accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.''' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Med. Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007); *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here the Registrant did not avail itself of the opportunity to refute the Government's case. In light of Registrant's egregious violations, which go to the heart of the CSA's purpose of ''prevent[ing] addiction and recreational abuse'' of controlled substances,[27] Registrant's silence weighs against the Registrant's continued registration. *Zvi H. Perper, M.D.,* 77 FR at 64,142 (citing *Med. Shoppe,* 73 FR at 387); *see also Jackson,* 72 FR at 23,853.

Accordingly, I find that the factors weigh in favor of revocation, and I shall order the sanctions that the Government requested, as contained in the Order below.

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 BH9966904 issued to Care Point Pharmacy, Inc. 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 Care Point Pharmacy, Inc. to renew or modify this registration. This order is effective August 27, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–16005 Filed 7–27–21; 8:45 am]

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[27] *Gonzales* v. *Oregon,* 546 U.S. at 274.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Creekbend Community Pharmacy; Decision and Order

On May 29, 2019, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Creekbend Community Pharmacy (hereinafter, Respondent Pharmacy). Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed to revoke Respondent Pharmacy's DEA Certificate of Registration Number FL4375730 (hereinafter, registration) and to deny any pending applications for renewal or modification of the registration, pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent Pharmacy's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

I. Procedural History

The OSC alleged that Respondent Pharmacy committed a number of record keeping violations. *Id.* at 2–4. Specifically, the OSC alleged failures in Respondent Pharmacy's inventory documentation in violation of 21 CFR 1304.11(a) and (c) and 1304.04(h)(1); failures to properly complete and execute DEA Form 222s in violation of 21 CFR 1305.12(a)–(e); failures to record the receipt date on invoices in violation of 21 CFR 1304.21(a), (d), and 1304.22(a)(2)(iv) and (c); and failure to maintain complete and accurate records of invoices, returns, and controlled substance transactions in violation of 1304.21(a). *Id.* The OSC further alleged that Respondent Pharmacy lacked candor by failing to be candid and truthful in the DEA investigation. *Id.* at 4–6. In particular, the OSC alleged that Respondent Pharmacy lacked candor with regard to its filling of fraudulent prescriptions and its hiding of controlled substances. *Id.*

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. OSC, at 7 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 8 (citing 21 U.S.C. 824(c)(2)(C)).

Following service of the OSC,[1] Respondent Pharmacy sent a letter to the Government which appears to be a written response to the OSC, dated June 25, 2019. RFAAX 3. The letter was not signed and the author was not explicitly identified; however, it appears to have been written by or from the perspective of Respondent Pharmacy's owner, Binta Barry. RFAAX 3; RFAAX 1, at 1; RFAAX 47 (Declaration of Diversion Investigator), at 1–2. The letter did not state that Respondent Pharmacy intended to request an administrative hearing, and the Government did not otherwise receive a hearing request. RFAAX 3; RFAAX 5 (correspondence from the hearing clerk), at 1. The letter was accompanied by a document titled ''Corrective Action Plan,'' which the Government submitted into the record. RFAAX 4. The Corrective Action Plan proposed nine changes and improvements to Respondent's Pharmacy's policies and practice.[2] Then, Respondent Pharmacy's Owner sent a signed letter dated July 29, 2019, stating that she would not ''fight [her] case with the D.E.A.'' and that she was planning to ''sell [her] business.'' [3] RFAAX 5, at 2 (hereinafter, RFAAX 3 and RFAAX 5, at 2 are collectively referred to as the ''written response'').

On September 10, 2019, the Government forwarded a Request for Final Agency Action, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Respondent Pharmacy committed acts rendering its continued registration inconsistent with the public interest. Accordingly, I conclude that the appropriate sanction is for Respondent Pharmacy's DEA registration to be revoked.

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 FL4375730 at 8103

[1] I find that the Government's service of the OSC was adequate.

[2] Respondent Pharmacy's proposed corrective action plan proposed, among other things, that Respondent Pharmacy put into place three new policies that would reflect requirements that already exist in law, enforce compliance with two existing policies that reflect requirements that already exist in law (without explaining how those policies would be enforced), and would stop working with the Pharmacist-in-charge (hereinafter, PIC) involved in this case. RFAAX 4. Additionally, the corrective action plan explained that the Respondent Pharmacy was trying to move to a ''close door pharmacy'' model, and proposed putting in place policies saying that it no longer accepted walk-in prescriptions and would only accept ''e-scripts'' for controlled substances. *Id.*

[3] I find that Respondent waived her right to a hearing in this matter.

Creekbend Drive, Suite G, Houston, Texas 77071. RFAAX 1, at 6 (Certificate of Registration). According to the Certificate of Registration, the Registration expired on August 31, 2020.[4] *Id.*

B. Government's Case

The Government attached to the RFAA forty-eight exhibits (over 850 pages) consisting primarily of records from Respondent Pharmacy including, but not limited to, inventory records, DEA Form 222s (hereinafter, 222 Form), prescription logs, and invoices; and records related to DEA's investigation and inspection including, but not limited to, audit records, a Texas Prescription Monitoring Profile Report, notices of inspection, and pictures. RFAAX 1–48. The Government also included declarations from a DEA Diversion Investigator (hereinafter, DI) and a Texas State Board of Pharmacy (hereinafter, State Board) Investigator (hereinafter, SI). RFAAX 47–48.

DI's declaration explained that she entered the DI training school in 2017, and that she was employed in the DEA Houston Division Office. RFAAX 47, at 1. As a Diversion Investigator, DI stated that her work includes investigations of DEA registered pharmacies to ''ensure compliance with all applicable DEA regulations.'' *Id.* DI stated that her investigation revealed that Binta Barry was one of Respondent Pharmacy's owners, and that Ms. Barry was also employed as one of Respondent Pharmacy's pharmacy technicians. *Id.* at 2. Additionally, DI explained that ''[t]he Pharmacist-in-charge [was] Yucabeth Kumenda.'' *Id.*

On November 1, 2017, DEA conducted its first on-site inspection of Respondent Pharmacy. RFAAX 47, at 2; RFAAX 7 (Notice of November 1, 2017 Inspection). PIC Kumenda signed the notice of inspection and participated in the inspection process; Ms. Barry was present and met with DEA only briefly during the inspection. RFAAX 47, at 2; RFAAX 7. As part of the inspection, DEA conducted a closing inventory of Respondent Pharmacy's controlled substances, interviewed responsible management, and took custody of original controlled substance records including prescriptions and inventories. RFAAX 47, at 2.

On May 24, 2018, DEA conducted its first on-site follow-up inspection of Respondent Pharmacy. RFAAX 47, at 5; RFAAX 33 (Notice of May 24, 2018 Inspection). Ms. Barry signed the notice of inspection and both Ms. Barry and PIC Kumenda were present for and participated in the inspection process. RFAAX 47, at 5; RFAAX 33; RFAAX 48, at 1. The State Board investigator, SI, was also present during the follow-up investigation. RFAAX 47, at 5; RFAAX 48, at 1. As part of the inspection, DEA requested and received updated prescriptions,[5] purchase records, and dispensing logs. RFAAX 47, at 5; RFAAX 35 (DEA–12, Receipt for Cash or Other Items dated May 24, 2018); RFAAX 48, at 1.

