] prescriptions for hydrocodone written by Dr. C.V. ALJ–1, at 4, para. 10(c). Again, the Government has not advanced any theory as to why this same allegation should be considered three times. *See* ALJ–35. Thus, while the allegation contained in paragraph 10(d) of the OSC is *sustained,* and weighs in favor of revoking the Respondent's registration, the allegation's substance will only be considered once.

Recordkeeping Violation

Finally, the Government alleged that a DEA audit of the Pharmacy's 10 mg hydrocodone, covering the period of September 25, 2013, through June 18, 2015, revealed a shortage of 47,183 dosage units. Because the Controlled Substances Act requires the maintenance of ''complete and accurate'' inventories, as well as a ''complete accurate record of each substance . . . received, sold, delivered or otherwise disposed of,'' this shortage violated 21 U.S.C. 827(a). ALJ–1, at 5, para. 13.

As noted above, the CSA mandates that ''[e]very registrant . . . shall maintain, on a current basis, a complete and accurate record of each [ ] substance manufactured, received, sold, delivered, or otherwise disposed of . . . .'' 21 U.S.C. 827(a)(3). On June 18, 2015, DEA investigators conducted an inspection of the Pharmacy, and asked Ms. Igwe to produce a copy of the Pharmacy's dispensing history of hydrocodone. FF 15, 23. In response, Ms. Igwe gave the inspectors a report of the Pharmacy's hydrocodone dispensing history, contained in Government Exhibit 6, with a date range of October 23, 2013 to June 18, 2015. FF 24–25. Following the inspection, and using the report provided by Ms. Igwe, DI 1 conducted an audit of the Pharmacy's hydrocodone. FF 36; Tr. 47–48. DI 1's audit revealed that the Pharmacy was short 47,183 tablets of hydrocodone. FF 37.

Government Exhibit 6 clearly does not report all of the hydrocodone that the Pharmacy dispensed. FF 41. After the inspection, Ms. Igwe discovered that she had not provided the DEA inspectors with a complete listing of the hydrocodone the Pharmacy had dispensed. FF 26–27. At the hearing, the Respondent produced Respondent's Exhibit C for the first time, which Ms. Igwe claimed is the complete dispensing report. FF 27, 43–44. Although Ms. Igwe testified that she had provided Respondent's Exhibit C to an attorney so that he might provide it to the DEA, there is no evidence the DEA ever received it. FF 27, 43–44. At the hearing, both Ms. Igwe and Mr. Litman testified that if Respondent's Exhibit C was considered during the audits of the Pharmacy's hydrocodone, there would have been no shortage. Tr. 472–73, 730. Ms. Igwe, however, did not know if her own audit showed an overage. *Id.* at 605.

The Administrative Record reveals several deficiencies concerning the Respondent's records. First, the Respondent's hydrocodone dispensing log was not ''readily retrievable'' as is required under 21 U.S.C. 827. Second, the ''complete'' dispensing log which Ms. Igwe allegedly gave to DEA sometime after the inspection does not comply with DEA regulations. Lastly, even a manual count of the Respondent's ''complete'' dispensing log reveals a substantial overage.

Although the Pharmacy takes the position that it produced ''complete and accurate'' records after the inspection, these records were not ''readily retrievable'' as is required by the CSA and DEA regulations. [The regulatory definition of ''readily retrievable'' calls for locating the records ''in a reasonable time.'' 21 CFR 1300.01(b). In *Edmund Chein, M.D.,* the Agency stated ''what

[58] *See supra* notes 45 and 56.

constitutes 'a reasonable time' necessarily depends on the circumstances'' but that ''under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request.'' 72 FR 6580, 6593 (2007), *pet. for rev. denied, Chein* v. *Drug Enforcement Admin.,* 533 F.3d 828, 832 n.6 (D.C. Cir 2008), *cert. denied,* 555 U.S. 1139 (2009). During the hearing, Ms. Igwe was unable to specify the date on which she gave the ''complete'' dispensing log to her then-attorney to forward to DEA, but it is safe to say it was at least several days after the inspection. *See* Tr. 466–69. Moreover, there is nothing in the record establishing that DEA ever received the log until it was exchanged in the course of these proceedings.[59] Tr. 549–50. For these reasons, the Respondent violated its duty to maintain records that were ''readily retrievable.'' 21 U.S.C. 827(b); 21 CFR 1304.04(a), 1304.04(h)(1), (3); *see Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR at 10901, *aff'd Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x 724, 730 (2019) (finding that producing records as an exhibit for the hearing did not comply with the ''readily retrievable'' requirement of the regulation).] [*CC]

