ACTION: Notice.

SUMMARY: This notice publishes the approval of the Gaming Compact (Compact) between the Standing Rock Sioux Tribe (Tribe) and the State of South Dakota (State).

DATES: The compact takes effect on August 19, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary.

The Compact increases the number of slot machines the Tribe may operate, specifies one gaming location in Corson County, South Dakota, increases the maximum bet allowance, and specifies a rate for the Tribe to reimburse the State for its expenses incurred in performing its responsibilities under the compact. The Compact has a three-year duration that may renew for additional three-year terms upon written agreement of the parties. The Compact is approved.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2020–18080 Filed 8–18–20; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–20]

Morning Star Pharmacy & Medical Supply 1; Decision And Order

The Drug Enforcement Administration (hereinafter, DEA or Government) served Morning Star Pharmacy & Medical Supply 1 (hereinafter, Respondent Pharmacy) with an Order to Show Cause (hereinafter, OSC) seeking to revoke DEA Certificate of Registration Number FM 3950070 (hereinafter, registration). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC). In response to the OSC, Respondent Pharmacy submitted a timely request for a hearing before Administrative Law Judge (hereinafter, ALJ) Charles Wm. Dorman. ALJX 2. The hearing was held in Dallas, Texas from July 17–19, 2017.

On October 31, 2017, the ALJ issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, ''Recommended Decision'' or ''RD''), which recommended that I revoke Respondent Pharmacy's registration and that I deny any pending application for renewal or modification of Respondent Pharmacy's registration. Respondent Pharmacy filed Exceptions to the Recommended Decision, and the record was forwarded to me for final agency action.

Having considered the record in its entirety, including Respondent Pharmacy's Exceptions, I agree with the RD that the record established, by substantial evidence, that Respondent Pharmacy's continued registration is inconsistent with the public interest. I further agree with the RD that Respondent Pharmacy failed to accept responsibility for its failures to meet the responsibilities of a registrant and that Respondent Pharmacy did not present adequate evidence of mitigation or remedial measures. Accordingly, I conclude that the appropriate sanctions are (1) for Respondent Pharmacy's DEA registration to be revoked; and (2) for any pending application by Respondent Pharmacy to modify or renew its registration be denied.

I. ALLEGATIONS

The Government alleged that Respondent Pharmacy has violated various federal and state laws related to controlled substances.

1. Ijeoma Amadi (hereinafter, Ms. Amadi) employed her husband, Dr. Emmanuel Amadi (hereinafter, Dr. Amadi), as a pharmacist at Respondent Pharmacy, in violation of 21 CFR 1301.76(a). Having surrendered two DEA registrations, Dr. Amadi is ineligible for employment in a capacity where he has access to controlled substances absent a waiver from the DEA. ALJX 1, at 2. Though Ms. Amadi wrote to the DEA in July 2015 to ask for a waiver, her request was denied and, by continuing to employ Dr. Amadi at Respondent Pharmacy, Respondent Pharmacy remains in ongoing violation of 21 CFR 1301.76(a).

2. Ms. Amadi also employed Dr. Amadi as a pharmacist at a second pharmacy she owned, Morning Star Pharmacy located in Cedar Hill, Texas (hereinafter, Cedar Hill), in violation of 21 CFR 1301.76(a). *Id.* at 2.

3. Between August 2014 and May 2015, pharmacists at Respondent Pharmacy and Cedar Hill filled over 200 controlled substance prescriptions outside the usual course of professional practice, in violation of 21 CFR § 1306.06, and in contravention of their ''corresponding responsibility'' under 21 CFR 1306.04(a). *Id.* at 2.

4. Between August 2014 and June 2015, pharmacists at Respondent Pharmacy and Cedar Hill, including Dr. Amadi, failed to comply with the above federal laws and were also in violation of the following federal and state laws relating to controlled substances, 21 U.S.C. 823(f)(4); Tex. Health & Safety Code § 481.074(a); Tex. Health & Safety Code § 481.128; and 22 Tex. Admin. Code § 291.33(c)(2). Additionally, Respondent Pharmacy engaged in conduct that demonstrates negative experience in its dispensing with respect to controlled substances. *Id.* at 3–4 (citing 21 U.S.C. 823(f)(2)). Specifically, the OSC alleged that Respondent Pharmacy filled prescriptions that lacked required information and/or that contained two or more of the following red flags, without resolving those red flags: (1) Prescriptions for highly abused controlled substances such as hydrocodone,[1] alprazolam, promethazine with codeine, and carisoprodol; (2) prescriptions written to individuals who travelled long distances and/or unusual routes to obtain their prescriptions and fill them at Respondent Pharmacy or Cedar Hill; (3) prescriptions from individuals obtaining the same or similar combinations of controlled substances from the same small number of providers; (4) prescriptions for highly abused drug cocktails, such as hydrocodone and alprazolam, hydrocodone and promethazine with codeine, and hydrocodone and carisoprodol; and (5) prescriptions for controlled substances which were purchased with cash. Respondent Pharmacy also failed to document specific information as legally required on either the hard-copies of the prescriptions or in the pharmacy's electronic patient profiles. *Id.* at 3–7.

5. Respondent Pharmacy failed to provide an initial inventory of controlled substances, in violation of 21 U.S.C. 827(a)(1) and 21 CFR 1304.11(b). *Id.* at 7.

6. Respondent Pharmacy failed to document the date it received approximately 80 different shipments of controlled substances on its invoices, in violation of 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(d). *Id.* at 7.

[1] All of the referenced prescriptions for hydrocodone are actually for hydrocodone/APAP, which is hydrocodone plus acetaminophen.

7. Respondent Pharmacy, as a purchaser of controlled substances, failed to document the date and number of items received on four DEA 222 Order Forms, in violation of 21 U.S.C. 828(a) and 21 CFR 1305.05(a).[2] *Id.* at 7.

8. Respondent Pharmacy, as a purchaser of controlled substances, authorized one or more individuals to issue orders for controlled substances on its behalf without executing a power of attorney for each such individual, in violation of 21 CFR 1305.05(a). *Id.* at 7.

II. Findings of Fact

A. DEA Registration

Respondent Pharmacy is registered with the DEA as a retail pharmacy authorized to handle controlled substances in schedules II–V under DEA Registration number FM3950070 at 2700 W. Pleasant Run Road, Suite W250, Lancaster, Texas 75146.

Respondent Pharmacy is owned by a corporation called COIF–SOE, Inc., which in turn is owned by Ms. Amadi.[3] RD, at 13. COIF–SOE, Inc. also owned Cedar Hill, which was previously registered with the DEA as a retail pharmacy authorized to handle controlled substances in schedules II–V under DEA Registration No. FM3343960. *Id.* at 14. The Cedar Hill registration was surrendered on June 16, 2015. *Id.* In December 2015, Ms. Amadi changed the point of contact with the DEA for Respondent Pharmacy from herself to Dr. Amadi. GX 17, at 1.

B. Government's Case

The Government presented its case through the testimony of four witnesses. First, the Government presented the testimony of a Diversion Investigator (hereinafter, Investigator One) who also testified as a rebuttal witness. Hearing Transcript (hereinafter, Tr.) 27–214, 754–59. Investigator One has served as a Diversion Investigator with the DEA for 18 years. *Id.* at 28–29. Investigator One testified about the DEA investigation of Respondent Pharmacy and Cedar Hill, the inspections of Respondent Pharmacy and Cedar Hill on June 16, 2015, *id.* at 32, 57, and the audit she conducted of two controlled substances at Respondent Pharmacy, *id.* at 116–22. Investigator One also testified concerning Dr. Amadi's surrender of the DEA registration for Cedar Hill, *id.* at 98–104, 205–06, 759, and Dr. Amadi's surrender of a DEA registration for Bestaid Pharmacy in 2011, a pharmacy that Dr. Amadi owned, *id.* at 90–92, 194–95, 754–58.

I agree with the ALJ's finding that Investigator One's testimony was credible. RD, at 7.

The Government next presented the testimony of its expert, Amy Witte, Pharm.D. (hereinafter, Dr. Witte). Tr. 215–99, 330–454, 725–53. After Respondent Pharmacy's counsel conducted *voir dire* examination of Dr. Witte, he stated that he had no objection to Dr. Witte's qualifications. *Id.* at 227. Dr. Witte was then accepted as an ''[e]xpert in the field of pharmacy in the state of Texas.'' *Id.*

Dr. Witte presented testimony concerning what a pharmacist practicing in Texas is required to do before filling a prescription for a controlled substance. *Id.* at 227–29. In addition, she testified about those circumstances that may give rise to a red flag, which a pharmacist would need to resolve before filling a prescription for a controlled substance. *E.g., id.* at 229–34, 242, 250. She also provided testimony based upon her review of Government Exhibits 2–10, which were copies of prescriptions and prescription fill labels from Respondent Pharmacy and Cedar Hill and the patient profiles Respondent Pharmacy produced in response to a Government subpoena, and the ''updated'' patient profiles Respondent Pharmacy provided before the hearing. Dr. Witte rendered her opinion as to whether filling various prescriptions in those exhibits fell below the minimum standard of practice of pharmacy in Texas and whether filling those prescriptions was within the usual course of professional practice of pharmacists in Texas. *See, e.g.,* Tr. 256–57.

The ALJ found Dr. Witte's testimony to be credible, RD, at 8, and I agree.

The Government's third witness was another Diversion Investigator (hereinafter, Investigator Two), who participated in the inspection of Respondent Pharmacy and delivering the OSC to Respondent Pharmacy. Tr. 457–88. Investigator Two testified that she has been a Diversion Investigator with the DEA for 12 years. *Id.* at 458. She testified about the process of a registrant voluntarily surrendering a DEA registration. *Id.* at 459–60. She also provided testimony concerning Dr. Amadi's surrender of the Bestaid Pharmacy registration in 2011 and the Cedar Hill registration in 2015, having witnessed both surrenders. *Id.* at 459–68, 470–73, 478–88.

I agree with the ALJ's finding that Investigator Two's testimony was credible. RD, at 8.

The Government's final witness was Emmanuel Amadi, Pharm.D (hereinafter, Dr. Amadi). Dr. Amadi was also called as a witness by Respondent Pharmacy. An assessment of his credibility is contained under the discussion of Respondent Pharmacy's case.

C. Respondent Pharmacy's Case

Respondent Pharmacy presented its case through the testimony of two witnesses. The first witness Respondent Pharmacy called was Dr. Amadi. Tr. 490–632. Dr. Amadi received his pharmacy degree from Temple University, and he has been a pharmacist since 2008. *Id.* at 492. Dr. Amadi presented testimony about his background, education, and employment. *Id.* at 492–98, 512, 518. Dr. Amadi also testified concerning: His employment duties at Respondent Pharmacy; his interaction with the DEA concerning his surrender of two pharmacy registrations, Bestaid and Cedar Hill; his production of Respondent Pharmacy's records in response to a DEA subpoena; and his resolution of red flags associated with prescriptions that Respondent Pharmacy filled. *Id.* at 512–22, 531–37, 564–69, 571–601, 606–09, 620–21. The ALJ found, however, and I agree, that there were ''numerous aspects of Dr. Amadi's testimony that stretched the limits of belief.'' RD, at 9.

In his Recommended Decision, the ALJ detailed a number of credibility issues in Dr. Amadi's testimony that included internal inconsistencies, inconsistencies with documented evidence, and conflicts with the credible testimony of other witness.[4] Having reviewed the record, including the hearing transcripts, I agree with the ALJ that Dr. Amadi's testimony was riddled with inconsistencies and merits only limited belief. I adopt the ALJ's findings regarding Dr. Amadi's credibility and summarize them here. RD, at 9–13.

First, Dr. Amadi testified that he did not talk to Ms. Amadi, the owner of Respondent Pharmacy and Cedar Hill, before he surrendered the registration

[2] As discussed, *infra* III.B.3.b, the federal regulation that the Government cited in support of this allegation is unrelated to the requirement to document the date and number of items received on a DEA 222 Form.

[3] Although the parties stipulated that COIF–SOE, Inc. is owned by Ms. Amadi and Stephen Amadi, the documentary evidence does not indicate that Stephen Amadi is an owner. *See* RD, at 13–14; GX 19, at 14; GX 12, at 1 (waiver application to DEA in which Ms. Amadi refers to Respondent Pharmacy as ''my pharmacy''). However, whether COIF–SOE is owned solely by Ms. Amadi or jointly by Ms. Amadi and Stephen Amadi is irrelevant to my ultimate finding in this matter.

[4] The ALJ noted that he detailed only ''a few of the examples that could be given'' of Dr. Amadi's ''shifting testimony and [ ] inconsistencies.'' RD, at 13.

for Cedar Hill,[5] and that he did not even have the authority to interact with the DEA concerning Cedar Hill. Tr. 512, 517. His testimony stands in stark contrast to that of Investigator One, who testified that Dr. Amadi called Ms. Amadi, and put Investigator One on the phone to speak with Ms. Amadi, who told Investigator One that Dr. Amadi ''could take care of anything regarding the pharmacy.'' *Id.* at 103. Unlike Dr. Amadi, Investigator One had no problem recalling that Dr. Amadi contacted Ms. Amadi, *id.* at 102–03, and Investigator One's testimony was further corroborated by Investigator Two, *id.* at 467–68, 484–85.

Dr. Amadi also testified that although he was the pharmacist-in-charge of Respondent Pharmacy, his duties were limited to ''do[ing] all the paperwork and direct[ing] the affairs of the pharmacy.'' *Id.* at 518. He also testified that he did not fill any prescriptions for controlled substances at Respondent Pharmacy. *Id.* at 519. He explained that he simply entered information about those prescriptions in Respondent Pharmacy's computer system for the pharmacist who had the authority to fill the prescriptions. *Id.* Yet, Dr. Amadi testified rather extensively about how he did the clinical review of the prescriptions to determine whether the prescriptions should be filled and how he resolved the red flags of the prescriptions that were presented to Respondent Pharmacy. *Id.* at 521–22, 564–621. The ALJ gave no credence to this testimony, and I agree. First, Dr. Amadi's description of what he did as the pharmacist-in-charge of Respondent Pharmacy is inconsistent with the duties of a pharmacist-in-charge. In essence, Dr. Amadi testified that he was the pharmacist-in-charge, except he really was not a pharmacist. It is the pharmacist's responsibility to perform the clinical review and to resolve red flags before the pharmacist fills a prescription for a controlled substance. Dr. Amadi's testimony is also undercut by the documentary evidence. The operational standards issued by the Texas State Board of Pharmacy require the ''*dispensing* pharmacist'' to put his or her initials on the prescription fill sticker. *See* 22 Tex. Admin. Code § 291.33(c)(7)(A)(iv) (2020) (emphasis added).[6] Dr. Amadi's initials appear on the fill sticker on almost every prescription contained in Government Exhibits 2–9. His signature also appears as the ''pharmacist'' on numerous hard-copy prescriptions that contained a signature block for the pharmacist. *See* GX 4, at 4, 8, 10, 16; GX 6, at 2, 7, 10, 12; GX 7, at 17, 20, 21; GX 8, at 5, 14, 16, 20.[7] Clearly, Dr. Amadi was filling prescriptions for controlled substances at Respondent Pharmacy.