On April 3, 2019, DEA conducted its second on-site follow-up inspection of Respondent Pharmacy. RFAAX 47, at 6; RFAAX 36 (Notice of April 3, 2019 Inspection). PIC Kumenda signed the notice of inspection, RFAAX 36, and, according to DI, called Ms. Barry to tell her that DEA was there to conduct an inspection. RFAAX 47, at 6. According to DI, Ms. Barry said ''she was sick'' but came into the pharmacy for the inspection. RFAAX 47, at 6; *see also* RFAAX 3, at 2. DI stated that following each of the three inspections, she audited and assessed the documents DEA had received to determine Respondent Pharmacy's compliance with all applicable DEA regulations. RFAAX 47, at 1, 9–16.

SI's declaration explained that he had been an investigator with the State Board since October 2008. RFAAX 48, at 1. As an investigator, SI conducted ''investigations and audits for the [State Board] regarding matters that concern diversion or any other violations of the Texas pharmacy act.'' *Id.* SI stated that he was assigned to investigate Respondent Pharmacy in April 2018, and he participated in DEA's May 24, 2018 inspection of Respondent Pharmacy. *Id.* SI's declaration also provided information about the Texas Prescription Monitoring Program (Texas PMP), and about prescriptions he obtained from Respondent Pharmacy following the May 24, 2018 inspection. *Id.* at 2.

C. Respondent Pharmacy's Case

Respondent Pharmacy presented its case through its written response consisting of an unsigned, unsworn letter, a second letter signed by Ms. Barry, and no supporting documentation or evidence. RFAAX 3; RFAAX 5, at 2. Some of the factual assertions contained in the written response, though lacking in detail, align with the investigatory timeline and with DI's declaration and the record as a whole. *Compare* RFAAX 3 and RFAAX 5 *with* RFAAX 47. For example, the written response states that the Respondent Pharmacy's license was renewed in February 2018, which is consistent with the certificate of registration. RFAAX 3, at 2; RFAAX 1, at 6. The written response also states that DEA conducted inspections on May 24, 2018, and April 3, 2019, and contains factual assertions regarding those inspections that are consistent with the record as a whole. RFAAX 3, at 2; *infra* Section, II.D.2. The written response contains no facts and no evidence contradicting the allegations in the OSC and does not diminish the record evidence presented by the Government.

Instead, the written response questions DEA's motive in investigating

[4] Pursuant to DEA's online registration database, Respondent Pharmacy's registration did expire on August 31, 2020, and DEA records show that Respondent Pharmacy is ''out of business.'' Under, 21 CFR 1301.52, a registration of any entity ''shall terminate, without any further action by the Administration, if and when such [entity] . . . discontinues business. . . .'' However, the Agency has discretion to adjudicate this Order to Show Cause to finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68,474, 68,479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication); *Steven M. Kotsonis, M.D.,* 85 FR 85,667, 85,668–69 (2020) (concluding that termination of a DEA registration under 21 CFR 1301.52 does not preclude DEA from issuing a final decision on an order to show cause against that registration and stated that the Agency would assess such matters on a case-by-case basis to determine if a final adjudication is warranted or if the matter should be dismissed); *The Pharmacy Place,* 86 FR 21,008, 21,008–09 (2021) (adjudicating to finality a registration terminated under 21 CFR 1301.52 in order to create a final record of allegations and evidence related to the matter).

As in *The Pharmacy Place,* I have evaluated the particular circumstances of this matter and determined that the matter should be adjudicated to finality. 86 FR at 21,008–09. As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is . . . a history of having a registration suspended or revoked.* . . . having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.'' 84 FR at 68,479. Here, absent a final adjudication, there would be no final record of the allegations and evidence from this matter. (*Contrast with Kotsonis* in which the plea agreement and judgment from the respondent's concurrent criminal case provided a final record on which the Agency could rely in any future interactions with the respondent. 85 FR at 85,667). Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Respondent Pharmacy's owners, employees, or other persons who were associated with Respondent. Moreover, as in *The Pharmacy Place,* ''adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrant pharmacies under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices.'' 86 FR 21,008–09 (*applying Olsen,* 84 FR 68,479).

[5] SI took physical custody of the original prescription records and provided scanned copies to DI thereafter. RFAAX 48, at 1.

the Respondent Pharmacy.[6] RFAAX 3; RFAAX 5, at 2. The written response states that DEA had ''an intent of closing [Respondent Pharmacy] and thus subject [sic] the pharmacy to various harassments and false accusations.'' RFAAX 3, at 3. The written response also alleged that the DEA investigation was a ''witch hunt . . . by an agent who [did not] hesitate to show her hatred and Might [sic] to the owner.'' *Id.* at 2. I cannot find any evidence in the record that supports Respondent Pharmacy's allegations of threats and bias. Instead the substantial evidence in the record validates each of the accusations. *Infra* Section, II.D.

D. The Inspection and Audit of Respondent Pharmacy

1. Respondent Pharmacy's Recordkeeping

a. Inventory Documentation Failures

As part of the November 1, 2017 inspection, DI obtained copies of Respondent Pharmacy's biennial inventory, dated May 25, 2016 (RFAAX 9), and of its most recent physical inventory dated October 24, 2017, at beginning of business (RFAAX 10). RFAAX 47, at 2. The OSC alleged that the biennial inventory failed to identify whether it was conducted at the beginning or end of the business day, and alleged that both inventories failed to separate Schedule II controlled substances from Schedule III through V controlled substances. OSC, at 2. I have reviewed the inventories at issue and agree with DI's findings.

According to DI, Respondent Pharmacy ''failed to record on its biennial inventory (May 25, 2016) . . . whether the inventory was conducted at the beginning or end of the business day . . . .'' RAAX 47, at 9. DI stated that Respondent Pharmacy ''failed to separate on its biennial inventory . . . and on its October 24, 2016 inventory . . . Schedule II controlled substances from Schedule III through V controlled substances.'' [7] *Id.* On both inventories, DI states, ''a Schedule II controlled substance, hydrocodone, [was] listed with Schedule III–V controlled substance[s], including alprazolam and carisoprodol.'' *Id.* at 9–10. Respondent Pharmacy offered no evidence to contest these facts. *See* RFAAX 3.

b. Improperly Completed 222 Forms

During the inspection, DI collected records related to Respondent Pharmacy's purchases of controlled substances, including DEA Form 222s and invoices. The OSC alleges that Respondent ''[f]ailed to properly complete and execute multiple DEA Form 222 order forms.'' OSC at 2. Respondent Pharmacy broadly contests these allegations, stating in its response ''[c]ontrary to what [DEA] said, most of our D.E.A. forms are filled and signed.'' RFAAX 3, at 2. I have reviewed all of the 222 Forms and largely agree with DI's findings.