Additionally, not only were the Pharmacy's dispensing records produced significantly late, but they also failed to include required information. This was the situation in *Chein,* where the registrant's dispensing records, produced after a delay of several hours, lacked information required by DEA regulations. 72 FR at 6593. The same has occurred here to the extent that Respondent Exhibit C, the Pharmacy's ''complete'' hydrocodone dispensing report, is missing the patient's addresses and the dispensing pharmacist's initials, in violation of 21 CFR 1304.22(c). Significantly, the dispensing log Ms. Igwe gave to investigators at the time of the inspection *does contain* this required information. 21 CFR 1304.22(c); GE–6; RE–G. It is also noteworthy that the ''complete'' dispensing log's format is strikingly different than the original dispensing log printed during the inspection. *Compare* RE–C *with* GE–6 and RE–G. Additionally, the lack of any date or date range on the ''complete'' dispensing log makes it difficult, if not impossible, to ascertain whether the document is ''complete and accurate.'' 21 U.S.C. 827(a)(3); RE–C; Tr. 551.

Further, a manual count of the quantities listed in the ''complete'' dispensing log revealed an overage, itself a violation of the CSA and DEA regulations, albeit different than that alleged in the OSC. Respondent Exhibit C is broken into four sections separated by green pages. RE–C, at 1, 2, 3–30, 31–43; Tr. 470–71, 603; FF 27–28. The third section represents the same information in Government Exhibit 6 that Ms. Igwe gave to investigators during the inspection and that DI 1 used to conduct an audit. RE–C, at 3–30; GE–6, at 1–85; Tr. 47–48. The first, second, and fourth sections contain additional dispensing information not contained in the report that DI 1 used to conduct his audit. RE–C, at 1–2, 31–43. The information in the third column from the left is the quantity of hydrocodone dispensed. *Id.* A manual count of the quantity dispensed in the first, second, and fourth sections of Respondent Exhibit C revealed a total of 48,288 dosage units of hydrocodone. *Id.* The Government alleged that the Respondent's hydrocodone shortage was 47,183. ALJ–1, at 5, para. 13.

Applying the 48,288 units counted in Respondent Exhibit C to DI 1's audit computation produces an overage of 1,105 units. GE–7, at 1. The computation report shows that DI 1 reached the 47,183 figure by subtracting ''distributions in period'' (90,209) and ''closing inventory'' (3,908) from ''purchases in period'' (141,300). GE–7, at 1. The difference between the shortage calculated by DI 1 (47,183) and the total derived from a count of Respondent Exhibit C (48,288) is +1,105.[60] If DI 1 had the information in Respondent Exhibit C when he conducted the audit, he would have found an overage of hydrocodone instead of a shortage. *Cf.* Tr. 76. An overage of a thousand tablets of hydrocodone, however, is still sufficient circumstantial evidence that the Pharmacy failed to maintain complete and accurate records. *See Superior Pharmacy I & Superior Pharmacy II,* 81 FR at 31,337 (finding recordkeeping violation where audit revealed overage of about 4,000 dosage units).

Accordingly, the Government's allegation contained in paragraph 13 of the OSC that the Pharmacy failed to maintain ''complete and accurate'' records in violation of 21 U.S.C. 827(a)(3) is *sustained,* and weighs in favor of revoking the Pharmacy's registration.

Discussion and Conclusions of Law

I have sustained, with minor variations, [the overwhelming majority][*DD] of the Government's allegations contained in the OSC. Specifically, I find that between August 2014 and May 2015, the Pharmacy filled 75 controlled substance prescriptions outside the usual course of pharmacy practice, in violation of 21 CFR 1306.06, and in contravention of the Pharmacy's ''corresponding responsibility'' under 21 CFR 1306.04(a). The Pharmacy did so by repeatedly filling controlled substance prescriptions that contained red flags of diversion and/or abuse without addressing or resolving those red flags. The Pharmacy's conduct in doing so violated 21 U.S.C. 823(f)(4); Tex. Health & Safety Code § 481.070-.075; and Tex. Health & Safety Code § 481.128; [ ] [*EE]. These allegations are contained in paragraphs [3 and 6] [*FF] of the OSC. ALJ–1, at 2–3.[*GG]