Dr. Amadi testified that he would call a prescriber's office when a patient presented a prescription with a red flag to Respondent Pharmacy, Tr. 567, but his testimony on these matters contained a number of inconsistencies. For example, for one of the subject patients, Dr. Amadi testified that there were no red flags on the prescriptions, yet he also testified that he called the prescriber. *Id.* at 564–67. This testimony is inconsistent. If there were no red flags, there would have been no reason to call the prescribing doctor. Dr. Amadi was also equivocal on how he handled prescriptions for drug cocktails, such as hydrocodone and alprazolam. He testified that Respondent Pharmacy knew that prescriptions for drug cocktails had a ''potential for abuse,'' and therefore, Respondent Pharmacy was ''sure'' to contact the doctor before filling such prescriptions. *Id.* at 571. However, almost immediately after providing that testimony, Dr. Amadi stated that a prescription for alprazolam along with a prescription for a opioid was ''not necessarily'' a red flag and that he did not consider it to be a red flag if a person were to fill one of those two prescriptions on one day and return the following day to fill the other prescription. *Id.* at 571–72. Again, this represents an inconsistency in his testimony. Dr. Amadi also testified that if a patient lived outside of the local geographic area, he would question the prescription, *id.* at 591, but this testimony was contradicted by the documentary evidence, which displayed no indication that Dr. Amadi investigated prescriptions presented by such individuals, *see id.* at 588–89, 612, 617; GX 4, at 4. Finally, Dr. Amadi's testimony regarding how he investigated and documented the resolution of red flags presented further inconsistencies, including testimony regarding calling prescribers that was both internally inconsistent and conflicted with documentary evidence. *See* Tr. 573–81; RX A, at 27. *See also,* Tr. 620–21; RX A, at 1.

Dr. Amadi also provided an explanation for the differences in the content of the patient profiles contained in the Government's Exhibits with the content of the patient profiles contained in Respondent Pharmacy's Exhibits. Tr. 531–33, 537. He testified that, although the profiles in Respondent Pharmacy's Exhibits were not printed until May 25, 2017, the information was in the Respondent Pharmacy's computer system prior to 2017. *Id.* at 530–33. When Dr. Amadi was asked why those patient profiles were not produced to the DEA in 2016, Dr. Amadi responded: ''Because I didn't know how to add this remark at the beginning—at that time. I had to call for system support to—for them to show me how to get this included in the printout.'' *Id.* at 533. The ALJ found that this explanation lacked credibility because Dr. Amadi had been using this same software program since the Respondent Pharmacy opened in 2013. *Id.* at 521. I agree with the ALJ that Dr. Amadi's explanation lacks credibility both for the reason cited by the ALJ, and because at the hearing, Dr. Amadi was evasive in his responses to questions regarding the ''updated'' profiles. *Id.* at 531–34, 537–39.

Based on the ALJ's findings regarding Dr. Amadi's credibility and my own assessment of the record, I give Dr. Amadi's testimony limited credence, and where it conflicts with the testimony of other witnesses, or with the documentary evidence of record, I credit that other testimony and those documents over Dr. Amadi's testimony.

The Respondent Pharmacy's second witness was Kenneth Emelonye, Pharm.D. (hereinafter, Dr. Emelonye). Following *voir dire* by counsel for the Government, Dr. Emelonye was accepted as an expert witness, without objection, ''in the area of pharmacy.'' *Id.* at 647. In general, his testimony was consistent with the testimony of the Government's expert witness, Dr. Witte.

The ALJ found Dr. Emelonye to be a credible witness, and I agree. RD, at 13.

D. Dr. Amadi's Employment at Respondent Pharmacy

Respondent Pharmacy employed Dr. Amadi as a staff pharmacist and as a pharmacist-in-charge. RD, at 14. Dr.

[5] Later, Dr. Amadi modified his testimony indicating that he did not recall talking to Ms. Amadi on the day he surrendered the registration for Cedar Hill. Tr. 609.

[6] Throughout this Decision, I have cited to the administrative compilation for the state of Texas current as of June 1, 2020. Although I have cited to a contemporary compilation, the portions of the Texas Administrative Code that I cite in this Decision were in effect when the prescriptions at issue in this matter were dispensed in 2014 and 2015 and have remained unchanged. *See* Texas Secretary of State, *Historical Listing for the Texas Administrative Code, http://www.texreg.sos.state.tx.us* (last visited June 1, 2020).

[7] Significantly, these exhibits stand in stark contrast to the exhibits offered by Respondent Pharmacy. While Respondent Pharmacy presented prescriptions that contained a signature block for a pharmacist to sign, not a single one of these prescriptions is signed. Tr. 601; RX A, at 55, 58, 68, 80, 82, 93, 105; RX C, at 2, 3; RX E, at 8; RX H, at 12; RX I, at 4. In fact, GX 4, at 4 and RX C, at 2, are the same document, except that Dr. Amadi's signature is only on the Government's Exhibit.

Amadi was unsure of his exact dates of employment, Tr. 517–18, but information on file with the Texas State Board of Pharmacy showed that, as of November 17, 2015, Dr. Amadi was a staff pharmacist at Respondent Pharmacy, and he was the pharmacist-in-charge of Respondent Pharmacy, as of November 7, 2016. GX 18, at 1, 3. Dr. Amadi was also the pharmacist-in-charge at Cedar Hill, the second pharmacy owned by Ms. Amadi, Respondent Pharmacy's owner, until he surrendered the Cedar Hill DEA registration in June of 2015. GX 16, at 1.

Prior to working at Respondent Pharmacy and Cedar Hill, Dr. Amadi was the owner of Bestaid Pharmacy, DEA registration number FB2238067. Tr. 496. Dr. Amadi voluntarily surrendered the DEA registration for Bestaid Pharmacy on October 5, 2011, by signing a form stating that the surrender was ''in view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances . . . .'' GX 11. Investigator Two, who witnessed the surrender, testified that Dr. Amadi surrendered the Bestaid resignation at the end of a hearing following an Order to Show Cause the DEA had issued to Bestaid, but prior to the final decision. *See* GX 11; Tr. 460–64. Because Dr. Amadi has surrendered the Bestaid registration for cause, he was ineligible for employment in a capacity where he had access to controlled substances absent a waiver by the DEA.[8] [9] 21 CFR 1301.76(a). Ms. Amadi applied to the DEA for a waiver to employ Dr. Amadi as a pharmacist at Respondent Pharmacy with access to controlled substances by a letter dated June 25, 2015. GX 12. The DEA denied the waiver request on August 8, 2016. GX 13, at 1–5; RD, at 14.

The ALJ found that Dr. Amadi had access to controlled substances while employed at Respondent Pharmacy in spite of his ineligibility. RD, at 59–60. Respondent Pharmacy objected to this finding. Resp Exceptions, at 13. Respondent Pharmacy argued that Dr. Amadi did not have access to controlled substances while working at Respondent Pharmacy—that Dr. Amadi testified that his job at Respondent Pharmacy ''was to assist with the intake of new customer [sic], enter the prescriptions into their internal computer system, prep the prescriptions to be filled, contact the doctors [sic] offices to determine the validity of the prescriptions, do the clinical review, check the Texas patient monitoring system, and other trivial responsibilities.'' *Id.* Respondent Pharmacy stated the only person with access to controlled substances at Respondent Pharmacy was pharmacist Kweku Ohene. *Id.*

I reject this Exception and give no weight to Dr. Amadi's testimony that he did not have access to controlled substances at the Respondent Pharmacy, as it is controverted by the documentary evidence and the credible testimony of DEA investigators. First, as I have already found, the documentary evidence establishes that Dr. Amadi was filling prescriptions for controlled substances at Respondent Pharmacy. *Supra* II.C. Additionally, Dr. Amadi ordered and received controlled substances on behalf of Respondent Pharmacy. Tr. 62, 70. He was Respondent Pharmacy's sole employee with access to the DEA's Controlled Substances Ordering System (''CSOS'') for electronic ordering of Respondent Pharmacy's schedule II controlled substances, *id.;* GX 28, and he used CSOS to record the date on which schedule II drugs were received by Respondent Pharmacy, Tr. 70–71.[10] Dr. Amadi also signed invoices for controlled substances for Respondent Pharmacy. *Id.* at 140–41; GX 23, at 7–12, 15–22, 25, 27, 34–38. Investigator One credibly testified that the person who signs and dates an invoice has access to controlled substances because to retrieve the invoice, the person must open the box, allowing access to the controlled substances inside the box. Tr. 140–41. Finally, Investigator One observed Dr. Amadi working behind the counter at Respondent Pharmacy on several occasions, including after Respondent Pharmacy's waiver to allow Dr. Amadi access to controlled substances had been denied. *Id.* at 72–73, 97–98. Based on the foregoing, I agree with the ALJ and find that Dr. Amadi had access to controlled substances while employed at Respondent Pharmacy.

E. The Investigation and Inspection of Respondent Pharmacy and Cedar Hill

DEA conducted simultaneous inspections of Respondent Pharmacy and Cedar Hill on June 16, 2015. During the inspections, the DEA investigators gathered and otherwise requested various types of records from the pharmacies.

1. Respondent Pharmacy's Records

a. Initial Inventory

During the June 16 inspection, Inspector One requested the initial inventory of Respondent Pharmacy's controlled substances from Dr. Amadi. Tr. 59–60. Dr. Amadi claimed the initial inventory existed but that he could not locate it. *Id.* Investigator One made a second request for the initial inventory on June 23, 2015. *Id.* at 60. Dr. Amadi responded to Investigator One's request by stating that he ''didn't look for it,'' and Investigator One testified that she never did receive an initial inventory for Respondent Pharmacy. *Id.* at 60–61.

Respondent Pharmacy filed an Exception to the ALJ's finding that Respondent Pharmacy failed to provide an initial inventory to the DEA. Resp Exceptions, at 22–23. Respondent Pharmacy claimed that it had included the initial inventory as ''Exhibit U'' in its exhibits for the hearing in this matter. *Id.* I reject Respondent Pharmacy's Exception. Respondent Pharmacy's claim that an initial inventory was included in the record as Respondent's Exhibit U is incorrect. There is no Respondent's Exhibit U in the record, and Respondent Pharmacy did not provide a citation to the transcript showing that ''Exhibit U'' was introduced at the hearing. *See* 21 CFR 1316.66(a) (requiring a party's exceptions to include a statement of supporting reasons with evidence of record including specific citations of the pages of the transcript). I have reviewed the transcripts of the hearing and find Respondent Pharmacy did not introduce an ''Exhibit U'' or any other exhibit

[8] During the hearing, Respondent Pharmacy seemed to argue that the surrender of the Bestaid registration was not for cause. 21 CFR 1301.76(a) defines ''for cause'' to include ''a surrender in lieu of, or as a consequence of, any federal . . . administrative . . . action resulting from an investigation of the individual's handling of controlled substances.'' Because Dr. Amadi's surrender of his Bestaid registration occurred at the conclusion of a hearing in which he was responding to an OSC as to why the Bestaid registration should not be revoked, I find that the surrender of the Bestaid registration was for cause. *See JM Pharmacy Grp., Inc., d/b/a/Farmacia Nueva & Best Pharma Corp.,* 80 FR 28,667, 28,669 (2015) (''[P]ersons of ordinary intelligence cannot dispute that a surrender which occurs in response to allegations of misconduct raised by the Agency's Special Agents and Diversion Investigators is 'for cause,' . . . .'').

[9] The Government also argued that Dr. Amadi is ineligible based on his surrender of the DEA registration for Cedar Hill. Respondent Pharmacy disputes both the Government's factual and legal basis for this claim. I find it unnecessary to resolve this issue in this case, however, because 21 CFR 1301.76(a) clearly is applicable to Dr. Amadi's surrender of the Bestaid registration.

[10] Dr. Amadi lacked the necessary power of attorney to order schedule II controlled substances for Respondent Pharmacy. The Controlled Substance Act designates the DEA registrant—in this case, Ms. Amadi—as the individual authorized to order controlled substances on behalf of a pharmacy. Tr. 61; *see* 21 U.S.C. 822(b). The CSA allows the pharmacy owner to delegate the authority to order schedule II controlled substances to someone else via a power of attorney, 21 CFR 1305.05, but Respondent Pharmacy did not have any powers of attorney on file, Tr. 62.

which it purported to be an initial inventory. I have also reviewed all of Respondent's Exhibits that were introduced at the hearing, and there is no initial inventory in any of Respondent Pharmacy's introduced exhibits. Accordingly, I find that Respondent Pharmacy did not produce an initial inventory.

b. 222 Forms and Invoices for Controlled Substances

During the inspection, Investigator One collected copies of records related to Respondent Pharmacy's purchases of controlled substances, including DEA Form 222s (hereinafter, 222 Form) and invoices. Pharmacies use 222 Forms to purchase schedule II controlled substances and must document the date and number of items received on the form when they receive the purchased items from the supplier. 21 CFR 1305.13(e). The Government has alleged that four 222 Forms from Respondent Pharmacy were not in compliance with DEA requirements, because they did not document the date on which the controlled substance/s were receive and the quantity received. Respondent Pharmacy ordered multiple controlled substances on each of the four subject 222 Forms. GX 22, at 1, 2, 4, 6. On three of the four forms, Respondent Pharmacy recorded the date and quantity received for all but one of the controlled substances on the form. *Id.* at 1, 4, 6. On the fourth of the 222 Forms, Respondent Pharmacy failed to record the date or quantity received for three controlled substances. *Id.* at 2.

Although the four subject 222 Forms were missing receipt dates for at least one of the controlled substances ordered on each of forms, GX 22, at 1, 2, 4, 6, there is no evidence that Respondent Pharmacy received those controlled substances. Investigator One testified that there was no evidence ''in front of [the ALJ] that the Pharmacy actually received those controlled substances.'' Tr. 211. There is, in fact, evidence that Respondent Pharmacy did *not* receive some of the controlled substances. Invoices from Respondent Pharmacy's supplier show that some of the controlled items were never shipped. The chart below illustrates the four subject 222 Forms and shipping information from their corresponding invoices when available:

Exhibits	Date/ packages received	Shipped/not shipped	Evidence of receipt
GX 22, at 1, 8	Blank	• Hydrocodone: Unknown	No.
GX 22, at 4, 11	Blank	• Hydromorphone: Unknown	No.
GX 22, at 6, 13	Blank	• Hydrocodone 10/325: Not Shipped	No.
GX 22, at 2, 9	Blank	• Hydrocodone 10/325 (500): Not Shipped	No.
		• Hydrocodone 10/325 (1000): Not Shipped	
		• Hydrocodone 5/325: Shipped	

The Government has also alleged that Respondent Pharmacy failed to record the date it received shipments of controlled substances on 47 invoices, representing approximately 80 different shipments of controlled substances, that the Government gathered from Respondent Pharmacy. ALJX 1, at 7. DEA regulations require pharmacies to record the date they receive orders of controlled substances. 21 CFR 1304.21(d), 1304.22(c).

Respondent Pharmacy conceded that ''several of the invoices provided to the Government did not include dates'' but argued that all of the subject invoices complied with DEA regulations. Resp Exceptions, at 23. I have reviewed the invoices, and while I reject Respondent Pharmacy's assertion that all of the invoices fully complied with DEA regulations, I do find that 16 of the 47 subject invoices were mis-categorized. The 16 mis-categorized invoices were for schedule II controlled substances. GX 22, at 3; GX 23, at 16, 33, 41, 43, 45, 47–49, 51–55, 57, 82. In contrast to schedules III–V, pharmacies must record the date they receive schedule II substances on either the 222 Form or in CSOS, whichever was used to order the drugs—pharmacies are not required to also record the date of receipt for schedule II substances on the invoice.[11] 21 CFR 1305.13(e), 1305.22(g). However, I find that on the 31 invoices for schedule III–IV controlled substances Respondent Pharmacy did not record the date it received the controlled substances that were shipped by the supplier as required by DEA regulations.