First, according to DI, Respondent Pharmacy ''failed to properly include information to be filled in by [the] purchaser, including the number of packages, size of package, and name of item, on four (4) DEA Form 222 order forms. . . .'' RFAAX 47, at 10. Specifically, DI identified these failures in RFAAX 13 (222 Forms for Supplier Cochran), at pages 1, 24, and 56; and in RFAAX 14 (222 Forms for Supplier Nationwide), at page 3. I have reviewed these four Form 222s and agree with DI that each of the four forms has one or more blanks in the ''No. of Packages,'' ''Size of Package,'' and ''Name of Item'' sections on lines that have other sections, namely ''No. of Packages Received'' and ''Date Received,'' completed. RFAAX 13, at 1, 24, 56; RFAAX 14, at 3.

Second, according to DI, Respondent Pharmacy ''failed to properly include the last line on a DEA Form 222 order form, specifically from [RFAAX 13, at 3].'' RFAAX 47, at 10. I agree with DI that the section ''Last Line Completed'' was left blank on the 222 Form at issue. *Id.* Third, DI states that the 222 Form at RFAAX 13, at 1,[8] ''failed to properly include the name and address of a supplier. . . .'' RFAAX 47, at 10. I agree with the DI that the ''To: (Name of Supplier),'' and corresponding sections for the supplier's address were left blank on the 222 Form at issue. RFAAX 13, at 1. Fourth, according to DI, Respondent Pharmacy ''failed to properly sign and/or date a DEA Form 222 order form'' at RFAAX 13, at 4. RFAAX 47, at 10–11. I agree with the DI that the ''Signature of Purchaser or Attorney or Agent'' section was left blank. RFAAX 13, at 4.

Finally, according to DI, Respondent Pharmacy ''failed to properly include the number of packages received and the date received on eleven (11)[9] DEA Form 222 order forms.'' RFAAX 47, at 11. Specifically, DI identified these failures on RFAAX 12 (Invoices and Forms 222 for Supplier Apotheca, Inc.), at pages 4, 6, 10, 16, 18, and 20; RFAAX 13, at pages 2, 5, 30, and 34; and RFAAX 15 (Forms 222 for Supplier QK Healthcare), at page 1. RFAAX 47, at 11. I agree with DI that each of these eleven 222 Forms have otherwise completed lines with blanks for ''No. of Packages Received'' and ''Date Received.'' RFAAX 12, at 4, 6, 10, 16, 18, 20; RFAAX 13, at 2, 5, 30, 34; RFAAX 15, at 1. DI also identified corresponding invoices obtained either from Respondent Pharmacy showing that Respondent Pharmacy received the controlled substances, or from Respondent Pharmacy's suppliers showing that the controlled substances were invoiced and shipped to Respondent Pharmacy to establish that the items were received by Respondent Pharmacy. RFAAX 47, at 11. The Government established Respondent Pharmacy's receipt of the controlled substances, and therefore established Respondent Pharmacy's obligation to complete the ''No. of Packages Received'' and ''Date Received'' sections, for ten of the 222 Forms at issue. *See* RFAAX 12, at 3, 5, 9, 15, 17, 19; RFAAX 22, at 5, 6; RFAAX 29 (Invoices from Supplier Cochran), at 5, 9, 136, 140–44, 146, 148–53. However, I was not able to find invoices or other evidence that Respondent Pharmacy actually received the items identified on lines 4–8 of the eleventh Form 222,[10] and accordingly, the Government has not demonstrated that the eleventh

[6] The evidence on the record provides no indication of any sort of improper motive in commencing the investigation, and in fact, the evidence demonstrates that such an investigation is routine. On August 2017, Respondent Pharmacy submitted an application to renew its registration. RFAAX 47, at 2. In the application, Respondent Pharmacy answered ''yes'' when asked ''has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' *Id.* This prompted DEA to initiate an investigation into Respondent Pharmacy. *Id.* at 1–2. It is routine for DEA to initiate investigations based on affirmative answers to the liability questions on the application. *See e.g. Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,802 (2015) (including testimony that when a registrant answers yes to a liability question the file is assigned for further investigation); *Barry H. Brooks, M.D.,* 66 FR 18,305, 18,306 (2001).

[7] The DI stated that, as relevant to this case, Hydrocodone is a Schedule II controlled substance, and Alprazolam and Carisoprodol are Schedule III–V controlled substances. RFAAX 47, at 9.

[8] I found this 222 Form, RFAAX 13, at 1, to be deficient in the preceding paragraph. *Supra.* While I find RFAAX 13, at 1, to have multiple deficiencies representing multiple regulatory violations, *infra,* I have only included it once in my total count of deficient Form 222s.

[9] The OSC alleged that there were thirteen DEA Form 222s missing information for the number of packages received and the date received. RFAAX 2, at 2. The RFAA only seeks final agency action as to eleven of the 222 Forms. RFAA, at 9.

[10] The controlled substances identified in lines 1–3 on Form 222 No. 170706317, RFAAX 15, at 1, are supported by invoices or records. RFAAX 25 (Invoices from Supplier QK Healthcare), at 1–3; and RFAAX 31 (QK Healthcare Controlled Substance History Report), at 5. And Respondent Pharmacy properly completed the corresponding ''No. of Packages Received'' and ''Date Received'' sections for those lines. RFAAX 15, at 1.

Form 222 was incomplete. RFAAX 15, at 1.

In total, I find the substantial evidence in the record establishes that Respondent Pharmacy failed to properly complete and execute sixteen Form 222s: RFAAX 12, at 4, 6, 10, 16, 18, 20; RFAAX 13, at 1 (multiple deficiencies), 2, 3, 4, 5, 24, 30, 34, 56; and RFAAX 14, at 3.

c. Records of Receipt Date

As part of the November 1, 2017 inspection, DI obtained copies of Respondent Pharmacy's invoices for Schedule III through V controlled substances. RFAAX 47, at 3, 12. The OSC alleged that Respondent Pharmacy ''failed to record the receipt date on nine (9) invoices for Schedule III through V controlled substances.'' OSC, at 2.

According to DI, Respondent Pharmacy ''failed to properly record the receipt date'' on these nine invoices: RFAAX 22 (Respondent Pharmacy's Copy of Cochran Invoices), at 89; RFAAX 26 (Respondent Pharmacy's Copy of QK Healthcare Invoices), at 78, 79, 81, 86, and 90; RFAAX 27 (Respondent Pharmacy's Copy of RXChange Invoices), at 2; RFAAX 28 (Respondent Pharmacy's Copy of VitaRX Invoices), at 5 and 7. RAAX 47, at 12. I have reviewed the nine invoices identified by DI and agree with DI that they do not contain a receipt date. However, the undated VitaRX invoice located at RFAAX 28, at 7, is accompanied by a packing slip that is signed and dated with the receipt date and contains the same substantive information that the invoice contained. *Compare* RFAAX 28, at 7 *with* at 6. Respondent Pharmacy offered no evidence to contest these facts. *See* RFAAX 3.