I also find that all of the specific allegations contained in paragraphs 10 and 10(a)–(d) of the OSC are included in the general allegation that the Pharmacy violated 21 CFR 1306.04(a) and 21 CFR 1306.06 when it filled 75 prescriptions between August 2014 and May 2015. ALJ–1, at 2, para. 3. Thus, while the allegations contained in paragraphs 10 and 10(a)–(d) of the OSC are sustained, the substance of those allegations will not be considered more than once in assessing whether the

[59] *See supra* note 50.

[*CC] Text adjusted for clarity.

[60] This overage amount would be different, or reduced entirely, if the on-hand quantity was closer to 1,200 tablets as Ms. Igwe claimed at one point in the hearing. Tr. 602–03. At first, Ms. Igwe was unable to recall the quantity on the shelf: ''I don't remember what it [was] without looking.'' Tr. 602. When I asked if the on-hand quantity was 1,200, as stated in her Prehearing Statement, she agreed that was the correct figure. Tr. 602. She also stated early in her testimony that Respondent Exhibit C showed that her inventory was accurate in that all the hydrocodone she purchased and dispensed was accounted for. Tr. 472. When pressed further regarding the accuracy of her hydrocodone records, her testimony waivered. Tr. 605. I asked if there was an overage and she stated, ''I can't really say yes or no to that . . . .'' Tr. 605. Overall, this part of Ms. Igwe's testimony created the impression that she was unsure about the on-hand quantity of hydrocodone on the day of the inspection and whether her inventory was in fact completely accurate. Further, Mr. Litman testified that there was no way of knowing whether the information contained in Respondent's Exhibit C was created prior to the DEA audit. Tr. 723–25. For that reason, I give more weight to the on-hand quantity counted on the day of the inspection contained in Government Exhibit 7—3,908 tablets of hydrocodone on-hand—than I do to Ms. Igwe's testimony that the Pharmacy had 1,200 hydrocodone pills on the shelves. GE–7, at 1.

[*DD] Text adjusted in response to Respondent's Exceptions.

[*EE] Text removed in response to Respondent's Exceptions.

[*FF] Text removed in response to Respondent's Exceptions.

[*GG] For the reasons given, *supra,* in the section on Respondent's Exceptions, the Government's allegation from paragraph 7 of the OSC that Respondent violation 22 Tex. Admin. Code § 291.33(c)(2) is not sustained.

Government has presented a *prima facie* case for revocation of the Pharmacy's COR. Stated differently, the prescriptions discussed in paragraphs 10 and 10(a)–(d) are subsumed within the allegation in paragraph 3.

Lastly, I have sustained the allegation contained in paragraph 13 of the OSC, alleging that the Pharmacy violated 21 U.S.C. 827(a) by failing to maintain accurate records. The records in question in this case were the Pharmacy's receipt and dispensing records for hydrocodone. An audit of the records the Pharmacy produced in response to a DEA inspection warrant revealed that the Pharmacy could not account for a significant portion of the hydrocodone it had received when called upon to do so.

The preponderance of evidence clearly establishes that the Pharmacy violated its corresponding responsibility by dispensing controlled substances outside the normal course of professional practice. Beginning in August 2014 and continuing into May 2015, the Pharmacy repeatedly filled 75 prescriptions from the Prescribers, who over and over again prescribed the same medications and usually in the same dosages, strengths, and quantities. Frequently, too, the patients would present with prescriptions for drug cocktails, where the hydrocodone prescription was written by one of the Prescribers and the alprazolam was written by a different Prescriber. This is a well-known behavior of those seeking to hide the true reason they are obtaining drug cocktails. Most of the prescriptions were issued in a manner that should have given rise to concerns of the therapeutic value of the prescription. [The minimum standard of the practice of pharmacy in Texas requires pharmacists to have consultations with prescribers when there are concerns about the medical legitimacy of a prescription and then to document that consultation. FF 90.] [*HH] In this case there are no records that document any such consultations. FF 177.