2. DEA Inventory and Audit

Investigator One testified that during the inspection of Respondent Pharmacy, another Diversion Investigator conducted an inventory of Respondent Pharmacy's oxycodone 30mg and hydrocodone 10/325. Tr. 117–19. Dr. Amadi signed the investigator's closing inventory, documenting his agreement with the count. *Id.* at 119; GX 21, at 2. Following the inspection, and after obtaining Respondent Pharmacy's records, Inspector One conducted an audit of the two drugs the DEA had inventoried, finding that Respondent Pharmacy had an overage of 16,731 tablets of hydrocodone 10/325 and a 200 tablet shortage of oxycodone 30mg.[12] Tr. 116–22; GX 21, at 1. Investigator One testified that she compared invoices she obtained from one of Respondent Pharmacy's suppliers and found that Respondent Pharmacy was missing records for purchases of controlled substances. Tr. 165–67. She believed that the hydrocodone 10/325 overage she found in her audit could be attributed to the missing purchase records. *Id.* In regard to the oxycodone 30mg shortage, Investigator One testified that she had no evidence that Respondent Pharmacy actually received the missing 200 tablets. *Id.* at 210.

F. The Subject Prescriptions

During the inspections of Respondent Pharmacy and Cedar Hill, the DEA Investigators also collected records for prescriptions, which the Government alleged were filled despite containing ''one or more unresolved red flags for diversion.'' Govt Posthearing, at 30. The first set of prescriptions, Government Exhibits 2–9, were obtained during the inspection of Respondent Pharmacy.

[11] Two of the mis-categorized invoices also indicate that the supplier did not ship any of the controlled substances listed on the invoice to Respondent Pharmacy. GX 23, at 33 and 52. Respondent Pharmacy could not record the date it received the controlled substances because the controlled substances were never received.

[12] An overage indicates that a pharmacy sold more drugs than it had in inventory—an impossibility that is attributable to recordkeeping or computation errors; a shortage indicates a pharmacy could not account for all drugs that it had purchased. *See* Tr. 117, 121. Because Respondent Pharmacy did not provide an initial inventory, Inspector One testified that she began her audit from the time Respondent Pharmacy opened using the assumption that the initial inventory count was zero. *Id.* at 121–22.

The second set, Government Exhibit 10, was obtained from Cedar Hill and includes nearly 100 prescriptions all issued by a physician in Houston, Texas, Dr. R.G.

On August 18, 2016, following the inspection, the DEA subpoenaed Respondent Pharmacy for the patient profiles (or any other records that Respondent Pharmacy maintained on the patients pursuant to state law) for the 31 patients whose prescriptions were collected from Respondent Pharmacy and included in Government Exhibits 2–9. GX 27; Tr. 74–79. The DEA subpoena specifically requested ''a copy of the complete patient profile record or any other patient record (paper or electronic) that [the] pharmacy maintained [for the 31 subject patients], pursuant to the requirements of Texas Administrative Code Title 22 § 291.33(c)(2)(A) & (C) Operational Standards.'' GX 27, at 1. The subpoena further clarified that the response should include any and all ''[p]harmacist comments relevant to the individuals [sic] drug therapy, including any other information peculiar to the specific patient or drug as well as any consultation with the prescribing practitioner . . . .'' *Id.* Respondent Pharmacy responded to that subpoena through its counsel in October 2017, nearly a month after a response was due, with records containing all of the requested profiles. *See id.* at 6–52. A review of the patient profiles Respondent Pharmacy provided reveals that none of the profiles contain any pharmacist remarks regarding consultations with prescribing practitioners. *See id.* Respondent Pharmacy provided no other records in response to the August 18 subpoena.

On June 27, 2017, less than three weeks before the hearing on the OSC, Respondent Pharmacy filed a complete set of ''Amended Exhibits.'' ALJX 21. These exhibits included patient profiles (hereinafter, Respondent's profiles) that contained additional information that was not in the profiles provided to the DEA in October 2016. The Respondent's profiles contain the patient's address, phone number, date of birth, allergies, and a remarks section with comments. *See* RX A–J. None of the comments in the remarks section of the Respondent's profiles contain a date indicating when the comment was added to the profile, and there are no other dates on the Respondent's profiles that provide documentary support that the additional information in the profiles was in the records at the time of the Government subpoena. *See id.*

The ALJ wrote in the RD that, although he would discuss the Respondent's profiles when considering the Government's allegations against Respondent Pharmacy, he would give no weight to any of the information contained therein that was not contained in the patient profiles Respondent Pharmacy provided in response to the DEA subpoena in October 2016. RD, at 52. The ALJ decided not to give any weight to the information in Respondent's profiles, because (1) per the subpoena, Respondent Pharmacy was required to provide the information to the DEA by September 7, 2016; (2) Respondent Pharmacy did not produce the information until shortly before the hearing; (3) all of Respondent's profiles have a date range that runs until at least May 2017, more than eight months after Respondent Pharmacy was supposed to have produced the documents ordered by the DEA subpoena; (4) the ALJ did not find Dr. Amadi's testimony credible that he did not know how to print off the remarks section of the patient profiles in October 2016; and (5) the comments in the remarks section of the Respondent's profiles do not contain any dates that establish that the remarks were entered into the profile contemporaneously with Respondent Pharmacy filling the prescriptions involved with this matter. RD, at 52–53.

Respondent Pharmacy has objected to the ALJ's decision to give no weight to Respondent's profiles. Resp Exceptions, at 14. Respondent Pharmacy acknowledges that Respondent's profiles contain information that was not provided to the DEA in October 2016, but it argues that the DEA subpoena did not specify the exact information it was seeking in its request. *Id.* Respondent Pharmacy further explained that when printing the profiles for the DEA in October 2016, Dr. Amadi ''did not check the box to include the patient remarks to be outputted,'' and after receiving the Government's Prehearing Statement, Dr. Amadi ''contacted tech support to help him print out the client profiles with the remarks section included.'' *Id.* at 14–15.

Having considered Respondent Pharmacy's arguments, I agree with the ALJ that Respondent's profiles deserve no weight. Contrary to Respondent Pharmacy's assertions, the DEA subpoena clearly specified the exact information it was requesting from Respondent Pharmacy—all of which was information Respondent Pharmacy was legally required to maintain pursuant to the Texas Operational Standards for Community Pharmacies—and further highlighted that the subpoena was requesting all documentation of the pharmacists' consultations with prescribing physicians. GX 27, at 1; *see* 22 Tex. Admin. Code § 291.33(c)(2). This information was clearly missing from the patient profiles Respondent Pharmacy provided in response to the subpoena. *See* GX 27, at 13–40, 49–52. If Respondent Pharmacy needed to contact tech support to learn how to print the requested information, the time to do that was when responding to the subpoena, not three weeks before the hearing. I further agree with the ALJ that Dr. Amadi's testimony regarding the patient profiles is not credible. RD, at 52–53. Dr. Amadi testified that the pharmacist's remarks from Respondent's profiles were contemporaneous documentation, but none of the remarks contain dates or other evidence that establish the remarks were entered into the profiles contemporaneously with the time Respondent Pharmacy filled the prescriptions, a requirement under Texas law. 22 Tex. Admin. Code § 291.33(c)(2)(i). *See, e.g.,* RX A; RX B, at 7; RX C, at 1; RX E, at 7; RX H, at 4. Finally, as I will explain in detail below, even had Respondent's profiles been credible, the remarks on the profiles were insufficient to meet the minimum requirements set forth by Texas law.

1. Texas Pharmacists' Standard of Practice

Dr. Witte, the Government's expert witness, and Dr. Emelonye, the Respondent Pharmacy's expert witness, testified about a Texas pharmacy's/pharmacist's standard of practice and how pharmacists apply federal and state law when presented with a prescription for a controlled substance. Dr. Witte's testimony was largely uncontroverted or supported by Dr. Emelonye's testimony. As will be discussed *infra,* Dr. Emelonye's testimony did have minor disagreements with Dr. Witte's testimony in regard to whether particular circumstances presented a red flag on a controlled substance prescription.

When presented with a prescription, a Texas pharmacist must first look over the prescription to ensure it meets all of the requirements of Texas and federal law. Tr. 228. The pharmacist must check the prescription has the patient's name, address, date of birth, the physician's signature and DEA number; the drug name and strength; the quantity; and instructions for use. *Id.* at 228, 242, 647; Tex. Health & Safety Code Ann. § 481.074(k)(3), (7) (West 2019) (mandating 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). If a prescription is missing the patient's address and date of birth, the pharmacist should contact the prescriber for the missing information. Tr. 424–26. Alternatively, if the prescription was missing only the address, the pharmacist could check the name and the patient's date of birth against a valid government identification to obtain the patient's address.[13] *Id.* at 424–27, 650. Once the pharmacist verifies the patient's information, the pharmacist should fill in the required information on the prescription and only then dispense the controlled substance. *Id.* at 335, 424–27.

The pharmacist must also review the prescription for red flags—any issue that calls into question a prescription's legitimacy. *Id.* at 228. If the prescription has a red flag, the pharmacist must investigate and resolve the red flag before dispensing the prescription. The investigation would include steps such as interviewing the patient, speaking with the prescriber, and reviewing the Texas Prescription Monitoring Program. *Id.* at 228–29, 233–34, 675. The pharmacist should refuse to fill a prescription if he or she is unable to resolve a red flag on the prescription. *Id.* at 233–34. Filling a prescription without resolving a red flag would fall outside the minimal standard of practice of pharmacy in the state of Texas. *Id.* at 235.

These standards of practice are broadly codified in Texas law, which 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 Ann. § 481.074(a). 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.* 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. A Texas pharmacist is expected to ''exercise sound professional judgment with respect to'' determining if a prescription was issued for a legitimate medical purpose by a practitioner in the course of medical practice. 22 Tex. Admin. Code § 291.29(a), (b) (2020).

[13] Dr. Witte testified that a pharmacist should always call the prescriber if the prescription is missing the address and date of birth because many people share the same name. Tr. 425.

In addition to the Texas statutes, the Texas 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 a patient's medication record. Such review shall at a minimum identify clinically significant: . . . (III) reasonable dose and route of administration; (IV) drug-drug interactions; . . . [and] (X) proper utilization, including overutilization and underutilization.
>
> 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).

If the pharmacist fills the prescription, the pharmacist is obliged to document the results of his investigation in the electronic patient notes or on the prescription and the documentation should always be contemporaneous. Tr. 234; *see* 22 Tex. Admin, Code § 291.33(c)(2)(C) (requiring pharmacists to document discussions with the prescriber concerning red flags either ''on the prescription or in the pharmacy's data processing system''). While Texas law does not dictate the amount of detail and specificity a pharmacist's note must include to adequately resolve a red flag, Tr. 738, Texas operational standards state the documentation, at a minimum, must include ''(i) 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 . . . of the pharmacist . . . clearly recorded for the purpose of identifying the pharmacist who performed the consultation,'' 22 Tex. Admin. Code § 291.33(c)(2)(C). These notes are used upon a patient's return to the pharmacy to demonstrate to the pharmacist or to the next pharmacist that the red flags have been investigated and resolved. Tr. 723, 738, 743.

Drs. Witte and Emelonye testified regarding some of the red flags that a Texas pharmacist is expected to recognize and resolve before filling a prescription for a controlled substance. The Texas State Board of Pharmacy also has non-exhaustive, codified lists of circumstances and red flags that a pharmacist must weigh when evaluating a prescription's legitimacy. 22 Tex. Admin. Code § 291.29(c), (f). Dr. Witte explained that there is no exhaustive list of every red flag of diversion and no specific number of red flags trigger a pharmacist's obligation to refuse to fill a prescriptions. Rather, pharmacists are expected to exercise judgment in detecting and responding to red flags. Tr. 234, 288. Dr. Witte's testimony on this matter is supported by Texas regulations, which require pharmacists to use their professional judgment to determine if a prescription was issued for a legitimate medical purpose. *See* 22 Tex. Admin. Code § 291.29(a), (b).

Dr. Witte first explained the concept of high-alert drugs. High-alert drugs are referred to as such because they are highly abused controlled substances. Tr. 229–30. Hydrocodone, oxycodone, alprazolam, and promethazine with codeine are high-alert drugs. *Id.* at 229. A prescription consisting of some combination of high alert drugs is referred to as a ''drug cocktail'' and is a red flag. *Id.* at 229–32, 352–53; *see* 22 Tex. Admin. Code § 291.29(f)(3). A drug cocktail will generally include a narcotic, such as hydrocodone or oxycodone, along with alprazolam, carisoprodol, or promethazine with codeine. Tr. 229–31, 251, 282, 352.

Travelling a long distance or an unusual route from the patient's home to see a particular physician and then to fill the prescription is also a red flag. *Id.* at 231–32, 400; 22 Tex. Admin. Code § 291.29(c)(4) (reasons to suspect a prescription is not legitimate include ''the geographical distance between the practitioner and the patient or between the pharmacy and the patient''). Dr. Witte testified that the distance a patient travels to obtain and fill a prescription can, by itself, be sufficient reason for a pharmacist to decline to fill a prescription, while Dr. Emelonye minimized the significance of distance, testifying that distance alone would not be sufficient to raise his concern. Tr. 671–74. Dr. Emelonye agreed with Dr. Witte, however, that a pharmacist should investigate why an out-of-town patient was at a pharmacy to fill a prescription for a controlled substance. *Id.* at 400, 671–72, 718–19. To the extent Dr. Witte and Dr. Emelonye's testimony on this matter differ, I credit Dr. Witte's testimony as it is consistent with 22

Tex. Admin. Code § 291.29(c)(4), which states that distance is a red flag.[14]

Paying cash for a prescription can be a red flag. Tr. 232, 387; 22 Tex. Admin. Code § 291.29(f)(12). A cash payment for a prescription, in isolation, may be not a great concern to a pharmacist as some patients do not have insurance. Tr. 659. When a cash payment, however, is coupled with other issues, then the cash payment is a concern. *Id.*

Prescriptions from individuals obtaining the same or similar combinations of controlled substances from the same prescriber is a red flag commonly referred to as ''pattern prescribing.'' *Id.* at 228–29, 232–33, 353. Pattern prescribing can take several forms including when prescriptions by a prescriber are routinely for controlled substances commonly known to be abused drugs, 22 Tex. Admin. Code § 291.29(f)(3); prescribers that commonly write prescriptions for the highest strength and/or for large quantities of controlled substances, *id.* at (f)(5); and prescriptions from a prescriber that display a reasonably discernable pattern of substantially identical prescriptions for controlled substances for numerous persons, indicating a lack of individual drug therapy, *id.* at (f)(1). Unlike some red flags, such as drug cocktails and cash payments, pattern prescribing can manifest over an extended period of time and may not be immediately recognizable to a pharmacist. *See* Tr. 439, 449.