Accordingly, I find that the substantial evidence in the record establishes that the Respondent Pharmacy failed to properly record the receipt date on eight invoices.

d. Improper Maintenance of Records Including Invoices and Returns

DI declared that following the November 1, 2017 inspection and the April 3, 2019 second follow-up inspection, she ''conducted accountability audits that revealed that Creekbend failed to keep complete and accurate records of controlled substances maintained.'' [11] RFAAX 47, at 13. DI's audit revealed that Respondent Pharmacy's had a surplus of some controlled substances on hand, and a shortfall of others.[12] RFAAX 47, at 14–15. DI also found variances during the audit conducted after the April 3, 2019 second follow-up inspection, which looked at the records between May 24, 2018, and April 3, 2019.[13] RFAAX 47, at 15. According to DI, ''[the] variances demonstrate that [Respondent Pharmacy] clearly failed to keep complete and accurate records of controlled substances maintained.'' *Id.* at 16. While Respondent Pharmacy, in its response, generally asserted that it ''would be impossible'' for the audit counts to be off, it provided no evidence to support the assertion. RFAAX 3, at 3. I find that the audit results and record as a whole clearly identify surpluses and shortfalls in Respondent Pharmacy's controlled substances and clearly demonstrate that Respondent Pharmacy was not maintaining adequate records.

To better understand the variances uncovered during the initial audit, DI verified all of the controlled substances transactions between Respondent Pharmacy and its suppliers from January 1, 2016, to November 1, 2017. RFAAX 47, at 12. To do so, DI ''cross-verified records maintained by [Respondent Pharmacy] ([RFAAX] 20–28) with those obtained from the various suppliers ([RFAAX] 29–32). *Id.* As a result of DI's efforts, the OSC alleged that Respondent Pharmacy ''failed to provide and maintain [certain] invoices and a record of returns.'' OSC, at 2.

Specifically, DI determined that Respondent Pharmacy ''failed to properly provide and maintain [eight] invoices.'' RFAAX 47, at 12. The invoices at issue are numbers I029975 and I029976 from Nationwide Medical, located at RFAAX 30, at 1–2; numbers 3427858 and 3831964 from QK Healthcare located at RFAAX 31, at 3, and 5; numbers 0019035–IN, 0022273–IN, 0025288–IN, and 0025702–IN from Cochran located at RFAAX 29, at 85, 109, 145, and 150–51. RFAAX 47, at 12–13. I have reviewed Respondent Pharmacy's records and agree that its records did not contain these eight invoices, which were obtained from Respondent Pharmacy's suppliers. However, one of the invoices in question, Nationwide Medical Number I029976, reflected only the purchase of hydrocodone/acetaminophen, a Schedule II substance. RFAAX 30, at 2; *supra* note 7. In contrast to schedules III–V, pharmacies must record the necessary purchase and receipt information regarding schedule II substances on either the 222 Form or in the electronic Controlled Substances Ordering System, whichever was used to order the drugs. *See supra* Section II.D.1.b*; infra* Section, III.A.2. I did not see any purchase orders or other records containing the information that would have otherwise been reflected on the invoices for the remaining seven invoices at issue. Respondent Pharmacy

[11] In conducting the audit, DI stated that she determined the number of applicable controlled substances that Respondent Pharmacy was accountable for by adding the controlled substances listed in Respondent Pharmacy's October 24, 2016 inventory, found in RFAAX 10, to the total number of applicable controlled substances received from suppliers (according to invoices received from Respondent Pharmacy and from its suppliers), found in RFAAX 20–32. RFAAX 47, at 13. DI then determined the number of applicable controlled substances that Respondent Pharmacy had accounted for by adding the controlled substances on hand during Respondent Pharmacy's November 1, 2017 inventory, RFAAX 11, to the sum of the applicable controlled substances distributed by Respondent Pharmacy, RFAAX 16–19 (Respondent Pharmacy's prescription logs). RFAAX 47, at 14. DI then subtracted the total controlled substances Respondent Pharmacy was accountable for from the total controlled substances accounted for to determine the ''Total Difference.'' According to DI, ''[i]f the registrant's record keeping is accurate, the results of the ''Total Difference'' column for each controlled substance should be zero, as that would demonstrate that all accountable controlled substances are accounted for in registrant's records and physical inventory.'' RFAAX 47, at 14. She further explained that ''[a] positive difference indicated that the registrant's records show it has more controlled substances on hand and distributed than what its initial inventory and invoices show it has received, which means at the very least that the registrant's record keeping is not accurate.'' *Id.* ''A negative difference indicates the opposite, that the registrant's records show it has received more controlled substances than it now has on hand or has distributed, which also means that the registrant's record keeping is not accurate. Moreover, it likely demonstrated that diversion has occurred, as the registrant cannot account for all of the controlled substances it has received.'' *Id.*

[12] Based on the record evidence and using on the methodology provided by the DI in the affidavit, I was able to confirm the presence of variances. RFAAX 47, at 14–15. The extent of the variances I calculated differed from the DI's, sometimes significantly, and it is unclear to me why the numbers were so variable. But what is clear to me, is that there were shortfalls and surpluses that clearly demonstrate that Respondent Pharmacy was not maintaining adequate records. This finding is further supported by the fact that Registrant was missing invoices and did not properly complete the DEA Form 222s. *See supra,* II.D.1.

[13] According to DI, the April 3, 2019 audit was conducted in the same manner as the November 2, 2017 audit. *Id.* at 15–16. She first determined the number of applicable controlled substances that Respondent Pharmacy was accountable for by adding the controlled substances listed in Respondent Pharmacy's May 24, 2018 inventory, found in RFAAX 34, to the total number of applicable controlled substances received from suppliers, which according to Respondent Pharmacy's owner and PIC was zero because they ''had not received any controlled substances since the May 24, 2018 inspection.'' *Id.* at 15. DI then determined the number of applicable controlled substances that Respondent Pharmacy had accounted for by adding the controlled substances on hand during Respondent Pharmacy's April 3, 2019 inventory, RFAAX 40, to the sum of the applicable controlled substances distributed by Respondent Pharmacy, RFAAX 42 (Respondent Pharmacy's Dispensing Log from May 24, 2018 to April 3, 2019)[13]. RFAAX 47, at 15–16. DI then calculated the ''Total Difference,'' *see* RFAAX 46, which again revealed variances. RFAAX 47, at 16.

offered no evidence to contest these facts. *See* RFAAX 3.

DI also determined that Respondent Pharmacy failed to maintain one record of return. RFAAX 47, at 12. According to DI, Respondent Pharmacy ''maintained an invoice that had a handwritten note that indicated that these controlled substances were received on September 5, 2017, as set forth in [RFAAX] 26, [at] 2.'' *Id.* However, QK Healthcare Inc., verified that the product was initially lost in transit[, and] [w]hen it was finally found and delivered, [Respondent Pharmacy] no longer wanted it and it was returned to QK Healthcare Inc.'' *Id.; see also* RFAAX 32 (QK Healthcare Records of Return from Respondent Pharmacy). I reviewed the Respondent's records and agree with DI's determination. Respondent Pharmacy offered no evidence to contest these facts. *See* RFAAX 3.

Based on the evidence in the record, I find that Respondent Pharmacy generally maintained incomplete and/or inaccurate controlled substance records between October 24, 2016, and April 3, 2019, and specifically failed to properly maintain seven invoices and one return record.