The Government's expert testified that an overriding concern she had concerning the prescriptions at issue in this case was that of pattern prescribing and the lack of individualization of treatment. Tr. 171, 244, 260, 296, 317, 333, 335, 358–59; FF 61–62. Unquestionably, it is easier to identify patterns in retrospect. In addition, DEA has stated that ''two prescriptions do not establish pattern prescribing.'' *Superior Pharmacy,* 81 FR at 31325 n.27. But this is not a case of only two similar prescriptions. This is a case of the Prescribers writing essentially the same prescriptions to various patients who had their prescriptions filled by the same pharmacist, Ms. Igwe, over an extended period of time. In fact, apparently out of the blue, the Pharmacy, a small pharmacy north of Dallas, started receiving prescriptions written by the Prescribers at the Redbird clinic in January or February of 2014. FF 11. The Redbird clinic was located 31 miles from the Pharmacy. GE–12, at 3. In addition, many of the prescriptions were sent directly to the Pharmacy by the Prescribers, rather than giving the patient the option of going to a pharmacy possibly more convenient for the patient. FF 10, 127.

The Respondent has attempted to make much out of the fact that Government Exhibit 2 contains prescriptions of less than 30 patients, while the Prescribers wrote ''over a thousand scripts.'' Tr. 368; *see also* Tr. 289. While true that less than 30 patients is a small percentage of the prescriptions written by the Prescribers, I concur with Dr. Witte's assessment that ''if [she] reviewed a thousand [prescriptions], more than likely there would be more than 26 that had some of the same similarities'' based on the patterns she observed. Tr. 370–71. Indeed, a review of Government Exhibit 6 reveals many of the same similarities. That exhibit shows that of the 927 prescriptions for hydrocodone the Pharmacy filled between July 7, 2014 and May 21, 2015, all but 25 were written by one of the Prescribers. Respondent Exhibit C reveals even more prescriptions for hydrocodone written by one of the Prescribers. *See supra* note 46. In fact, at one point Ms. Igwe filled 28 consecutive prescriptions for hydrocodone written by Dr. C.V. and at another time she filled 23 consecutive prescriptions for hydrocodone written by Dr. NE GE–6, at 29–31, 83–85. In the face of such repetitive prescriptions, Ms. Igwe simply assumed ''that that's what the doctor preferred . . . .'' Tr. 595. While she did testify that she would call the prescriber the first time a patient presented with a prescription for a controlled substance ''if [she] was concerned,'' she provided no documentation of those calls. Tr. 546–47, 595; FF 177. With close to the thousand prescriptions, documented in Government Exhibit 6, written by the Prescribers, beginning in January or February 2014, and extending until May 2015, Ms. Igwe should have easily recognized pattern prescribing.[*II] Her failure to do so, her unwillingness to acknowledge the pattern, [demonstrates willful blindness to the high probability] [*JJ] that many of the prescriptions she filled lacked a legitimate medical purpose.

Dr. Witte also addressed the red flag of cash payments with respect to many of the prescriptions involved in this case. *See, e.g.,* Tr. 172, 223, 238. Here, the Administrative Record supports a finding that most of the prescriptions involved a large quantity of controlled substances of both hydrocodone and alprazolam. FF 47, 50. A reasonable pharmacist should know paying cash for a large quantity of controlled substances raises a red flag, *see Jones Total Health Care Pharmacy,* 81 FR at 79194; however, there is no evidence that the Pharmacy's customers were paying exorbitant prices for their prescriptions. Nevertheless, paying for a prescription in cash is ''the preferred payment method for illegitimate prescriptions,'' because it is not traceable. *Masters Pharm.,* 861 F.3d at 220. DEA has noted, however, that absent other signs of diversion, prices in the range of $25 to $220 may be insufficient to prove that a pharmacist violated his or her corresponding responsibility. *Hills Pharmacy,* 81 FR at 49839 n.39.

Here, numerous patients paid $239.98 upon picking up prescriptions for both alprazolam and hydrocodone at the same time. Tr. 498; FF 167, 173. While these fees were not exorbitant, the Pharmacy made between $154.00 and $161.00 profit when a customer paid $179.99 for an order of hydrocodone. Tr. 498; GE–6, at 45, 54. Furthermore, most insurance plans cover hydrocodone. FF 39. Such a heavy profit margin per sale could certainly be an incentive to turn a blind eye to illegitimate prescriptions, particularly when they were so numerous. Nevertheless, were cash payments the only red flag involved in the prescriptions in this case, I would not sustain a violation of the Pharmacy's duty to resolve that red flag. As noted, however, cash purchases were not the only red flags that Ms. Igwe should have readily identified.