Other relevant red flags identified by Drs. Witte and Emelonye and/or codified in the Texas Administrative Code include, doctor shopping, when a patient receives prescriptions for controlled substances from different doctors, Tr. 678, 728; 22 Tex. Admin Code § 291.29(c)(7); pharmacy shopping, when a patient is using multiple pharmacies to fill prescriptions for controlled substances, 22 Tex. Admin. Code § 291.29(c)(7); Tr. 656; inappropriate dosing instructions, Tr. 664; and prescriptions for multiple drugs in the same class, such as multiple narcotics, *id.* at 234, 440–42.

2. Alleged Red Flags on the Subject Prescriptions

The Government has alleged that the subject prescriptions from Respondent Pharmacy and Cedar Hill all presented two or more red flags and that Respondent Pharmacy and Cedar Hill filled the prescriptions without resolving the red flags. The Government alleged that by filling prescriptions with these red flags without properly investigating, documenting, and resolving the red flags, Respondent Pharmacy and Cedar Hill fell below the minimum standards of the practice of pharmacy in Texas and were outside the usual course of professional practice of a pharmacy in Texas.

a. Prescriptions Issued by Dr. T.T.

From August 2014 to March 2015, Respondent Pharmacy filled prescriptions issued by Dr. T.T. GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22. The Government alleged that the Dr. T.T. prescriptions had red flags including cash payments, distance, drug cocktails, and inappropriate dosing; and that, taken together, the Dr. T.T. prescriptions evince the red flag of pattern prescribing. ALJX 1, at 4–6. The Government further alleged that Respondent Pharmacy filled the prescriptions with red flags from Dr. T.T. without investigation, documentation, or resolution of the alleged red flags. *Id.*

To support these allegations, the Government submitted prescriptions written by Dr. T.T. and Respondent Pharmacy's patient profiles for five patients: H.P., V.S., R.J., M.H., and K.L. GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22. Dr. Witte testified that the prescriptions showed red flags. First, Dr. T.T. prescribed all five patients red flag drug cocktails of high-alert controlled substances. *See* GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22. As part of the drug cocktails, all five patients were prescribed large quantities of hydrocodone, another red flag. GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22; *see* Tr. 419–20. All of the prescriptions were also paid for in cash. *See* GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22.

Dr. Witte also testified that the prescriptions from Dr. T.T. displayed pattern prescribing. Tr. 265, 353. Dr. Witte observed that Dr. T.T. repeatedly prescribed cocktails containing combinations of hydrocodone, alprazolam, and promethazine with codeine, and all of Dr. T.T.'s prescriptions for hydrocodone had been for 120 tablets. *Id.* at 419–20. Dr. Witte also highlighted that Dr. T.T. prescribed promethazine with codeine for a cough over several months. *Id.* at 340–41. In her expert opinion, Dr. Witte would not expect a patient to need a cough syrup month after month. *Id.* Dr. Witte also testified that the Dr. T.T. prescriptions for promethazine with codeine were written for a suboptimal dose,[15] another red flag. *See id.* at 233, 392–95; *see also id.* at 664–65 (Dr. Emelonye testifying that the dose was suboptimal and that he would call the prescriber if presented with a promethazine with codeine prescription with those dosing instructions.). Dr. Witte also pointed out that many of Dr. T.T.'s prescriptions included the same diagnosis, providing further evidence of an illegitimate pattern. *Id.* at 264–65, 279.

Finally, Dr. Witte testified that all of the patients travelled unusual distances or routes to Dr. T.T. to obtain their prescriptions and/or to Respondent Pharmacy to fill their prescriptions. *Id.* at 263, 271–72, 280–81, 298–99, 342. The Government presented evidence of the routes and distances the patients travelled: H.P. travelled approximately 123 miles, V.S. travelled approximately 106 miles; R.J. travelled approximately 59 miles; and M.H. and K.L. each travelled approximately 65 miles. *See* GX 25. Dr. Witte opined that in an urban setting such as the Dallas/Ft. Worth Metroplex, where all of the patients lived, she would consider all of the distances and/or routes the patients travelled to raise red flags.[16] *See* Tr. 263, 271–72, 280–81, 298–99, 342–43.

The ALJ concurred with Dr. Witte's testimony and found that Respondent Pharmacy filled prescriptions from Dr. T.T. that displayed red flags of drug cocktails, high dosages of high-alert drugs, inappropriate dosing, pattern prescribing, unusual routes and/or distances, and cash payments. RD, at 29–32. I agree.

Respondent Pharmacy objected to the ALJ's findings that the prescriptions from Dr. T.T. presented the red flags of pattern prescribing, unusual or long distances, and cash payments. Resp Exceptions, at 17–22. In its Exceptions,

[14] The experts' disagreement on this matter was also inconsequential to this matter, as I found that all of the subject prescriptions had multiple red flags. *Infra* II.F.2.

[15] Both Dr. Witte and Dr. Emelonye testified that the standard dosing instruction for promethazine with codeine cough syrup is one to two teaspoons every four to six hours. Tr. 261, 392, 663. The prescriptions the Government presented from Dr. T.T. were for one teaspoon every twelve hours. Dr. Emelonye testified that, although a prescriber may have a legitimate medical reason to prescribe a suboptimal dose, he would always call the prescriber in such circumstances. *Id.* at 665–68.

[16] The ALJ made the following finding in the Recommended Decision, which I adopt: ''Dr. Witte was accepted as an expert in the field of pharmacy in the state of Texas, not geography. Tr. 227. 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 in a rural one.'' RD, at 57, n.27.

Respondent Pharmacy stated that it ''did not intentionally or unintentionally identify or detect pattern prescribing when filling any of its prescriptions from Dr. T.T.'' *Id.* at 18. Respondent Pharmacy argued that ''filling a small number of prescriptions from Dr. T.T. does not equate to [sic] red flag indicating pattern prescribing,'' because ''pattern prescribing occurs when a physician prescribes the same drug and dosage to every patient the physician sees,'' and the prescriptions filled by Respondent Pharmacy were for varying drugs such as hydrocodone, alprazolam, and promethazine with codeine. *Id.* at 17–18.

Respondent Pharmacy correctly argues that varying substances and doses could weigh against a finding of pattern prescribing, but I credit Dr. Witte's expert testimony that the Dr. T.T. prescriptions did display pattern prescribing. As Dr. Witte testified, Respondent Pharmacy's experience filling prescriptions from Dr. T.T., in which he routinely prescribed an identical, large amount of hydrocodone and suboptimal dosing of promethazine with codeine, was sufficient for Respondent Pharmacy to have recognized Dr. T.T.'s pattern prescribing. I, therefore, reject Respondent Pharmacy's Exception to the ALJ's finding that the Dr. T.T. prescriptions displayed pattern prescribing.

Respondent Pharmacy also argued that the distances the Dr. T.T. patients travelled was not a red flag. Resp Exceptions, at 18. Respondent Pharmacy argued that its patients travel from all over the Dallas/Forth Worth Metroplex, an area Respondent Pharmacy states covers 9,286 square miles, to visit their doctors and run errands. *Id.* at 19. I reject this Exception.

The Government submitted evidence of the long distances that Dr. T.T.'s patients travelled with routes that had them pass from one side of Dallas to the other (some also passed through Ft. Worth and Arlington, Texas). *See* GX 25. In its Exceptions, Respondent Pharmacy specifically highlighted patient H.P.—arguing that the 123-mile trip she took from her home west of Ft. Worth to Dr. T.T.'s office in North Dallas to Respondent Pharmacy in South Dallas was not unusual. Resp Exceptions, at 19–20. Respondent Pharmacy's argument strains credulity. Clearly, a 123-mile trip is a long distance to travel to obtain a prescription and fill it in an urban setting.[17] Although there could have been a valid reason for the distances and routes the Dr. T.T. patients travelled, the minimum standards of practice 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. 22 Tex. Admin. Code § 291.33(c)(2); *see id.* at § 291.29 (c)(4) (requiring a pharmacist to consider geographic distance between the practitioner and the patient or between the pharmacy and the patient when evaluating a prescription's legitimacy).

Respondent Pharmacy finally argued that the cash payments for the Dr. T.T. prescriptions did not present a red flag because ''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.'' Resp Exceptions, at 21–22 (citing *Hills Pharmacy, L.L.C.,* 81 FR 49,816, 49,839 n.39 (2016)). The Dr. T.T. prescriptions, however, presented multiple other red flags of diversion in addition to cash payments. The Texas Administrative Code also states that cash payments are a red flag without reference to price. 22 Tex. Admin. Code § 291.29(f)(12). Accordingly, I reject Respondent Pharmacy's Exception.

After finding the Dr. T.T. prescriptions displayed red flags, the ALJ found that Respondent Pharmacy had no documentation on the hard-copies of the prescriptions or the patient profiles that the red flags were investigated or resolved and that any documentation that was in Respondent's profiles was inadequate. RD, at 66, 68, 71–73, 78. For the reasons that follow, I agree with the ALJ's finding.

Respondent Pharmacy argued that it had resolved any red flags that existed on the Dr. T.T. prescriptions before filling the prescriptions. Resp Exceptions, at 15. Dr. Amadi testified regarding the protocol pharmacists at Respondent Pharmacy followed when presented with a prescription for a controlled substance. Tr. 565–66. He stated that a pharmacist at Respondent Pharmacy would look for previous records that the patient had received the prescription before, and if the patient had, he would look at the prescriber, the dosing, and the duration; if the pharmacist still had questions, he would then check the prescription monitoring program; and, if there was reason to, the pharmacist would call the prescriber. *Id.* There is no evidence, however, that Respondent Pharmacy followed this protocol for the Dr. T.T. prescriptions. None of the hard-copy prescriptions or the patient profiles have documentation of any investigation pharmacists at Respondent Pharmacy allegedly conducted on the Dr. T.T. prescriptions. *See* GX 4; GX 5, at 13–15; GX 6, at 1–15; GX 7, at 16–29; GX 8, at 11–22. Respondent's profiles, the patient profiles Respondent Pharmacy furnished three weeks before the hearing, have pharmacists' remarks for some of the Dr. T.T. prescriptions, but none of them meet the minimal requirements of 22 Tex. Admin. Code 231.33(c)(2)(C). *See* RX C, at 1; RX D, at 13; RX H, at 10. Dr. Witte also credibly testified that the pharmacist remarks from Respondent's profiles were insufficient to satisfactorily resolve the red flags on the prescriptions. Tr. 346–47. Furthermore, as discussed *supra* at II.F, I give Respondent's profiles no weight.

In summary, I find that the Dr. T.T. prescriptions displayed red flags including pattern prescribing, distance, cash payments, drug cocktails, and high dosages of high-alert controlled substances and that the pharmacists at Respondent Pharmacy knew or should have known the prescriptions raised red flags. I further find that, even if the red flags were resolvable, there was no credible evidence that Respondent Pharmacy addressed or resolved them before filling the prescriptions. I do not place any weight on Dr. Amadi's testimony that Respondent Pharmacy resolved the red flags, because Respondent Pharmacy did not maintain contemporaneous documentary evidence in accordance with Texas standards of practice to support the claim that it resolved the red flags before filling the prescriptions, and because Dr. Amadi's testimony was not credible. *See supra* II.C.

b. Prescriptions From AC Medical Clinic

The Government alleged that Respondent Pharmacy filled prescriptions written by prescribers at AC Medical Clinic in Arlington, Texas that raised red flags without proper investigation, resolution, and documentation of the red flags. ALJX 1, at 4–6. The Government further alleged that filling the prescriptions without resolving and documenting the red flags fell below the minimum standard of practice for a Texas pharmacy/pharmacist and was outside the usual course of professional practice for a pharmacy/pharmacist in Texas. *Id.*

To support these allegations, the Government presented into evidence

[17] In light traffic, it would take 2 hours and 16 minutes to complete this round trip. GX 25, at 1; *see E. Main St. Pharmacy,* 75 FR 66149, 66164 (2010) (finding that driving two or more hours to fill a prescription would be a red flag to any pharmacist).

dozens of prescriptions written by prescribers at AC Medical and filled at Respondent Pharmacy between August 16, 2014 and May 8, 2015 (hereinafter, the AC Medical prescriptions). GX 2, 5–9. The Government also introduced Respondent Pharmacy's electronic patient profiles for the patients who received the AC Medical prescriptions. *Id.* Finally, the Government presented testimony from Dr. Witte that all of the AC Medical prescriptions presented red flags, that there was no evidence that Respondent Pharmacy resolved the red flags prior to filling the prescriptions, and that filling the prescriptions fell below the minimum standard of practice and was outside the usual course of professional practice of pharmacy in Texas. *See, e.g.,* Tr. 270–73, 278, 293–94, 332–35.

The AC Medical staffers who prescribed the AC Medical prescriptions were Dr. N.E; Dr. C.V.; L.R., ACNS–BC; S.G., FNP; and C.Z., PA. *Id.* Almost all of the paper AC Medical prescriptions were written on prescription pads from AC Medical making it easy to identify that the prescription came from a prescriber at the clinic.[18] Many of the AC Medical prescriptions prescribed by Dr. C.V. were electronic prescriptions, which all listed an address different from the address listed on the paper AC Medical prescriptions, but Dr. C.V.'s electronic prescriptions still clearly identified that they came from AC Medical. *See, e.g.,* GX 2, at 13, 24, 34.

i. December 12 and 13, 2014 AC Medical Prescriptions

On December 12, 2014, Respondent Pharmacy dispensed identical prescriptions of alprazolam to patients M.B. and L.B. at approximately the same time.[19] GX 8, at 3, 7. L.B. and M.B. reside at the same address. *Id.* The next day, Respondent Pharmacy filled identical prescriptions for hydrocodone for M.B. and L.B. *Id.* at 1, 9. These prescriptions were also filled one right after the other according to the prescription numbers. *Id.* All of the prescriptions were prescribed by Dr. NE *Id.* M.B. and L.B. paid for the alprazolam and hydrocodone prescriptions with cash. *Id.* at 1–9.

As already discussed, hydrocodone and alprazolam are a drug cocktail, which constitutes a red flag. *Supra* II.F.1. Paying cash for controlled substances is also a red flag. *Id.* Additionally, Dr. Witte testified that when two patients living at the same address obtain prescriptions from the same provider for the same highly abused drug cocktail, in this case hydrocodone and alprazolam, it is a red flag indicating diversion. Tr. 293; *see also* 22 Tex. Admin. Code § 291.29(f)(11) (It is a red flag when ''multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner.'').

Despite the red flags on the prescriptions, there was no documentation on M.B.'s and L.B.'s prescriptions or patient profiles that Respondent Pharmacy had resolved the red flags of pattern prescribing, drug cocktails, or cash payments. GX 8, at 1, 3, 6, 7. The Respondent's profiles did contain remarks on both M.B. and L.B.'s profiles, RX A, at 62, 66, but as discussed *supra* at II.F, I give the Respondent's profiles no weight. I also credit Dr. Witte's testimony that neither remark adequately resolved the red flags, *see* Tr. 734–35, and agree with the ALJ's finding that neither remark had the minimum information a pharmacist must document regarding a resolved red flag under the Texas Operational Standards,[20] RD, at 63–64; 22 Tex. Admin. Code § 291.33(c)(2). Respondent Pharmacy claimed the remarks in the Respondent's profiles met the Texas Operational Standards. Resp Exceptions, at 15. The remarks on the December 12, 2014 AC Medical prescriptions, however, did not meet the standards as they were missing the date of the consultation, the name of the person communicating the prescriber's instructions, and the initials of the pharmacist performing the consultation—all required information under the Texas Operational Standards when documenting the resolution of a red flag. *See* 22 Tex. Admin. Code § 291.33(c)(2)(C).

ii. January 14 and 15, 2015 AC Medical Prescriptions

On January 14 and 15, 2015, Respondent Pharmacy dispensed prescriptions for alprazolam and hydrocodone to patients L.H., R.C., and K.W. (male). GX 7, at 1, 5, 9. Respondent Pharmacy filled prescriptions for alprazolam for L.H. and R.C. on January 14. *Id.* at 1, 5. On January 15, Respondent Pharmacy filled an alprazolam prescription for K.W. (male) and hydrocodone prescriptions for all three patients. *Id.* at 1, 5, 9. All of the alprazolam prescriptions were identical and prescribed by Dr. NE *Id.* All of the hydrocodone prescriptions were identical and prescribed by Dr. C.V. *Id.* The three patients paid cash for the prescriptions. GX 7, 1–15.