2. Respondent Pharmacy's Candor During the Investigation

The Government has alleged that Respondent Pharmacy lacked candor during the course of DEA's investigation regarding its filling of fraudulent prescriptions and regarding various controlled substances hidden throughout the pharmacy.

a. Lack of Candor Regarding Filled Fraudulent Prescriptions

During the November 1, 2017 Inspection, DEA obtained a number of prescriptions that had been filled by Respondent Pharmacy and determined that they were fraudulent. RFAAX 47, at 5. In making that determination, DI interviewed Dr. C.K. regarding fifty-seven prescriptions issued in his name that DI obtained from Respondent Pharmacy during the inspection. *Id.* According to DI, ''Dr. [C.K.] reviewed the prescriptions and verified that they were not issued by him and that all were fraudulent.'' *Id.* According to DI, the ''prescriptions contained handwritten notes indicating that they had been verified by 'Donna Lavender' or 'Gloria.' '' *Id.* Dr. C.K. stated that ''he had no idea who Donna Lavender was,'' and that ''a woman named 'Gloria' worked in this office, . . . [but] she had not verified the prescriptions.'' *Id.* Based on this interview, DI determined that Respondent Pharmacy ''was filling fraudulent prescriptions that had been issued in Dr. [C.K.'s] name.'' *Id.*

During the May 24, 2018, follow-up inspection, DI ''observed a customer in the waiting area who was acting suspicious,'' while waiting for a prescription purportedly issued by Dr. S.S. to be filled. *Id.* Specifically, DI observed that the customer ''kept coming in and out of the pharmacy to ask about the status of her prescription'' and when she left the pharmacy, ''she would drive her car to the back of the parking lot and talk to someone in a black tinted Lincoln MKX with temporary tags.'' *Id.* at 5–6. DEA asked PIC Kumenda to demonstrate how she verified the validity of the customer's prescription. *Id.* at 6. According to DI, PIC Kumenda stated, that ''[s]he called the [phone] number on the prescription and talked with a person named 'Melissa,' who verified the prescription.'' *Id.* DEA then ''told PIC Kumenda to take additional steps to verify the contact information for the doctor, such as by looking at the Texas Medical Board . . . Website or doing a Google search.'' *Id.* According to DI, PIC Kumenda found a different phone number for Dr. S.S., and the doctor's office ''verified that the customer was not a patient and that no one named Melissa worked there.'' *Id.* DI and another diversion investigator then approached the customer in the waiting area and reported that the customer ''could not provide the exact location where Dr. S.S.'s office was located.'' *Id.* The customer then left the pharmacy and drove off, and ''[a] few minutes later, the black Lincoln also drove off.'' *Id.*

Also during the May 24, 2018, follow-up inspection, DI ''saw prescriptions allegedly issued by Dr. [C.K.].'' *Id.* Again, PIC Kumenda stated to DI, that ''she verified the prescriptions by the phone number on the prescription.'' *Id.* Again, PIC Kumenda did a Google search for Dr. C.K. and called the resulting phone number. *Id.* And, like before, Dr. C.K.'s office ''told PIC Kumenda that the prescriptions she had were fraudulent.'' *Id.*

According to DI, DEA then ''informed PIC Kumenda and Ms. Barry that [Respondent Pharmacy] was filling fraudulent prescriptions.'' *Id.* I find, that as of May 24, 2018, Respondent Pharmacy knew that it had been presented with and had filled fraudulent prescriptions that purported to be issued by Dr. C.K. *See* RFAAX 47, at 18. I further find that as of May 24, 2018, Respondent Pharmacy was aware of the correct phone number for Dr. C.K. to verify future prescriptions. *See Id.*

According to the Texas Prescription Monitoring Program (Texas PMP), Respondent Pharmacy went on to fill eight controlled substances prescriptions purportedly issued by Dr. C.K. on May 25, 2018 and May 26, 2018. *Id.* at 2–3. However, during the April 4, 2019 second follow-up inspection, PIC Kumenda informed DI, and Ms. Barry later confirmed, that Respondent Pharmacy had not ordered or dispensed controlled substances since the DEA inspection on May 24, 2018. RFAAX 47, at 6 and 8. I find that these statements lacked candor. After these representations, DI ''asked Ms. Barry to print out a dispensing log from May 24, 2018, to April 3, 2019.'' *Id.* at 8. According to DI, Ms. Barry then printed out a blank dispensing log that began on May 28, 2018. *Id.; see also* RFAAX 41. I find that in providing an incomplete dispensing log, Respondent Pharmacy lacked candor. DI stated that she noticed that the ''dispensing report was not for the complete date range'' and again requested and finally received a dispensing log starting May 24, 2018. RFAAX 47, at 8. This dispensing log showed that Respondent Pharmacy dispensed controlled substances for eight fraudulent [14] prescriptions purportedly issued by Dr. C.K. in the hours following DEA's last inspection. *Id.; see also* RFAAX 42.

However, contrary to the information contained in the Texas PMP and Respondent Pharmacy's own dispensing log, Ms. Barry informed DI that ''[SI] had returned to the pharmacy after the May 24, 2018 inspection and had taken the prescriptions[;] . . . the prescriptions were logged into the system, but were never filled.'' [15] RFAAX 47, at 8. I find that this statement lacked candor.

According to SI, his actions did not in any way interfere with Respondent Pharmacy's ability to fill the eight controlled substance prescriptions that Respondent Pharmacy reported to the Texas PMP that it filled. RFAAX 48, at

[14] DI contacted Dr. C.K. who stated that, with regard to the eight prescriptions purporting to have been issued by Dr. C.K. and presented to Respondent Pharmacy on May 25 and 26, 2018, none of the individuals were patients of his. *See* RFAAX 47, at 18; RFAAX 44. I agree with DI's determination that these eight prescriptions were fraudulent. *See* RFAAX 47, at 18. Respondent Pharmacy has not been charged with any violations related to dispensing these fraudulent prescriptions; however, the fact that the substantial evidence in the record shows these prescriptions were fraudulent, as Respondent Pharmacy no doubt knew or was willfully blind to, is relevant to my determination that Respondent Pharmacy lacked candor and impeded the investigation in a way that threatened public health and safety.

[15] Respondent Pharmacy repeated this assertion in its written response. RFAAX 3, at 2.

1–2. He also stated that shortly after the May 24, 2018 follow-up inspection, he was contacted by PIC Kumenda who asked him to ''pick up a handful of prescriptions that had been filled after the inspection.'' *Id.* at 2. SI retrieved prescriptions [16] from Respondent Pharmacy on May 31, 2018. *Id.* at 2. SI reported that on August 13, 2018, he returned to Respondent Pharmacy and, while there, obtained a dispensing record from Respondent Pharmacy, which reflected that the eight prescriptions purportedly issued by Dr. C.K. as discussed above ''had been filled.'' *Id.* at 2, 5.