Dr. Witte also testified that the distance and route that several

[*HH] Text adjusted in response to Respondent's Exceptions.

[*II] The Government's allegations of unlawful dispensing were limited to the prescriptions listed in the OSC that Respondent dispensed between August 2014 and May 2015. Evidence of additional prescriptions Respondent dispensed is relevant in this matter only to the extent that it supports findings of violations in the subject prescriptions or rebuts Respondent's Exceptions. I have not considered the evidence of additional prescriptions from the Prescribers as evidence of further violations for consideration under Factors 2 and 4.

[*JJ] Text adjusted clarity.

customers took to obtain and then fill their prescriptions created a red flag. FF 62, 63. Additionally, even Texas regulations include the distance a patient traveled as one factor pharmacists should be aware of before dispensing a controlled substance. 22 Tex. Admin. Code § 291.29(c)(4). The distances that most of the Pharmacy customers traveled are detailed in Government Exhibit 3, and range from 64 miles to 121 miles. GE–3, at 54, 104. More telling than the miles, however, are the routes these customers would have traveled.[61] While Ms. Igwe might not have known the actual routes a customer took to arrive at the Pharmacy, from having been in the Dallas/Fort Worth area since at least 2006, Tr. 445–46, she should have had an appreciation for the distances and traffic involved. Even a short distance, such as 30–40 miles, may be a concern where the route involves ''a lot of stop lights'' and traffic, making a relatively short distance appear suspicious given the added inconvenience. *Hills Pharmacy,* 81 FR at 49826. Given the facts in this case, particularly the paths the customers would have taken in a metropolitan environment, at a minimum, Ms. Igwe should have made inquiry of the six customers whose round trip distances exceeded 100 miles, J.W., H.J., M.H., A.S., K.S., and M.A. Ms. Igwe's failure to do so, and her failure during these proceedings to acknowledge that she should have, demonstrates willful blindness to the [high probability] *KK that many of the prescriptions she filled lacked a legitimate medical purpose.

With respect to the Pharmacy's recordkeeping violations, the Government has established by a preponderance of the evidence that the Pharmacy failed to produce a complete dispensing log for the hydrocodone it dispensed between the date the Pharmacy opened and June 18, 2015. FF 22, 24–28, 44. As a result of this poor recordkeeping, when the DEA conducted an audit of the Pharmacy's hydrocodone, the Pharmacy had a shortage of over 47,000 tablets of hydrocodone. FF 37. Although the Respondent eventually produced Respondent Exhibit C, which Ms. Igwe testified was the Pharmacy's complete dispensing log, Tr. 467–71, it does not comply with DEA's requirements for a dispensing log. 21 CFR 1304.22(c); *Chein,* 72 FR at 6593. Further, even using the data contained in Respondent Exhibit C, the Pharmacy's inventory of hydrocodone does not balance out. The Pharmacy's recordkeeping shortcomings reinforce the DEA's position that strict adherence to inventory requirements is crucial so that DEA can ''closely monitor the flow of controlled substances'' and effectively combat diversion. *United States* v. *Blanton,* 730 F.2d 1425, 1428 (11th Cir. 1984).

Prima Facie Showing and Balancing

Factors Two and Four strongly weigh in favor of revoking the Pharmacy's COR. Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that the Pharmacy's registration is inconsistent with the public interest.

After the Government presents a *prima facie* case for revocation, the Respondent has the burden of production to present ''sufficient mitigating evidence'' to show why it can be entrusted with a DEA registration. *See Medicine Shoppe—Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the Respondent must both accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734–35 (2009).

The Respondent may accept responsibility by providing evidence of its remorse, its efforts at rehabilitation, and its recognition of the severity of its misconduct. *See Robert A. Leslie, M.D.,* 68 FR 15227, 15228 (2003). To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 FR 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *Wesley G. Harline, M.D.,* 65 FR 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct, *Jeffrey Patrick Gunderson, M.D.,* 61 FR 26208, 26211 (1996), and may be required to acknowledge the scope of its misconduct. *Arvinder Singh, M.D.,* 81 FR 8247, 8250–51 (2016). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013) (citation omitted).