The ALJ found, and I concur, that the prescriptions displayed red flags of drug cocktails, cash payments, and pattern prescribing. RD, at 33. I further find that K.W. (male)'s alprazolam prescription is invalid because it does not list the patient's address. GX 7, at 15; Tr. 423–24, 647–49. Dr. Witte testified that to resolve a missing address on a prescription, a pharmacist should confirm the address and fill it in on the prescription itself. Tr. 335. The line on K.W. (male)'s prescription for the patient address remains blank. GX 7, at 15.

I further find, as the ALJ did, that nothing in the record demonstrates that Respondent Pharmacy resolved the red flags on the prescriptions. *See* RD, at 69–71. Respondent Pharmacy argued it had resolved the red flags on patient R.C.'s prescription because Dr. Amadi testified that he had identified the hydrocodone and alprazolam combination as a red flag and had contacted the prescribing doctor's office to ensure the validity of the prescription. Resp Exceptions, at 15 (citing Tr. 572). I do not credit Dr. Amadi's testimony. There is no documentation on any of the three patients' prescriptions or patient profiles that any of the red flags on the prescriptions had been resolved. *See* GX 7. The Respondent's profiles do contain remarks for these patients, but even assuming I were to give those profiles any weight, the remarks do not comply with the operational rules for Texas pharmacists and are inadequate to address the red flags.[21] *See* 22 Tex. Admin. Code § 291.33(c)(2)(C).

[18] For unexplained reasons, Dr. C.V. wrote three of the subject prescriptions and Dr. NE wrote one of the subject prescriptions from a prescription pad individual to that doctor. *See* GX 2, at 3, 19, 33; GX 8, at 5.

[19] On December 12, 2014, M.B. and L.B filled five prescriptions at Respondent Pharmacy. The prescription numbers for those five prescriptions are in sequential order from 37218 through 37222. GX 8, at 3, 7.

[20] The remark on L.B.'s Respondent profile reads, ''md. oked rx.'' RX A, at 66. The remark on M.B's Respondent profile reads, ''rx info, did not have a diagnosis code. md confirmed pt has lower back pain.'' *Id.* at 62.

[21] The remark on K.W. (male)'s Respondent profile does not refer to any controlled substances, only two antidepressants. Tr. 729–30. The remark on R.C.'s profile states that a doctor was consulted and approved the combination of hydrocodone, alprazolam, and methocarbomal, but the comment does not specify which of the three doctors listed on the profile was consulted, identify the date of the consultation, or explain why the patient was receiving prescriptions from controlled substances from multiple doctors and paying in cash. RX A, at 21. The remark on L.H.'s Respondent profile states that the doctor said the patient had an accident and approved the medication. The remark, however, does not identify which of the two doctors on the profile the pharmacist spoke with, does not address why the patient was receiving controlled substances from two doctors, is undated, and according to Dr. Witte, did not resolve the red flags. RX A, at 43, Tr. 732.

iii. March 2–6, 2015 AC Medical Prescriptions

On March 2, 2015, Respondent Pharmacy dispensed alprazolam to patients V.B., F.S., and K.M.[22] GX 5, at 1, 4, 10. The following day, March 3, 2015, Respondent Pharmacy filled hydrocodone prescriptions for the same three patients.[23] *Id.* On March 4, 2015, Respondent Pharmacy filled alprazolam prescriptions for patients A.W. and C.M. GX 2, at 37; GX 9, at 12. The next day, March 5, 2015, Respondent Pharmacy filled hydrocodone prescriptions for A.W. and C.M. and alprazolam and hydrocodone prescriptions for patients J.W. and D.T. GX 2, at 38; GX 9, at 1, 5, 12. On March 6, 2015, Respondent Pharmacy filled another prescription for hydrocodone for D.T. GX 9, at 1. The prescriptions were all written by prescribers at AC Medical. The patients paid for the prescriptions with cash. GX 2, at 37–38; GX 5, at 1–12; GX 9.

The instructions on the alprazolam prescriptions stated the alprazolam was to be taken twice a day. GX 2, at 37–38; GX 5, at 1–12; GX 9. Three times a day, however, is the standard dose for alprazolam. Tr. 389–91, 661–62. The prescriptions for hydrocodone were all for 90 tablets and contained dosing instructions of 1 tablet to be taken 3 times a day as needed.[24] GX 2, at 38; GX 5, at 3, 6, 11; GX 9, at 3, 4, 10, 14. All of the hydrocodone prescriptions were written by Dr. C.V., a different doctor than the practitioners who wrote the prescriptions for alprazolam. GX 2, at 38; GX 5, at 3, 6, 11; GX 9, at 3, 4, 10, 14; Tr. 277–78.

Based on the documentary evidence and the testimony of Dr. Witte and Dr. Emelonye,[25] the ALJ found dispensing alprazolam and hydrocodone one day apart or the same day to the same patients, under these circumstances, raises the following red flags: Pattern prescribing, different prescribers of controlled substances; drug cocktails; and cash payments. RD, at 30, 34–35. I concur with the ALJ's findings. The expert testimony of Dr. Witte established that the same patient filling separate prescriptions for alprazolam and hydrocodone is a drug cocktail whether filled on the same day or on consecutive days. Tr. 344, 725. The pharmacist who filled the prescriptions one day apart for V.B., F.S., K.M, and C.M. should have known the patients were receiving a drug cocktail by looking at the patients' profiles. Tr. 432–34. The identical, suboptimal dosing instructions for patients filling prescriptions for controlled substances from the same medical clinic at the same time also evidences pattern prescribing as does that fact that all of the patients received the same hydrocodone prescription from Dr. C.V. Tr. 270, 278; *see* 22 Tex Admin Code § 291.29(f).

Respondent Pharmacy claimed the prescriptions did not display red flags of pattern prescribing and cash payments. Resp Exceptions, at 17–18, 21–22. Respondent Pharmacy did not provide any reasoning or argument why the prescriptions do not display pattern prescribing, *see id.* at 17–18; while the Government presented credible expert testimony that a Texas pharmacist would have recognized the pattern prescribing on the subject prescriptions. Tr. 270, 278. For the cash payments, Respondent Pharmacy argued that ''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.'' *Id.* at 21–22 (citing *Hills Pharmacy, L.L.C.,* 81 FR 49,816, 49,839 n.39 (2016)). The subject prescriptions, however, presented multiple other red flags of diversion in addition to cash payments. The Texas Administrative Code also states that cash payments are a red flag without reference to price. *See* 22 Tex. Admin. Code § 291.29(f)(12). Accordingly, I reject the Respondent Pharmacy's Exceptions to the ALJ's findings that the prescriptions presented the red flags of pattern prescribing and cash payments.

Despite the numerous red flags on the prescriptions, there is no documentation on either the hard-copy prescriptions or in Respondent Pharmacy's electronic patient profiles that the red flags were resolved. *See* GX 2, at 36–38; GX 5, 9. Additionally, and significantly, there are no notes explaining why patient D.T. obtained 180 tablets of hydrocodone in two prescriptions on consecutive days. The Respondent's profiles, to which I do not give weight, all have a remark for these patients, RX A, at 47, 50, 74; RX D, at 10, but the remarks fail to address all of the red flags raised by the suspect prescriptions and fail to meet the requirements set forth by the Texas Operational Standards. 22 Tex. Admin. Code § 291.33(c)(2)(C). Dr. Witte also testified that all of the Respondent's profiles fell below the minimum acceptable standard of practice for a pharmacy in Texas and specifically testified that the remarks for patients K.M. and C.M. failed to adequately resolve the prescriptions' red flags. Tr. 733, 746.

As with all of the subject prescriptions that had remarks in the Respondent's profiles, Respondent Pharmacy filed an Exception to the ALJ's finding that the remarks did not meet the Texas Operational Standards. Resp Exceptions, at 15. The remarks on the March 2–6, 2015 AC Medical prescriptions, however, did not meet the standards, as they were all missing the date of the consultation, the name of the person communicating the prescriber's instructions, and the initials of the pharmacist performing the consultation—all required information under the Texas Operational Standards when documenting the resolution of a red flag. 22 Tex. Admin. Code § 291.33(c)(2)(C).

In its Exceptions, Respondent Pharmacy also specifically argued that Dr. Amadi resolved the red flags on the prescriptions filled on March 4 and 5, 2015, for a patient A.W. before filling them. Resp Exceptions, at 15. Dr. Amadi testified during the hearing that he recognized that A.W.'s prescriptions for alprazolam and hydrocodone filled on consecutive days was a red flag drug cocktail and that he resolved the red flag by contacting the prescribing doctor's office to ensure the validity of the prescription. Tr. 563–65. Having considered Respondent Pharmacy's argument, I find there is substantial evidence to support the Government's allegation that Respondent Pharmacy filled prescriptions for patient A.W. without resolving the red flags on the prescriptions. Despite Dr. Amadi's claim that he resolved the red flags on the prescriptions, there is no documentation of his investigation on either the prescriptions or A.W.'s patient profile. *See* GX 2, at 36–38. The Respondent's profiles do have a remark for patient A.W., but it does not resolve the red flags on the prescriptions. RX A, at 1.[26]

[22] The three patients filled a total of 9 prescriptions at Respondent Pharmacy on March 2, 2015. All 9 prescriptions fell between prescription fill numbers 39126 and 39138. GX 5, at 2, 5, 12. When asked for her assessment of the prescriptions, Dr. Witte testified ''you wonder, did all the patients happen to be in the pharmacy at the same time, dropping of the same prescriptions from the same practice, or were they delivered by one person.'' Tr. 270.

[23] The prescription fill numbers for the three prescriptions were 192, 193, and 195. Tr. 176.

[24] Dr. Witte testified that hydrocodone is typically dosed one tablet every four to six hours. Tr. 252–53.

[25] Dr. Emelonye testified that he would ''ask questions to find out what was going on'' if a patient presented prescriptions for two different controlled substances written by two different doctors a day apart. Tr. 678.

[26] The remark states ''Dr. consulted and she confirmed that pt needs the meds for his conditions.'' This remark does not identify which of the two doctors listed on the profile the pharmacist spoke with, does not address why the patient was receiving controlled substances from two doctors, does not address why the patient was paying with cash, and is undated. Further, Dr. Witte

Continued

I, therefore, do not place any weight on Dr. Amadi's testimony that he resolved the red flag on A.W's prescription because Respondent Pharmacy produced no contemporaneous documentary evidence to support its claim that Dr. Amadi resolved the red flags before filling the prescriptions and because Dr. Amadi's testimony was not credible.

iv. Other AC Medical Prescriptions

The Government presented patient profiles and prescriptions demonstrating that Respondent Pharmacy filled prescriptions from AC Medical for patients receiving both hydrocodone and alprazolam to seven additional patients. GX 2, at 1–14, 17–27, 31–35, 39–42. As already discussed, a combination of hydrocodone and alprazolam is a drug cocktail and a red flag. The prescriptions were also all paid for with cash—another red flag. *Id.* There is no documentation on the hard-copy prescriptions or the patient profiles that Respondent Pharmacy resolved the red flags before dispensing the prescriptions. *Id.* The Respondent's profiles did contain pharmacist's remarks for most of these patients, but none of the remarks contained the minimum information required by the Texas Operational Standards. RX A, at 27, 34, 38, 53, 67; *see* Tex. Admin. Code § 291.33(c)(2)(C). Dr. Witte also testified that none of the remarks adequately resolved the red flags on the prescriptions. Tr. 346–47, 726–737, 746. I therefore find that Respondent Pharmacy filled prescriptions from AC Medical that had red flags of drug cocktails and cash payments without resolving the red flags or documenting the resolution of the red flags.

In summary, I find the AC Medical prescriptions displayed red flags including pattern prescribing, cash payments, patients receiving controlled substance prescriptions from different doctors, and drug cocktails and that the pharmacists at Respondent Pharmacy knew or should have known the prescriptions raised red flags. Notably, all of the patients who filled the subject prescriptions from AC Medical at Respondent Pharmacy received the drug cocktail of alprazolam and hydrocodone. I also find that one of the AC Medical prescriptions Respondent Pharmacy filled was facially invalid because it did not list the patient's address.[27] I further find that, even if the red flags on the prescriptions were resolvable, there was no credible evidence that Respondent Pharmacy addressed or resolved them before filling the prescriptions. I do not place any weight on Dr. Amadi's testimony that Respondent Pharmacy resolved the red flags because Respondent Pharmacy did not maintain contemporaneous documentary evidence in accordance with Texas standards of practice to support the claim that it resolved the red flags before filling the prescriptions and because Dr. Amadi's testimony was not credible. *See supra* II.C.

c. Prescriptions From KSW Medical Clinic

In March 2015, two of the prescribers from the AC Medical Clinic, Dr. NE and S.G., FNP, began writing prescriptions from a different clinic, KSW Medical Clinic in Desoto, Texas. The Government alleges that Respondent Pharmacy continued to fill prescriptions from these providers after they moved from AC Medical to KSW Medical without investigation, resolution, or documentation of red flags on the prescriptions in violation of the standard of practice for a Texas pharmacy/pharmacist and outside the usual course of professional practice for a Texas pharmacy/pharmacist. ALX 1, at 4–6. To support these allegations, the Government introduced prescriptions written by prescribers at KSW Medical Clinic and filled by Respondent Pharmacy between March 31, 2015 and May 8, 2015. GX 2, at 15–16, 29–30; GX 3. All of the KSW prescriptions were written on prescription pads from the KSW Medical Clinic making it easy to identify that the prescription came from a prescriber at the clinic. *Id.*

i. May 8, 2015 KSW Medical Prescriptions

On May 8, 2015, Respondent Pharmacy filled nine controlled substance prescriptions from KSW Medical for patients D.B., K.W., O.F., M.J., and C.F. GX 3. Dr. Witte testified that the prescriptions presented red flags that Respondent Pharmacy failed to resolve and that filling the prescriptions fell below the minimum standard of practice and was outside the usual course of professional practice of pharmacy in Texas. Tr. 250–57.