I find that substantial evidence in the record establishes that Respondent Pharmacy lacked candor during DEA's investigation with regard to its filling of fraudulent prescriptions on May 25–26, 2018. Specifically, I find Respondent Pharmacy lacked candor first when it stated that it had not dispensed any controlled substances since May 24, 2018, then when it printed out a dispensing log that did not include the controlled substances dispensed from May 24 to May 26, 2018 (the exact dates on which the controlled substances at issue were dispensed), and finally when it represented that it did not fill the prescriptions logged in the dispensing log between May 24 and May 26, 2018.

b. Lack of Candor Regarding Hidden Controlled Substances

During the April 3, 2019 second follow-up inspection, DI requested that PIC Kumenda show the investigators all of the controlled substances at the pharmacy. *Id.* According to DI, PIC Kumenda took them to the back room where DI saw ''two hydrocodone 10/325 bottles on a black garbage bag that was spread out on the floor.'' *Id.* PIC Kumenda told DI that ''she had taken the hydrocodone bottles out because she was going to take an inventory.'' *Id.* DEA asked PIC Kumenda if those two bottles of hydrocodone ''were the only controlled substances on the premises, and she answered yes.'' *Id.* at 6–7. PIC Kumenda also showed DI two safes; DI ''looked in and confirmed that there were no drugs in the smaller of the two safes.'' *Id.* at 7. PIC Kumenda, unable to open the larger one, ''represented there were no drugs inside.'' *Id.* Everyone returned to the front of the pharmacy where DEA instructed Respondent Pharmacy to conduct a closing inventory of all controlled substances. *Id.* According to DI, PIC Kumenda then walked to the back of the pharmacy again.

When DI returned to the back room, she observed ''there now were three bottles of carisoprodol placed on the floor next to the hydrocodone.'' *Id.* DEA asked ''from where the carisoprodol bottles had come, [and] PIC Kumenda would not answer.'' *Id.* DEA asked PIC Kumenda ''if these were the only controlled substances at the pharmacy, and she affirmed that they were.'' [17] *Id.* Ms. Barry and Respondent Pharmacy's attorney arrived during the count. *Id.*

When PIC Kumenda finished counting, DEA compared her counts to the closing inventory from the prior inspection on May 24, 2018. *Id.* According to DI, ''[s]ince PIC Kumenda had confirmed to us that [Respondent Pharmacy] had not filled any controlled substances since that inspection, the counts should have matched up. They did not.'' *Id.* According to DI, ''Ms. Barry then informed [the DIs] that PIC Kumenda hides drugs in the pharmacy to avoid thefts, and instructed her to go back and find more drugs.'' [18] *Id.* PIC Kumenda returned with plastic sandwich bags containing alprazolam 2mg. *Id.* Thereafter, ''PIC Kumenda again affirmed'' that those ''were the only drugs on the premise.'' *Id.*

According to DI, the inventory was still short, so Ms. Barry ''again told PIC Kumenda to go and search for drugs in the back of the pharmacy.'' *Id.*[19] DI states that she ''witnessed PIC Kumenda pulling plastic sandwich bags containing drugs from various hiding places, including taped underneath the sink and inside of plastic bins mixed under papers/records.'' [20] *Id.* DI reports that PIC Kumenda ''went to the back of the pharmacy about four times, and each time came back out with additional drugs that she had hidden.'' *Id.* Eventually, PIC Kumenda completed the closing inventory. *Id.;* RFAAX 40 (Closing Inventory dated April 3, 2019).

I find that substantial evidence in the record establishes that Respondent Pharmacy lacked candor during DEA's investigation with regard to identifying the location of and quantity of the controlled substances it had on hand.

III. Discussion

The Government alleged that Respondent Pharmacy's registration should be revoked because Respondent Pharmacy committed acts, as detailed above, that would render its registration inconsistent with the public interest as defined in 21 U.S.C. 823(f). OSC, at 1. The gravamen of the Government's allegations and evidence in this case focuses on whether Respondent Pharmacy violated federal laws relating to controlled substances when it failed to properly complete and maintain certain records. *Id.* at 2–4. The Government also alleged that Respondent Pharmacy's representations to the DEA investigators during the investigation lacked candor in a way that impeded the investigation and threatened public safety. *Id.* at 4–7.

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.

[16] SI states that he has ''looked for and verified that [his] office does not currently have the eight (8) prescriptions'' identified in the Texas PMP, and he ''cannot confirm whether or not [those] prescriptions [were] among the ones [he] obtained on May 31, 2018.'' RFAAX 48, at 2.

[17] I note that PIC Kumenda made similar representations during the May 28, 2018 follow-up inspection. At that time DEA asked Respondent Pharmacy to show it all of the controlled substances it had in stock. RFAAX 47, at 5. According to DI, ''PIC Kumenda showed [DI] patient-ready bottles of controlled substances and stated those were all the controlled substances that the pharmacy had on hand.'' *Id.* Later, DI ''saw a box next to PIC Kumenda that contained additional controlled substances[, and] PIC Kumenda apologized for missing the box.'' *Id.*

[18] This factual assertion is repeated in Respondent Pharmacy's written statement. RFAAX 3, at 3.

[19] *See also* Respondent's written response, stating ''I turned to the pharmacist-in-charge and told her to go back and looked [sic.] for the medications because she hides controls like hydrocodone, Soma, Alprazolam in different places and ways. . . . [T]he agent again informed me that the hydrocodone is [short] as to the original count. . . . Again I instructed the pharmacist-in-charge to go and check in her hiding places she went and came back with the hydrocodone. . . .'' RFAAX 3, at 3.

[20] DEA took pictures of some of the drugs which are part of the record, including pictures of ''tablets of hydrocodone in plastic sandwich bags [or] wrapped up in a ball inside of a sheet of paper.'' *Id.;* RFAAX 37–39 (Pictures from April 3, 2019).

(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 (DC 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,[21] the Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks revocation of Respondent Pharmacy's registration based solely under Public Interest Factors Two, Four, and Five. I find that the Government's evidence with respect to Factors Two, Four and Five 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 failed to provide sufficient evidence to rebut the Government's *prima facie* case. Specifically, as to Factors Two and Four, I find that the record contains substantial evidence that Respondent Pharmacy violated multiple federal recordkeeping requirements, and as to Factor Five, I find the record contains substantial evidence that Respondent Pharmacy's owner and PIC lacked candor during the course of the DEA investigation into Respondent Pharmacy.

A. 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 employees. *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 Respondent Pharmacy committed several recordkeeping violations. The CSA 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 proper completion and maintenance of records. Specifically, the government alleged and established that Respondent Pharmacy did not properly document its inventories, did not properly complete multiple 222 Forms, failed to record the receipt date of Schedule III through V controlled substances, and failed to properly maintain invoices, records of returns, and other records. *Supra* Section II.D.1.

1. Inventory Documentation Failures

With regard to Respondent Pharmacy's May 25, 2016 biennial inventory, the Government alleged that Respondent Pharmacy failed to record whether the inventory was conducted at the beginning or end of the business day, in violation of 21 CFR 1304.11(a) and (c). 21 CFR 1304.11(c) requires respondents to ''take a new inventory of all stocks of controlled substances on hand at least every two years,'' and § 1304.11(a) provides that each biennial inventory ''be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.'' It is uncontroverted that Respondent Pharmacy failed to record on the May 25, 2016 biennial inventory, whether the inventory was conducted at the opening or closing of the business day. *Supra* Section II.D.1.a.

Regarding both the May 25, 2016 biennial inventory and Respondent Pharmacy's October 24, 2017 inventory, the Government alleged that Respondent Pharmacy failed to separate

[21] As to Factor One, there is no evidence in the record to suggest that Respondent Pharmacy did not have a Texas license, *see* RFAAX 1, at 3, and there is no evidence in the record of any recommendation from Respondent's state licensing board or professional disciplinary authority. 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration. . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15,230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011).