There is nothing in the Administrative Record that suggests the Pharmacy has accepted responsibility for its actions. During her testimony, Ms. Igwe took no responsibility. Tr. 567. Further, a review of the Respondent's Proposed Findings and the Respondent's Brief gives no hint of acceptance of responsibility. *See* ALJ–36–37.

Because I have determined that the Government has met its *prima facie* burden, and that the Pharmacy has not accepted responsibility, I must next determine whether it is consistent with the public interest for the Pharmacy to maintain its DEA registration. When considering whether a registrant's continued registration is consistent with the public interest, the ALJ must consider both the egregiousness of the registrant's violations and the DEA's interest in deterring future misconduct by both the registrant as well as other registrants. *Ruben,* 78 FR at 38364; *see also Richard J. Settles, D.O.,* 81 FR 64940, 64,945 n.17 (2016) (''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009))).

Here, I find that both aspects of the misconduct proven in the Administrative Record are egregious and support the revocation of the Pharmacy's registration. First, time and again, Ms. Igwe filled prescriptions that ought not have been filled without the resolution of red flags. Significantly, this case started with the DEA investigating a pill mill. Tr. 31. Over a period of eight to nine months, Ms. Igwe filled prescriptions for a small group of medical practitioners, who wrote essentially identical prescriptions, including drug cocktail prescriptions involving hydrocodone and alprazolam, in such a manner that a preponderance of evidence establishes that those practitioners were engaged in pattern prescribing. Such lack of individualized dosing of these two highly-abused controlled substances [should have indicated to a pharmacist following the minimum standards of practice in Texas that there was a high probability that the medical practitioners were operating a controlled substance pill mill. Tr. 258–261;] *LL *Jones Total Healthcare Pharmacy,* 81 FR at 79195. This evidence of pattern prescribing by the Prescribers circumstantially establishes

[61] While Respondent's counsel argued at the hearing that the customers might not live where the addresses on the fill stickers say they do, those are the addresses the Pharmacy was on notice of concerning where those customers lived. Tr. 377–79.

*KK Text adjusted for clarity.

*LL Text adjusted to add references and citations to Dr. Witte's testimony.

that the Pharmacy knew, or should have known, that many of the Prescribers' prescriptions lacked a legitimate medical purpose. In addition to the pattern prescribing, the prescriptions raised other numerous red flags, to include: distance and route traveled; drug cocktails; multiple prescribers for controlled substances; suboptimal dosing; filling prescriptions on consecutive days to avoid filling drug cocktails on the same day; as well as some concern about cash payments.

Second, I find that the Pharmacy did not take its recordkeeping responsibilities seriously. The Pharmacy's failure to produce a complete dispensing record clearly prevented the DEA from being able to ''closely monitor the flow of controlled substances'' flowing in and out of the Pharmacy and to effectively combat diversion. *See United States* v. *Blanton,* 730 F.2d at 1428. In response, the Pharmacy subsequently produced a document that did not meet the requirements of a dispensing log, and asserted that all was well. Such a feeble response exacerbates the Pharmacy's recordkeeping failure.

I further find that the DEA's interest in deterring future misconduct by the Pharmacy, as well as by other pharmacies, supports revocation of the Pharmacy's registration.

Recommendation

In this case, the Government has established a *prima facie* case for revocation of the Pharmacy's Certificate of Registration. It did so by proving by a preponderance of the evidence that the Pharmacy: Repeatedly violated its corresponding responsibility [and acted outside the usual course of professional practice between August 2014 and May 2015 by filling 75 prescriptions that contained red flags of diversion and/or abuse, without addressing or resolving those red flags; and by failing to properly produce and maintain records of the controlled substances for which the Pharmacy was accountable.] *MM

*MM Text adjusted for clarity.

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, and other responsibilities of a registrant. In addition, the Pharmacy presented no evidence of mitigation or remediation.

Therefore, based upon my review of the entire Administrative Record, I recommend that the Certificate of Registration of The Pharmacy Place, Certificate of Registration Number FT4134805, be *revoked*. I further recommend that any pending application for renewal or modification of the Certificate of Registration of The Pharmacy Place be *denied*.

Dated: February 13, 2018.

Charles Wm. Dorman,

U.S. Administrative Law Judge

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