The ALJ found that the prescriptions for patients D.B., K.W., O.F., and M.J. raised the following red flags: Pattern prescribing, specifically, the prescriptions had the same directions for use, the prescriptions were issued by the same medical practice (KSW Medical), and the prescriptions were all presented to Respondent Pharmacy at approximately the same time;[28] drug cocktails (hydrocodone and alprazolam); and cash payments. RD, at 28. The ALJ also found that the alprazolam prescriptions for all four patients were facially invalid. *Id.* To be facially valid, a prescription must contain the patient's address and the provider's DEA number. Tr. 242, 335, 423–25, 647–49; Tex. Health & Safety Code § 481.074(k)(3), (7). The alprazolam prescriptions for K.W., O.F., and M.J. did not contain an address or the provider's DEA number, Tr. 242, 245–48; GX 3, at 6, 10, 14, and the alprazolam prescription for D.B. was missing the patient's address, Tr. 370; GX 3, at 2. On May 8, 2015, Respondent Pharmacy also filled a prescription for hydrocodone for patient C.F. GX 3, at 20. The ALJ found this prescription raised the red flags of pattern prescribing, specifically the prescription was the same quantity and dosing as the other hydrocodone prescriptions from KSW Medical that were brought to Respondent Pharmacy that day; a prescription for a high-alert controlled substance; and cash payment. RD, at 28. Having reviewed the record, I concur with the ALJ's findings.

Respondent Pharmacy filed an Exception to the ALJ's finding that the May 8, 2015 KSW Medical prescriptions displayed the red flags of pattern prescribing. Resp Exceptions, at 17–18. I reject Respondent Pharmacy's Exception and find that a reasonable pharmacist practicing within the standard of practice for a Texas pharmacist would have recognized the pattern prescribing displayed by the prescriptions. Dr. Witte credibly testified that a pharmacist working a typical 8 to 10 hour shift would be unlikely to encounter nine prescriptions on the same day in close proximity to one another for the same controlled substances, with similar dosing and instructions, all from the same medical practice. Tr. 251. While the pattern might not have been apparent when the first or second prescription was presented, Dr. Amadi should have realized by the time he received the third or fourth prescription that drug cocktails repeatedly coming from KSW Medical for hydrocodone and

provided credible expert testimony that the remark was inadequate to resolve the red flags on the prescriptions. Tr. 726–28.

[27] A review of the subject prescriptions from AC Medical in the Government's exhibits shows that many of the other prescriptions were missing addresses and/or the prescriber's DEA number, but the Government only charged one prescription from AC Medical as facially invalid. *See* ALJX 1, at 4–6. I am, therefore, only including a finding on the single prescription.

[28] Dr. Witte testified that the fill stickers for the prescriptions indicate the patients either came into the pharmacy at the same time or that one person was dropping of the prescriptions for all of the patients. Tr. 250–51.

alprazolam on the same date raised the concern of illegitimacy and diversion.

Respondent Pharmacy also argued that the prescriptions displayed the red flag of cash payments for the same reasons it objected to this finding for the Dr. T.T. and AC Medical prescriptions. Resp Exceptions, at 21–22. As with those prescriptions and for the same reasons, I reject Respondent Pharmacy's argument.

During the hearing Dr. Amadi agreed that the May 8, 2015 prescriptions from KSW Medical contained some red flags [29] but argued that he had investigated and resolved the red flags before the prescriptions were dispensed by calling the prescribers and checking the patients' identifications for the missing addresses. Tr. 584–85. The ALJ did not credit Dr. Amadi's testimony and found that (1) Respondent Pharmacy had not resolved the red flags before filling the prescriptions because there was no documentation on the prescriptions or the patient profiles that it had done so, RD, at 26; (2) the documentation in the Respondent's profiles did not adequately resolve the red flags on the prescriptions or meet the minimum standards for documenting the resolution of red flags, *id.* at 83–86; and (3) Respondent Pharmacy had not added the missing addresses as required to resolve the problems with the invalid prescriptions, *id.* at 28. Respondent Pharmacy disagreed with these findings. Resp Exception, at 15–17. I agree with the ALJ.

A pharmacist practicing in Texas must record notes on the hard-copy of the prescription or in the pharmacy's electronic patient profiles explaining whether a red flag was resolved and how it was resolved. 22 Tex. Admin. Code § 291.33(c)(2)(C). None of the hard-copies of the prescriptions or the patient profiles contained any notes resolving the red flags of drug cocktails, cash payments, or pattern prescribing. GX 3; RD, at 26. The hard-copy of the prescriptions for D.B., K.W., O.F., and M.J. also do not contain any notes or comments indicating how the pharmacist resolved the issue of the missing address before dispensing the high-alert controlled substance. GX 3; RD, at 26.

The Respondent's profiles for the patients contain remarks, but the remarks lack the information required by the Texas Operational Standards for resolving red flags. RX A, at 86, 88, 106, 112; 22 Tex. Admin. Code § 291.29(c)(2)(C). Every comment falls short of all four requirements outlined in the Texas regulation. Additionally, the patients' profiles show that all of the patients were receiving multiple drugs, both controlled and non-controlled substances, but the pharmacist's comments never say which drug the comment was addressing. Therefore, even if I were to give weight to the Respondent's profiles, and for the reasons I discussed *supra* I do not, the remarks fail to meet the standard of practice for a Texas pharmacy.

ii. Other KSW Medical Prescriptions With Red Flags

The Government presented prescriptions demonstrating that Respondent Pharmacy filled prescriptions from KSW Medical for patients receiving both hydrocodone and alprazolam on two other occasions. GX 2, at 15–16; GX 3, at 18–19. As already discussed, a combination of hydrocodone and alprazolam is a drug cocktail and a red flag. The prescriptions were also all paid for with cash, another red flag. GX 2, at 15–16; GX 3, at 18–19. There is no documentation on the hard-copy prescriptions or the patient profiles that Respondent Pharmacy resolved the red flags before dispensing the prescriptions. GX 2, at 9, 15–16; GX 3, at 17–19. I therefore find that Respondent Pharmacy filled prescriptions from KSW Medical that had red flags of drug cocktails and cash payments without resolving the red flags or documenting the resolution of the red flags.

In summary, I find the KSW Medical prescriptions displayed red flags including pattern prescribing, cash payments, and drug cocktails and that the pharmacists at Respondent Pharmacy knew or should have known the prescriptions raised red flags. I also find that four of the KSW Medical prescriptions Respondent Pharmacy filled were facially invalid because they did not list the patient's address or the prescriber's DEA registration number. I further find that, even if the red flags on the prescriptions were resolvable, there was no credible evidence that Respondent Pharmacy addressed or resolved them before filling the prescriptions. I do not place any weight on Dr. Amadi's testimony that Respondent Pharmacy resolved the red flags, because Respondent Pharmacy did not maintain contemporaneous documentary evidence in accordance with Texas standards of practice to support the claim that it resolved the red flags before filling the prescriptions and because Dr. Amadi's testimony was not credible. *See supra* II.C.

d. The Cedar Hill Prescriptions

The Government next alleged that between October 2014 and June 2015, Cedar Hill dispensed nearly 100 prescriptions that displayed red flags that were unresolvable.[30] The Cedar Hill prescriptions were all prescribed by the same doctor, Dr. R.G., in Houston for 21 patients who lived in the Dallas area. *See* GX 10. The Cedar Hill prescriptions contained 47 prescriptions for oxycodone, 49 for hydrocodone, and 26 for hydrocodone-oxycodone cocktails. *Id.* According to the fill stickers, the prescriptions were filled by pharmacist Kweku Ohene. Tr. 81; *see* GX 10. In addition to working at Cedar Hill, Mr. Ohene was also the pharmacist-in-charge of Respondent Pharmacy. GX 16, at 1.

Dr. Witte testified that the Cedar Hill prescriptions contained several red flags. First, hydrocodone and oxycodone are both high-alert controlled substances. Prescribed together, they constitute a red flag drug cocktail. *Supra* II.F.1. Dr. Witte testified that a prescription for multiple drugs in the same class, such as oxycodone and hydrocodone, which both treat pain, raises the concern of overdose. Tr. 440–41. She noted that two narcotics could be prescribed together under some circumstances; for example, prescribing one narcotic for break-through pain and the other for chronic pain, but that the directions on Cedar Hill prescriptions were not written that way. *Id.* at 289.

Second, Dr. Witte testified that the distance travelled to obtain the prescriptions in Houston and fill them at Cedar Hill is a red flag. Tr. 288. All of the patients lived in the Dallas area, meaning they travelled more than 400 miles round trip to obtain prescriptions for highly-abused controlled substances. *Id.* at 287. The diagnoses provided on the Cedar Hill prescriptions further call the distance travelled into question. Dr. Witte observed that many diagnoses on these prescriptions were chronic back pain, lumbar disc pain, or spinal stenosis, and the prescriptions stated, ''Pain functional limitation.'' *Id.* at 290; GX 10, at 35, 50, 68, 81, 99, 191, 157, 163, 167. Dr. Witte credibly testified

[29] Dr. Amaldi testified that the combination of ''the Xanax and the alprazolam'' in the prescriptions was cause for concern and would need to be addressed. Tr. 585. As alprazolam is the generic name for Xanax, I presume Dr. Almadi misspoke and intended to say it was the combination of the *hydrocodone* and the alprazolam that was the cause for concern. Dr. Amaldi also stated that a missing address is a red flag. *Id.*

[30] Respondent Pharmacy objected to the introduction of the Cedar Hill prescriptions on the basis of relevancy. I address Respondent Pharmacy's argument *infra* at III.B.2.

that she would not expect a patient suffering from mobility-impairing back pain to be capable of sitting in a car for the multi-hour trip between Dallas and Houston. Tr. 290.

Dr. Witte additionally testified that the prescriptions presented the red flag of pattern prescribing. All of the prescriptions were written by the same physician, Dr. R.G., and all were for hydrocodone, oxycodone, or a combination of the two. Tr. 287–89; *see* GX 10. Most of the prescriptions were also paid for in cash, another red flag. Tr. 287–88; GX 10, at 1–35, 38–41, 54–110, 131–192.[31] Only 19 of the prescriptions were billed to insurance. GX 10, at 36–37, 42–53, 111–30.

Dr. Witte opined that the combination of red flags on the Cedar Hill prescriptions—the extraordinary distances traveled by the patients to obtain their prescriptions, the pattern prescribing, the cash payments—were so egregious that they were unresolvable. Tr. 288–89. She explained that when a prescription has unresolvable red flags, there is ''nothing that could be done that would convince you as a pharmacist to fill these prescriptions.'' *Id.* at 436. Dr. Witte testified that with the Cedar Hill prescriptions, a pharmacist could perhaps have resolved the red flags on the first prescription he saw based on an explanation from the prescriber, but that after a few prescriptions, the pattern was apparent and the pharmacist should have refused to fill the prescriptions regardless of any explanation from the prescriber. *Id.* at 436–40. The ALJ concurred with Dr. Witte and found that the Cedar Hill prescriptions raised red flags and that the red flags were unresolvable. RD, at 87–89.

Respondent Pharmacy argued that the cash payments for the Cedar Hill prescriptions did not present a red flag. Resp Exceptions, at 21–22. Respondent Pharmacy argued that ''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.'' *Id.* (citing *Hills Pharmacy, L.L.C.,* 81 FR 49,816, 49,839 n.39 (2016). The Cedar Hill prescriptions, however, presented multiple other red flags of diversion in addition to cash payments. The Texas Administrative Code also states that cash payments are a red flag without reference to price. *See* 22 Tex. Admin. Code § 291.29(f)(12). Accordingly, I reject Respondent Pharmacy's Exception.

Based on the evidence on the record, I find that the Cedar Hill prescriptions raised red flags and that the pharmacists at Cedar Hill knew or should have known that the prescriptions raised the red flags. I further find that the pharmacists at Cedar Hill filled the prescriptions without resolving the red flags, as the red flags were unresolvable.[32]

III. Discussion

The Government alleged that Respondent Pharmacy's registration should be revoked because Respondent Pharmacy committed acts that would render its registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The gravamen of the Government's allegations and evidence in this case focuses on whether Respondent Pharmacy violated federal and state laws relating to controlled substances when it filled prescriptions, employed Dr. Amadi in a position with access to controlled substances, and failed to properly maintain certain records.

Section 304(a) of the Controlled Substances Act (hereinafter, CSA) provides that ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a). In the case of a practitioner, which includes a pharmacy, the CSA requires the Agency consider the following factors in determining whether Respondent Pharmacy's registration would be inconsistent with the public interest:

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

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

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

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

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

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

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (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 37,507, 37,508 (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 10,083, 10,094–95 (2009) (basing sanction on all evidence on record).

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has met its *prima facie* case, the burden then shifts to the Respondent to show that revoking registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

While I have considered all of the public interest factors, the Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of Respondent Pharmacy's registration based primarily on conduct most aptly considered under Public Interest Factors Two and Four. I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that Respondent Pharmacy's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). I further find that Respondent Pharmacy

[31] Respondent Pharmacy charged $480 for 120 tablets of oxycodone 500 30mg and $100 for 60 tablets of hydrocodone 10/325 mg meaning most patients who obtained hydrocodone-oxycodone cocktails from Dr. R.G. paid $580 for high-alert controlled substances that are typically covered by insurance. *See, e.g.,* GX 10, at 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24.

[32] The Cedar Hill prescriptions do not contain any notes or comments documenting the resolution of the red flags on the hard copies of the prescriptions, *see* GX 10; but the Government did not obtain the electronic patient profiles for the Cedar Hill prescriptions, which could have contained the documentation. I find, however, that it is irrelevant whether the Cedar Hill pharmacists investigated the red flags on the Cedar Hill prescriptions as Dr. Witte credibly testified that they were unresolvable. Further, Respondent Pharmacy did not argue in its Posthearing Brief or in the Exceptions that it filed to the Recommended Decision that Cedar Hill pharmacists had investigated or resolved the red flags on the Cedar Hill prescriptions.

failed to provide sufficient evidence to rebut the Government's *prima facie* case. Specifically, I find that the record contains substantial evidence that pharmacists at Respondent Pharmacy and Cedar Hill violated their corresponding responsibility when they dispensed over two hundred prescriptions. I also find there is substantial evidence on the record that Respondent Pharmacy employed Dr. Amadi in a capacity where he had access to controlled substances, a position for which he was ineligible under federal law, and violated multiple federal and state recordkeeping requirements.

A. Factors One and Three

Respondent Pharmacy filed exceptions to the findings in the Recommended Decision that Factors One and Three do not weigh for or against revocation of Respondent Pharmacy's registration. Respondent Pharmacy argues that Factors One and Three should weigh in favor of Respondent Pharmacy retaining its registration, because Respondent Pharmacy holds a valid state license to operate as a pharmacy and none of its employees have a conviction record related to controlled substances. Resp Exceptions, at 7–8.

It is undisputed that Respondent Pharmacy holds a valid state pharmacy license in Texas. 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 20,011, 20,018 (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 at 15,230. The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chein* v. *Drug Enf't Admin.,* 533 F.3d 828 (DC Cir. 2008).

In determining the public interest under Factor One, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). ''Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.'' *John O. Dimowo,* 85 FR 15,800, 15,809 (2020); s*ee, also, Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.'').

The record in this case contains no evidence of a recommendation regarding Respondent Pharmacy's privilege to operate as a pharmacy by the relevant state licensing board or professional disciplinary authority or any action by the state licensing board that demonstrates that it has considered the same facts in relation to Respondent Pharmacy's continued licensure. Prior Agency decisions have found that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation. *See, e.g., Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.''); *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62,316, 62,340 (2012); *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011). Accordingly, I agree with the ALJ's finding that Factor One does not weigh for or against revocation in this matter.