As to Factor Three, there is no evidence in the record 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, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

Schedule II controlled substances from Schedule III through V controlled substances in violation of 21 CFR 1304.04(h)(1). 21 CFR 1304.04(h)(1) states that registered pharmacies must maintain ''[i]nventories and records of all controlled substances listed in Schedule I and II . . . separately from all other records of the pharmacy.'' Here, it is uncontested that Respondent Pharmacy's May 25, 2016 biennial inventory and its October 24, 2017 inventory both comingled Schedule II controlled substances such as hydrocodone with Schedule III–V controlled substances such as alprazolam and carisoprodol. *Supra* Section II.D.1.a.

I find, therefore, that there is substantial record evidence that Respondent Pharmacy failed to properly prepare its inventory records and, therefore, violated 21 CFR 1304.04(h)(1) and 1304.11(a)&(c).

2. Improperly Completed 222 Forms

Next, the Government alleges and I find that Respondent Pharmacy, as a purchaser of controlled substances, failed to properly complete and execute multiple 222 Forms. First, 21 CFR 1305.12(a) requires purchasers to prepare and execute 222 Forms. As I have already found, four of Respondent Pharmacy's 222 Forms did not include required information, such as the number of packages, size of package, and name of item. *Supra* Section II.D.1.b. Second, 21 CFR 1305.12(b) required Respondent Pharmacy to note at the bottom of the Form 222 ''[t]he number of lines completed.'' I have already found that the ''Last Line Completed'' section was left blank on one of the 222 Forms at issue. *Supra* Section II.D.1.b. Third, under 21 CFR 1305.12(c), Respondent Pharmacy was required to include the ''name and address of the supplier from whom the controlled substances are being ordered'' on the 222 Forms, and I have found that information missing from one of the 222 Forms at issue. 21 CFR 1305.12(c); *supra* Section II.D.1.b. Fourth, 21 CFR 1305.12(d) provides that ''[e]ach DEA Form 222 must be signed and dated[,]'' and I have found that one of the 222 Forms at issue was not signed. *Supra* Section II.D.1.b.

The Government also alleged, and I find, that Respondent Pharmacy violated 21 CFR 1305.13(e). Under 21 CFR 1305.13(e), Respondent Pharmacy was required to ''record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.'' I have found that Respondent Pharmacy received controlled substances but failed to record the ''No. of Packages Received'' and ''Date Received'' sections corresponding to those controlled substances, on ten of the 222 Forms at issue. *Supra* Section II.D.1.b.

I find, therefore, that there is substantial record evidence that Respondent Pharmacy failed to properly complete and execute multiple 222 Forms in violation of 21 CFR 1305.12 and 1305.13(e).

3. Failure To Maintain Record of Receipt Date

The Government also alleged that Respondent Pharmacy violated 21 CFR 1304.21(a) and (d) and 1304.22(a)(2)(iv) and (c) when it failed to record the date it received controlled substance shipments. Under 21 CFR 1304.21(a), Respondent Pharmacy was required to maintain ''a complete and accurate record of each substance . . . received [or] sold, . . . and [of] returned mail-back package[s.]'' Under 21 CFR 1304.21(d), Respondent Pharmacy was required to maintain a record of the date each controlled substance was received, sold, or returned. For the purposes of controlled substances on Schedules III–V, the received date is generally recorded on invoices or packing slips. *See* 21 CFR 1304.21(d); *see also Rene Casanova, M.D.,* 77 FR 58,150, 58,153 and 58,161 (2012). 21 CFR 1304.22(c), which incorporates § 1304.22(a)(2)(iv) also requires that Respondent Pharmacy record the ''date of and number of units and/or commercial containers in each acquisition to inventory.'' 21 CFR 1304.22(a)(2)(iv).

I have already found that Respondent Pharmacy failed to record the receipt date for eight shipments of controlled substances on the accompanying shipment invoices or packing slips. *Supra* Section II.D.1.c. Respondent Pharmacy thus failed to comply with its obligation to maintain an accurate record of each controlled substance it received in violation of 21 CFR 1304.21(a) and (d) and 1304.22(a)(2)(iv) and (c).

4. Improper Maintenance of Records Including Invoices and Returns

Also relevant to Factors Two and Four, Respondent Pharmacy is required to ''maintain, on a current basis, a complete and accurate record of each substance . . . received, sold, delivered, . . . or otherwise disposed of by [it], and each . . . unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.'' 21 CFR 1304.21(a). As previously discussed, Respondent Pharmacy's records related to the receipt of Schedule III–V controlled substances were generally recorded on invoices or packing slips which were maintained by the pharmacy. RFAAX 20–22, 24, 26–28; 21 CFR 1304.21(d). Respondent Pharmacy kept records of controlled substances it sold or distributed in both electronic and handwritten prescription logs. RFAAX 16–19; 21 CFR 1304.22(c). DI declared that using Respondent Pharmacy's records, she ''conducted accountability audits that revealed that [Respondent Pharmacy] failed to keep complete and accurate records of controlled substances maintained.'' RFAAX 47, at 13; *supra* Section II.D.1.d. More specifically, the audit revealed that Respondent Pharmacy had surpluses and shortfalls of various controlled substances and demonstrated that not all ''controlled substances [were] accounted for in [Respondent Pharmacy's] records and physical inventory.'' RFAAX 47, at 14; *supra* Section II.D.1.d.

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). In short, what matters to the public interest inquiry is the fact that Respondent could not account for a significant number of controlled substances by adequate documentation. *Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy,* 76 FR 51,415, 51,416 (2011).

Here, the Government took the additional step of identifying in evidence some of the specific documentation that Respondent Pharmacy was not able to produce. DI ''cross-verified records maintained by [Respondent Pharmacy] ([RFAAX] 20–28) with those obtained from the various suppliers ([RFAAX] 29–32).'' *Id.* This effort established, as I found above, that Respondent Pharmacy failed to maintain invoices or perchance orders documenting the receipt of seven

Schedule III–V [22] controlled substance orders. *Supra* Section II.D.1.d. I further found that Respondent Pharmacy failed to maintain a record of return. *Id.*

In short, through both the audit which generally established that Respondent Pharmacy was missing records and through specifically identified missing records, I find that Respondent Pharmacy failed to comply with its obligation to maintain complete and accurate records in violation of 21 CFR 1304.21(a).

B. Factor Five

Under Factor Five, the Administrator is authorized to consider ''[s]uch other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). Although Factor Five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,141 (2012) (citing *Tony T. Bui,* 75 FR 49,979, 49,988 (2010)). ''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest.'' *Jerri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (internal citations and quotations omitted); *see also David A. Hoxie, M.D.,* v. *Drug Enf't Admin.,* 419 F.3d 477, 483 (6th Cir. 2005). It is appropriate to consider lack of candor allegations under Factor Five when the alleged conduct raises a probable or possible threat to public safety. *See e.g. Annicol Marrocco, M.D.,* 80 FR 28,695, 28,705 (2015) (analyzing under Factor Five the allegation that respondent's testimony regarding prescriptions issued to a particular individual, including prescriptions issued following a claim that the individual's pet monkey opened the bottle and threw the pills in the pool, lacked candor); *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5494–95 (2019) (analyzing under Factor Five allegations of an attempt to mislead DEA investigators, but declining to analyze a simple statement of opinion made by the respondent under factor five); *Island Wholesale, Inc.,* 68 FR 17,406, 17,407 (2003) (analyzing under Factor Five the allegation that respondent provided a false customer list to DEA investigators). The Government alleged that Respondent Pharmacy's lack of candor is ''inconsistent with the public interest'' and constitutes ''other such conduct which may threaten the public health and safety.'' RFAA at 15 (*citing* 21 U.S.C. 823(f)(5)). I agree and find that Respondent's alleged lack of candor impeded a DEA investigation.

The Respondent Pharmacy lacked candor with regard to the fraudulent prescriptions filled between May 25, 2018, and May 26, 2018. As I found above, Respondent Pharmacy took multiple steps to conceal its filling of prescriptions that it clearly knew or should have known were fraudulent. *Supra* Section II.D.2. Respondent Pharmacy initially provided a distribution log, omitting material portions of the requested timeframe, that supported the Pharmacy's narrative that it had not filled any prescriptions since DEA's prior inspection. *Id.* And then when the pharmacy's own records showed that prescriptions it should have known to be fraudulent were filled, Respondent Pharmacy attempted to contradict its records by saying that SI had taken the prescriptions and they were not filled. *Id.* There can be no question here that Respondent Pharmacy lacked candor.[23] Further, lack of candor during a DEA investigation about filling fraudulent prescriptions constitutes a threat to the public health and safety.

Additionally, the OSC alleged that during the May 24, 2018 inspection, Respondent Pharmacy falsely stated that all controlled substances had been identified when controlled substances were actually still hidden throughout the pharmacy. As I have found, PIC Kumenda informed DEA that she had counted all of the controlled substances in Respondent Pharmacy's inventory. *Supra* Section II.D.2. But when DEA identified discrepancies in the May 24, 2018 inventory, Ms. Barry stated that ''PIC Kumenda hides drugs in the pharmacy to avoid thefts, and instructed her to go back and find more drugs.'' *Id.* On multiple occasions thereafter, PIC Kumenda located more controlled substances throughout the pharmacy in sandwiches bags or wrapped up in wadded paper, represented to DEA that she had now identified all of Respondent Pharmacy's controlled substances. *Id.* However, she was still able to find more upon discovering that discrepancies remained. *Id.*

''[A] DEA registrant is obligated at all times to act in the public interest.'' *Peter F. Kelly, D.P.M.,* 82 FR 28,676, 28,688 (2017). Respondent Pharmacy's layered efforts to conceal its filling of known fraudulent prescriptions and to physically hide controlled substances that were not immediately locatable for DEA's investigation actively impeded DEA's investigation. I find that Respondent Pharmacy impeded DEA's investigation and in doing so, threatened public health and safety.

C. Summary of the Public Interest Factors

As found above, Respondent Pharmacy violated numerous federal record keeping requirements related to controlled substances and lacked candor. 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, 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

[22] 21 CFR 1305.13(e) explicitly requires that the receipt date for Schedule II controlled substances be recorded on the Form 222 order form. I do not see a requirement that an invoice containing only Schedule II controlled substances has to be maintained. *Morning Star Pharmacy and Medical Supply 1,* 85 FR 51,045, 51,049 (2020) (''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.'').

[23] I have found that the substantial evidence in the record shows that the Respondent Pharmacy's owner lacked candor when she told DI that the fraudulent prescriptions had not been filled (in effect finding that Respondent Pharmacy's records saying the prescriptions were filled were more reliable than the owner's representations). *Supra,* II.D.2. However, if *arguendo* Respondent Pharmacy did not actually fill the fraudulent prescriptions, then Respondent Pharmacy made a misrepresentation to the Texas PMP in reporting them as filled. Either way, Respondent Pharmacy lacked candor with regard to the filling (or not) of these fraudulent prescriptions.

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.'').

Here, Respondent Pharmacy has presented no evidence on the record that I could consider as accepting responsibility. I have considered the written response, which denies any misconduct, stating multiple times that it ''would be impossible'' for ''the medications [to be] short of the original count[s],'' and asserting that ''we were far from deceit when we talked to [DEA].'' RFAAX 3, at 2–3. The written response further seems to pass blame for the findings of violations against Respondent Pharmacy onto the DEA—claiming that DEA ''raided the pharmacy,'' on a ''witch hunt waged against [Respondent] Pharmacy'' arising from ''hatred toward the owner.'' *Id.* at 2. It is clear from the written response that Respondent Pharmacy has not accepted responsibility for its actions.

I have also considered the proposed Corrective Action Plan that the Government submitted into the record. RFAAX 4. The proposed Corrective Action Plan does not include any acceptance of responsibility; rather it proposes policies that essentially mirror the requirements already existing in law. *Id.* Even if I were to consider remedial measures, in spite of Respondent Pharmacy's complete lack of acceptance of responsibility, these proposed remedial measures are insufficient to convince me to entrust Respondent Pharmacy with a registration. 21 U.S.C. 824(c)(3); *see also Melanie Baker, N.P.,* 86 FR 23,998, 24,011 (2021) (*citing Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,202–03 2016).

Moreover, Respondent Pharmacy's found lack of candor during the investigation demonstrates an unwillingness to cooperate with this agency in future compliance inspections. Truthful cooperation with agency requests for information ensures that agency officials can easily monitor and ensure compliance with the CSA and help to correct violations. *See Jeffrey Stein, M.D.,* 84 FR 46,968, 46,973 (2019) (finding that a registrant's honesty during law enforcement regulations is ''crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population''). In order to entrust Respondent Pharmacy with a registration, I need to know that its personnel will not repeat their dishonest behavior, and in this case, Respondent Pharmacy has given me no reason to believe that I can trust it with a registration.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent Pharmacy's egregious behavior is not likely to recur in the future such that I can entrust it with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction. Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

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 FL4375730 issued to Creekbend Community Pharmacy. 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 Creekbend Community Pharmacy to renew or modify this registration. This order is effective August 27, 2021.

Anne Milgram,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

William Ralph Kinkaid, M.D.; Decision and Order

On November 7, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to William Ralph Kinkaid, M.D. (hereinafter, Respondent), of Johnson City, Tennessee. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration, Control No. W18085586C, because Respondent was ''mandatorily excluded . . . from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a)'' and that such exclusion ''warrants denial of [Respondent's] application pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 1–2 (citing *Richard Hauser, M.D.,* 83 FR 26,308 (2018)).

Specifically, the OSC alleged that, on June 24, 2013, the United States District Court for the Eastern District of Tennessee (hereinafter, E.D. Tenn.) issued a judgment against Respondent ''after [Respondent] pled guilty to one count of 'Receiving in Interstate Commerce a Misbranded Drug with Intent to Defraud or Mislead,' in violation of 21 U.S.C. 331(c).'' *Id.* at 2 (citing *U.S.* v. *William Ralph Kinkaid,* No. 2:12–CR–116 (E.D. Tenn. June 24, 2013)). The OSC further alleged that ''based on [Respondent's] conviction, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), mandatorily excluded [Respondent] from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a)'' effective June 28, 2013, for a period of ten years. *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each