As to Factor Three, there is no evidence that Respondent Pharmacy's owner or any of its employees have been convicted of an offense under either federal or state 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 49,956, 49,973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 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, I agree with the ALJ and find that Factor Three weighs neither for nor against revocation in this case.

B. Factors Two and Four

As already discussed, pursuant to section 304 of the CSA, in conjunction with section 303 of the CSA, I am to consider evidence of Respondent Pharmacy's compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances in determining whether Respondent Pharmacy's continued registration is ''consistent with the public interest.'' 21 U.S.C. 824(a)(4). ''[A] registrant's 'ignorance of the law is no excuse' for actions that are inconsistent with responsibilities attendant upon a registration.'' *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,809 (2015) (quoting *Sigrid Sanchez, M.D.,* 78 FR 39,331, 39,336 (2013)). Instead, ''[a]ll registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules.'' *Id.* at 74,809 (internal citations omitted). Further, the Agency has consistently concluded that a pharmacy's registration is subject to revocation due to the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, LLC,* 69 FR 63,178, 63,181 (2004); *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988).

In this matter, the Government alleged and presented evidence that pharmacists at Respondent Pharmacy and Cedar Hill filled over 200 prescriptions ''in contravention of their 'corresponding responsibility' under 21 CFR 1306.04(a)'' and ''outside the usual course of pharmacy practice in violation of 21 CFR 1306.06.'' ALJX 1, at 2. The Government further alleged that in the course of filling the prescriptions, Respondent Pharmacy violated Texas Health and Safety Code §§ 481.074(a), (k) and 481.128 and Title 22 of the Texas Administrative Code § 291.33(c)(2). *Id.* at 3–4. The Government also alleged and presented evidence that Respondent Pharmacy violated 21 CFR 1301.76(a) by employing Dr. Amadi in a position where he had access to controlled substances. *Id.* at 2. Finally, the Government alleged that Respondent Pharmacy committed several recordkeeping violations: Respondent Pharmacy failed to maintain an initial inventory as required by 21 U.S.C. 827(a)(1) and 21 CFR 1304.11; Respondent Pharmacy failed to notate whether individual controlled substances that it ordered were actually received, and if so, on what date they were received on DEA–222 forms, as required by 21 U.S.C. 828(a) and 21 CFR 1305.05, and on its invoices, as required by 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(d); Respondent Pharmacy authorized Dr. Amadi to issue orders for controlled substances on Respondent Pharmacy's behalf without executing a

power of attorney, as required by 21 CFR 1305.05(a); and an audit of Respondent Pharmacy's oxycodone and hydrocodone revealed a shortage of oxycodone and an overage of hydrocodone.[33] *Id.* at 7. These allegations and the evidence of record are addressed below.

1. Unlawful Employment

The Government alleged that Respondent Pharmacy employed Dr. Amadi as a pharmacist in violation of 21 CFR 1301.76(a). ALJX 1, at 2. Section 1301.76(a) provides, in part, that a ''registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has . . . surrendered a DEA registration for cause.'' [34] The Agency has explained that the purpose of this regulation is to prevent a DEA registrant from hiring an individual who would probably be denied a DEA registration due to his or her past experience with controlled substances. Registration of Manufacturers, Distributers, and Dispensers of Controlled Substances, 56 FR 36,727 (August 1, 1991). ''To hire such a person, the registrant must obtain a waiver under circumstances which clearly show that the registrant has been fully informed about the proposed employee's past experience with controlled substances and that the registrant intends to take adequate measures to ensure that no increased risk of diversion is occasioned by the proposed employment.'' *Id.* The employment prohibition in § 1301.76(a) applies both to an individual who that surrendered his or her own registration as a practitioner and to an individual who surrendered a registration on behalf of a pharmacy owned or principally operated by the individual. *See id.*

The ALJ recommended that I sustain the Government's allegation that Respondent Pharmacy violated § 1301.76(a) by employing Dr. Amadi as a pharmacist because Dr. Amadi had previously surrendered for cause the DEA registration of a pharmacy that he owned, Bestaid Pharmacy. RD, at 60. Respondent Pharmacy argued the ALJ's recommendation was incorrect because the Government did ''not meet its burden that Dr. Amadi controlled or had access to controlled substances during his employment'' at Respondent Pharmacy. Resp Exceptions, at 13. I agree with the ALJ.

Respondent Pharmacy employed Dr. Amadi as a staff pharmacist and pharmacist-in-charge. *Supra* II.D. Prior to his employment at Respondent Pharmacy, Dr. Amadi had surrendered the DEA registration for Bestaid Pharmacy for cause. *Id.* He was therefore ineligible for employment in a position with access to controlled substances pursuant to § 1301.76 absent a waiver from the DEA. As I already found, there is substantial evidence in the record that Dr. Amadi had access to controlled substances at Respondent Pharmacy—he was listed with the state as the pharmacist-in-charge, his initials appear on the prescription fill stickers for controlled substances throughout the Government's Exhibits, his signature appears on some of the filled prescriptions for controlled substances, and he ordered Respondent Pharmacy's controlled substances. *Id.* Accordingly, I find that Respondent Pharmacy violated 21 CFR 1301.76(a) by employing Dr. Amadi in a capacity where he had access to controlled substances absent a waiver from DEA.

2. Unlawful Dispensing Allegations

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

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation as evidenced by it ''repeatedly distribut[ing]

[33] As will be discussed, *infra,* the regulations the Government cited in the OSC for the alleged recordkeeping violations do not always align with the stated allegations.

[34] The regulation further defines ''for cause'' to include ''surrender in lieu of, or as a consequence of, any federal . . . administrative . . . action resulting from an investigation of the individual's handling of controlled substances.'' 21 CFR 1301.76(a).

controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion.'' Govt Posthearing, at 30.

As I already found, the subject prescriptions from Respondent Pharmacy and Cedar Hill presented multiple red flags including pattern prescribing, distance, cash payments, drug cocktails, high doses/quantities of high-alert controlled substances, different doctors prescribing controlled substances to the same patient, patients with the same last name and address presenting the same prescription within a short period of time, therapeutic duplication (two drugs in the same class prescribed together), 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., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,898, pet. for rev. denied, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49,816, 49,836–39 (2016) (multiple customers 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 59,504, 59,507, 59,512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62,316, 62,317–22 (2012) (long distances; multiple customers 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 virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Texas state law also leaves no question that Respondent Pharmacy and Cedar Hill knew, or should have known, that the prescriptions presented red flags as all of the red flags are explicitly identified in state law as circumstances a Texas pharmacist must identify before filling a prescription.[35] Dr. Witte credibly testified that a Texas pharmacist acting in the usual course of professional practice should have recognized these red flags and that a Texas pharmacist acting in the usual course of professional practice will not fill prescriptions for controlled substances without investigating, documenting the investigation, and resolving any red flags. *Supra* II.F.1. Dr. Amadi also admitted during his testimony that he had *actual* knowledge of some of the red flags on the prescriptions. For example, Dr. Amadi testified that he knew that a drug cocktail of hydrocodone and alprazolam has the potential for abuse and claimed that he often called doctors when patients presented with prescriptions for drug cocktails, demonstrating his awareness that drug cocktails are a red flag that require resolution, yet he repeatedly filled prescriptions for drug cocktails without adequate investigation and resolution of the red flag. Tr. 571–72, 575. From the fact that there is no evidence that Respondent Pharmacy or Cedar Hill adequately investigated and resolved the multiple, egregious red flags on the subject prescriptions before filling them, I find that Respondent Pharmacy and Cedar Hill 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 RD that the Government has proven by substantial evidence that Respondent Pharmacy and Cedar Hill filled prescriptions for controlled substances that the pharmacists knew were not prescribed for legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 CFR 1306.04(a). I also agree with the ALJ's finding that by filling the subject prescriptions without resolving the red flags and documenting the resolution, Respondent Pharmacy violated Tex. Health & Safety Code §§ 481.074(a) and 481.128 and 22 Tex. Admin. Code § 291.33(c) and acted outside the usual course of professional practice in violation of 21 CFR 1306.06.[36]

I considered and reject Respondent Pharmacy's claim that it investigated and resolved the red flags on the subject prescriptions before they were filled and therefore complied with its corresponding responsibility. Resp Exceptions, at 10, 15; Resp Posthearing, at 5, 8–10, 12–13. In its Exceptions, Respondent Pharmacy summarized Dr. Amadi's testimony regarding Respondent Pharmacy's protocol for filling controlled substance prescriptions, which he stated included ''looking to see if a prior record exist [sic] for the customer, had the filled the same prescription before [sic], which doctor prescribed the prescription, the dosage amount, duration, check the Texas prescription monitoring program, and call the doctor.'' Resp Exceptions, at 17 (citing Tr. 566). I reject Respondent Pharmacy's Exception for the following reasons. First, as I already discussed, I do not credit Dr. Amadi's testimony regarding his investigation and resolution of red flags on Respondent Pharmacy's prescriptions. His testimony

[35] 22 Tex. Admin. Code § 291.29(c) (distance, doctor shopping), (f) (pattern prescribing, drug cocktails, high doses/quantities or high-alert controlled substances, multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner, cash payments); *id.* at § 291.33 (c)(2)(A) (therapeutic duplication); Tex. Health & Safety Code § 481.074(k)(3), (7) (prescription for controlled substance must contain patient address and prescriber DEA number).

[36] As discussed *supra,* Tex. Health & Safety Code § 481.074(a) provides in relevant part that ''[a] pharmacist may not: (1) Dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice; (2) dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship; (3) fill a prescription that is not filled or issued as prescribed by [the Texas Controlled Substances Act].'' Section 481.128 states in relevant part ''[a] registrant or dispenser commits an offense if the registrant or dispenser knowingly: (1) Distributes, delivers, administers, or dispenses a controlled substance in violation of [§ 481.074].'' 22 Tex. Admin. Code § 291.33(c)(2) provides in relevant part that

(A)(i) . . . [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; . . . (V) duplication of therapy; (IV) drug-drug interactions; . . . (X) proper utilization, including overutilization or underutilization. . . . (ii) Upon identifying any clinically significant situations conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner . . . . (iv) 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. . . . (C) . . . [A]nd [such documentation] shall include the following information: (i) 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 or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

was riddled with inconsistencies, and the ALJ observed, and I agree, that ''I am left with the sense that Dr. Amadi was making up testimony to fit the questions that were posed to him.'' RD, at 12–13. Second, Respondent Pharmacy did not present contemporaneous documentation of its resolution of the red flags—documentation that is required in the state of Texas. None of the prescriptions or patient profiles from Respondent Pharmacy contain pharmacist remarks regarding the red flags on the prescriptions, and the remarks in the Respondent's profiles (which I give no weight for reasons already discussed) are undated, fail to address all of the red flags on the prescriptions, and universally lack information required by Texas law. Finally, the red flags on the Cedar Hill prescriptions were unresolvable. Dr. Witte credibly testified that the red flags on the Cedar Hill prescriptions were so egregious that no explanation from the prescriber could have justified filling the prescriptions. Tr. 288–89, 436; *see United States* v. *Hayes,* 595 F.2d at 260 (''Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.'').

I also considered Respondent Pharmacy's objection to the introduction of the Cedar Hill prescriptions on the bases of relevancy both during the hearing and in the Exceptions it filed to the Recommended Decision. Tr. 81–82; Resp Exceptions, at 22. Respondent Pharmacy argued that the propriety of filling the Cedar Hill prescriptions is a moot point as Cedar Hill ceased operating as a pharmacy and surrendered its DEA registration before the OSC issued and any violations of controlled substance laws by Cedar Hill are not relevant to Respondent Pharmacy.

The DEA treats two separately organized business entities as one integrated enterprise based on overlap of ownership, management, and operations of the two entities. *Jones Total Health Care Pharmacy,* 81 FR at 79,222 (citing *MB Wholesale, Inc.,* 72 FR 71,956, 71,958 (2007)). ''[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy.'' *Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31,310, 31,341, n.71 (2016). Further, the Agency may revoke a registration, even if there is no misconduct that can be attributed to the registration, if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.,* 82 FR 21,410, 21,430 (2017) (revoking physician's DEA registration in Florida due to conduct attributed to a Texas registration which had expired).

In this case, the evidence established that Respondent Pharmacy and Cedar Hill, though nominally two separate entities, were commonly owned, managed, and operated. COIF–SOE and Ms. Amadi own both pharmacies, *supra* II.A., and Ms. Amadi and Stephen Amadi are listed with the Texas State Board of Pharmacy as the only officers of the two pharmacies, GX 16, at 2; GX 18, at 2. In terms of management and operations, the pharmacies shared the same key employees. The pharmacist that filled the subject Cedar Hill prescriptions, Mr. Ohene, was the pharmacist-in-charge at Respondent Pharmacy at the time he filled the Cedar Hill prescriptions, and Mr. Ohene was still employed as a pharmacist at Respondent Pharmacy as of the hearing for this matter. GX 16, at 1; GX 18, at 3; GX 10 (prescriptions with Mr. Ohene's signature and fill stickers with his initials); Resp Posthearing, at 4 (claiming Mr. Ohene was the only person with access to controlled substances at Respondent Pharmacy). Dr. Amadi was the pharmacist-in-charge at Cedar Hill when the subject Cedar Hill prescriptions were filled and was the pharmacist-in-charge at Respondent Pharmacy at the time of the hearing. GX 16, at 1; GX 18, at 2. Additionally, when Cedar Hill surrendered its registration in June 2015, all of its controlled substances were transferred to Respondent Pharmacy further demonstrating the commonality between the ownership and operation of the two pharmacies.

Due to the commonality of ownership, management, and key employees between Respondent Pharmacy and Cedar Hill, any misconduct related to controlled substances at Cedar Hill is relevant to the determination of whether Respondent Pharmacy can be entrusted with registration. It is therefore appropriate that I consider whether the pharmacists at Cedar Hill satisfied their corresponding responsibility when filling the Cedar Hill prescriptions. However, even if I were to exclude the Cedar Hill prescriptions from consideration in this matter, it would in no way affect my decision in this case.

3. Recordkeeping Allegations

In addition to its mandate that controlled substances be dispensed properly, the CSA also recognizes that controlled substances are fungible and that a truly closed system requires that certain records and inventories be kept by all registrants who either generate or take custody of controlled substances in any phase of the distribution chain until they reach the ultimate user. *Satinder Dang, M.D.,* 76 FR 51,424, 51,429 (2011) (''Recordkeeping is one of the central features of the CSA's closed system of distribution.'') (internal citations omitted); *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009) (''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.''). The OSC alleged that Respondent Pharmacy violated multiple federal laws related to the maintenance of records.

a. Initial Inventory

The Government alleged Respondent Pharmacy violated 21 U.S.C. 827(a)(1) and 21 CFR 1304.11(b) by failing to provide an initial inventory of its controlled substances. ALJX 1, at 7. 21 U.S.C. 827(a)(1) requires all registrants to conduct an initial inventory of all controlled substances on hand on the first day it engages in the manufacture, distribution, or dispensing of controlled substances. *See also* 21 CFR 1304.11(b) (''Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the . . . distribution of controlled substances.''). Further, the inventory ''must be kept by the registrant and be available, for at least 2 years from the date of such inventory . . . for inspection and copying by authorized employees of the Administration.'' 21 CFR 1304.04(a).[37] Investigator One credibly testified that Respondent Pharmacy failed to provide

[37] The Government did not allege that Respondent Pharmacy violated 21 CFR 1304.04 as part of its recordkeeping allegations and therefore I am making no findings related to this section, but am instead including this reference in order to support my findings related to the alleged violation of 21 CFR 1304.11.

an initial inventory to the Government despite repeated requests from Investigator One both during and following the inspection of Respondent Pharmacy. *Supra* II.E.1.a. I also already found that Respondent Pharmacy did not produce an initial inventory during the hearing on this matter to counter the Government's allegation.[38] *Id.* I find, therefore, that there is substantial record evidence that Respondent Pharmacy failed to maintain an initial inventory and, therefore, violated 21 U.S.C. 827(a)(1) and 21 CFR 1304.11(b).

b. 222 Order Forms

Next, the Government alleges that Respondent Pharmacy, as a purchaser of controlled substances, failed to document the date and number of items received on four 222 Forms, in violation of 21 U.S.C. 828(a) and 21 CFR 1305.05(a).[39] To support this allegation, the Government presented four 222 Forms on which Respondent Pharmacy failed to record the date received or the quantity of items received for at least one of the controlled substances ordered on each of the subject 222 Forms. *Supra* II.E.1.b.

Under the CSA, purchases of schedule II controlled substances must be made using an Agency order form. 21 U.S.C. 828(a). DEA regulations require those order forms, known as 222 Forms, to be signed and dated by an authorized person. 21 CFR 1305.12(d). The regulations further provide that a purchaser of controlled substances must indicate on the 222 Form itself the date on which each substance was received and the quantity received. 21 CFR 1305.13(e). The purchaser, however, is under no regulatory obligation to document its failure to receive a controlled substance on a 222 Form if the controlled substance does not arrive from the seller. *Hills Pharmacy, L.L.C.,* 81 FR at 49,843 (''DEA regulations do not require a purchaser to notate on the order form that no portion of a particular item was received and a date.''). 21 CFR 1305.13(e) only requires recording the date and quantity of controlled substance actually received. There is no requirement to indicate the date of non-receipt.

Here, there is no evidence that Respondent Pharmacy ever received the controlled substances for which the date and quantity received were missing from the four 222 Forms presented by the Government. *Supra* II.E.1.b. The mere existence of an improperly completed 222 Form is insufficient to show that a registrant actually received the controlled substances listed on the form. *Superior Pharmacy,* 81 FR at 31,338. Thus, I find the Government has failed to prove this allegation.

c. Invoices

The Government also alleged that Respondent Pharmacy violated 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(d), when it failed to document the date it received shipments of controlled substances on the shipment invoices. ALJX 1, at 7. 21 U.S.C. 827(a)(3) requires registrants that dispense controlled substances, such as pharmacies, to maintain, on a current basis, an accurate record of each controlled substance it receives. DEA regulations implementing this requirement state that pharmacies must maintain a record of each order of controlled substances that includes the date of receipt, the quantity acquired, and the name, address, and registration number of the person from whom the substances were acquired. 21 CFR 1304.22(a)(2)(iv) and (c). DEA regulations further state that when recording the dates of receipt, the date on which the controlled substances are actually received will be used as the date of receipt. *Id.* at § 1304.21(d). I already found that Respondent Pharmacy did not record the date it received controlled substances on 31 invoices for schedule III–V controlled substances. Respondent Pharmacy thus failed to comply with its obligation to maintain an accurate record of each controlled substance it received.

d. Audit Discrepancies

The Agency has also considered a pharmacy registrant's inability to account for controlled substances under Factor Four. *Ideal Pharmacy Care, Inc.,* 76 FR 51,415, 51,416 (2011). Under the CSA, every registrant ''distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by [it].'' 21 U.S.C. 827(a)(3). In evaluating shortages under Factor Four, the Agency has held that, ''[w]hether the shortages are attributable to outright diversion by either pharmacy or store employees, theft, or the failure to maintain accurate records, does not matter.'' *Ideal Pharmacy Care,* 76 FR at 51,416. As the Agency has explained, the ''inability to account for [a] significant number of dosage units creates a grave risk of diversion.'' *Fred Samimi,* 79 FR 18,698, 18,712 (2014). The Agency has also made it clear that it is not only concerned with shortages, but that overages are equally indicative that a pharmacy registrant has ''failed to maintain complete and accurate records as required by the CSA.'' *Superior Pharmacy,* 81 FR at 31,341; *see also Hills Pharmacy,* 81 FR at 49,843–45 (considering allegations of overages and shortages).

Investigator One's audit of Respondent Pharmacy revealed an overage of 16,731 doses of hydrocodone 10/325 mg and a shortage of 200 doses of oxycodone 30 mg. GX 21, at 1. There is no evidence, however, that Respondent Pharmacy actually received the 200 tablets of oxycodone that were missing. Tr. 210. I find, therefore, that there is substantial evidence to support the allegation that Respondent Pharmacy failed to keep a current and accurate record of hydrocodone 10/325mg but that the Government did not prove by a preponderance of the evidence that Respondent Pharmacy failed to keep a current and accurate record of oxycodone 30mg.

e. Authority To Order Controlled Substances

Lastly, the Government alleged that Respondent Pharmacy, as a purchaser of controlled substances, authorized one or more individuals to issue orders for controlled substances on Respondent Pharmacy's behalf without executing a power of attorney for such individuals, in violation of 21 CFR 1305.05(a). ALJX 1, at 7. Section 1305.05(a) provides that a registrant may authorize an individual to order ''[s]chedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual.'' 21 CFR 1305.05(a).

I found, *supra,* that Dr. Amadi ordered schedule II controlled substances for Respondent Pharmacy. He was Respondent Pharmacy's sole employee with access to CSOS, through which Respondent Pharmacy placed electronic orders for schedule II controlled substances, and his signature

[38] As discussed *supra,* Respondent Pharmacy claimed it had produced an initial inventory as Respondent's Exhibit U, but there was no Respondent's Exhibit U in the record and none of Respondent Pharmacy's other exhibits contained an initial inventory. This Agency has applied, and I apply here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (DC Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (DC Cir. 2013). According to this legal principle, Respondent Pharmacy's decision not to provide evidence within its control gives rise to an inference that any such evidence is unfavorable to Respondent Pharmacy.

[39] Although cited by the Government in the OSC, 21 CFR 1305.05(a) has nothing to do with a registrant's obligation to document the date and number of controlled substances received on the purchaser's copy of the 222 Form. Neither the Government nor Respondent Pharmacy addressed this allegation in their posthearing briefs.

appears on 222 Order forms from Respondent Pharmacy. *Compare* GX 22, at 1, 2, 4, 8, 9, 12, *with* GX 23, at 7, 36; Tr. 70–71. In order for Dr. Amadi to lawfully order controlled substances, Ms. Amadi would have needed to grant power of attorney to Dr. Amadi. [40] Respondent Pharmacy did not have any powers of attorney on file. Tr. 62; Resp Posthearing, at 10 (admitting Ms. Amadi never executed a power of attorney to Dr. Amadi). Without the requisite power of attorney allowing Dr. Amadi to order controlled substances, his doing so violated 21 CFR 1305.05(a).

Accordingly, I find that there is substantial evidence to support the Government's allegation that Respondent Pharmacy violated 21 CFR 1305.05(a).

C. Summary of the Public Interest Factors

As found above, Respondent Pharmacy and Cedar Hill filled controlled substance prescriptions for dozens of patients in violation of their corresponding responsibility and Texas law. Respondent Pharmacy also violated numerous federal and state record keeping requirements related to controlled substances and knowingly violated DEA regulations by employing Dr. Amadi in a position where he had access to controlled substances after Respondent Pharmacy's waiver was denied. Thus, I conclude that Respondent Pharmacy has engaged in misconduct which supports the revocation of its registration. I therefore hold that the Government has established a *prima facie* case that Respondent Pharmacy's continued registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that the 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 18,882, 18,910 (2018) (citing *Samuel S. Jackson,* 72 FR 23,848, 23,853 (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 62,339 (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 78,745, 78,749, 78,754 (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).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019). A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction, *Garret Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases); as is whether the registrant's acceptance of responsibility is unequivocal, *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017) (collecting cases). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Wesley Pope,* 82 FR 14,944, 14,985 (2017) (citing *Joseph Gaudio,* 74 FR 10,083, 10,095 (2009)); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general as a component in analyzing the remedial efficacy of sanctions.'').

Regarding all of these matters, I agree with the analyses and conclusions contained in the Recommended Decision. RD, at 101–04. I agree with the ALJ that there is nothing in the record that suggests Respondent Pharmacy has accepted responsibility for its actions. Dr. Amadi took no responsibility for his actions or the actions of Respondent Pharmacy's other pharmacists during his testimony, and Respondent Pharmacy's owner, Ms. Amadi, did not appear at the hearing. A review of Respondent Pharmacy's Posthearing Brief and its Exceptions to the Recommended Decision also give no hint of acceptance of responsibility. Further, even if Respondent Pharmacy had unequivocally accepted responsibility for all its unlawfulness such that I would reach the matter of remedial measures, Respondent Pharmacy has not presented any remedial measures for me to consider.

The ALJ found that the record supports the imposition of a sanction. RD, at 105. I agree that is the appropriate result on the record in this case.

The egregiousness of Respondent Pharmacy's conduct and the interests of specific and general deterrence support a sanction of revocation. Respondent Pharmacy and Cedar Hill filled approximately 200 prescriptions that contained red flags of diversion and abuse sufficiently flagrant that they provide substantial evidence that the pharmacists knowingly filled prescriptions that lacked a legitimate medical purpose. The red flags surrounding the Cedar Hill prescriptions were so egregious the ALJ found that they support a conclusion that Cedar Hill was involved in the diversion of controlled substances. RD, at 103. Respondent Pharmacy also knowingly employed Dr. Amadi in a position where he had access to controlled substances, even after Respondent Pharmacy's request for a waiver was denied. As the ALJ found ''[s]uch a knowing violation totally undercuts any suggestion that the [Respondent] Pharmacy can be entrusted with the responsibilities inherent to a DEA certificate of registration.'' RD, at 103.

''Past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), and there is nothing in the record that lends support to the proposition that Respondent Pharmacy's future behavior will deviate in any positive respect from its past behavior. Due to the fact that Respondent Pharmacy has accepted no responsibility nor offered any remedial measures, it has given me no reassurances that I can entrust it with a controlled substances registration and no evidence that it will not repeat its egregious behavior.

Regarding general deterrence, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *David A. Ruben,* 78 FR at 38,385. Based on the number and egregiousness of the established violations in this case, a

[40] 21 CFR 1305.05(d) states that the power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration. Ms. Amadi signed the application for Respondent Pharmacy's DEA registration. GX 17, at 1.

sanction less than revocation would send a message to the regulated community that compliance with the law is not a condition precedent to maintaining registration.

A balancing of the statutory public interest factors, coupled with consideration of Respondent Pharmacy's failure to accept responsibility, the absence of any evidence of remedial measures to guard against recurrence, and the Agency's interest in deterrence, supports the conclusion that Respondent Pharmacy should not continue to be entrusted with a registration. Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

V. ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration FM3950070 issued to Morning Star Pharmacy & Medical Supply 1. 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 Morning Star Pharmacy & Medical Supply 1 to renew or modify this registration. This order is effective September 18, 2020.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David Mwebe, M.D.; Decision and Order

On August 17, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration to David Mwebe, M.D. (hereinafter, Registrant). Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 2, at 1 (Order to Show Cause and Immediate Suspension Order (hereinafter, collectively OSC)). The OSC informed Registrant of the immediate suspension of his DEA Certificate of Registration BM9925388 pursuant to 21 U.S.C. 824(d), ''because [his] continued registration constitute[d] an imminent danger to the public health and safety.'' *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant's ''continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* Specifically, the OSC alleges that Registrant issued at least 42 fraudulent prescriptions for controlled substances, either to himself using various aliases, or to other individuals, which Registrant filled himself in violation of 21 U.S.C. 843(a)(3), 21 CFR 1306.04(a), and Nebraska law. *Id.* at 2 (citing Neb. Rev. St. § 28–418(1)(c) (It is unlawful to ''acquire or obtain or to attempt to acquire or obtain possession of a controlled substance by theft, misrepresentation, fraud, forgery, deception, or subterfuge.'')).

In issuing the OSC, which immediately suspended the registration, the former Acting Administrator concluded that Registrant's ''continued registration is inconsistent with the public interest'' based on a preliminary finding that Registrant ''issued prescriptions for controlled substances that [Registrant] knew were without a legitimate medical purpose and were outside the course of professional practice'' and that were ''indicative of [Registrant's] general illegitimate practice of prescribing controlled substances in violation of State and Federal laws.'' *Id.* at 7. Citing 21 U.S.C. 824(d), he also made the preliminary finding that Registrant's ''continued registration during the pendency of the proceedings would constitute an imminent danger to the public health or safety because of the substantial likelihood that [Registrant] will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances unless [Registrant's] DEA COR is suspended.'' *Id.* The former Acting Administrator authorized the DEA Special Agents and Diversion Investigators serving the OSC on Registrant to place under seal or remove for safekeeping all controlled substances Registrant possessed pursuant to the immediately suspended registration. *Id.* (citing 21 U.S.C. 824(f) and 21 CFR 1301.36(f)). The former Acting Administrator also directed those DEA employees to take possession of Registrant's Certificate of Registration BM9925388 [1] and any unused prescription forms. *Id.*

According to the Declaration of a DEA Special Agent from the Philadelphia Field Division, the DEA Special Agent personally served the OSC on Registrant on August 17, 2018. RFAAX 3 (Declaration of Special Agent A). A DEA Diversion Investigator also stated that Registrant called her on August 17, 2018, regarding questions he had about the OSC he had received. RFAAX 4, at 2 (Declaration of DEA Diversion Investigator). Based on the Special Agent's Declaration, the Diversion Investigator's Declaration, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on August 17, 2018.

On April 23, 2019, the Government forwarded a Request for Final Agency Action, along with the evidentiary record for this matter, to my office.[2] The OSC notified Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 7–8 (citing 21 CFR 1301.43(c)). I find that more than thirty days have now passed since the Government accomplished service of the OSC. I further find, based on the Government's written representations, that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, or submitted a written statement while waiving Registrant's right to a hearing. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement. 21 CFR 1301.43(d). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering his continued registration inconsistent with the public interest. I also find that Registrant has submitted no evidence that he accepts responsibility for his failures to meet the responsibilities of a registrant nor presented any evidence of mitigation or remedial measures. Accordingly, I conclude that the appropriate sanctions are (1) for Registrant's DEA registration to be revoked; and (2) for any pending application by Registrant to be denied.

Based on the representations of the Government in its RFAA, I make the following findings of fact.

[1] The OSC identified Registrant's DEA registration number as BW9925388. RFAAX, at 1. The Government has stated that this was a scrivener's error, and the correct number for Registrant's DEA registration, which the Government seeks to revoke, is BM9925388. RFAA, at 2 n.1.

[2] In the RFAA, the Government alleged that, in addition to the allegations in the OSC, Registrant lacks ''authority to handle controlled substances in the state of Nebraska, the state where he is registered with the DEA.'' RFAA at 1. I find it unnecessary to address this allegation as I have found that Registrant's registration should be revoked based on the allegations from the OSC.