DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—CHEDE–8

Notice is hereby given that, on August 10, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), CHEDE–8 (''CHEDE–8'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Borgwarner Inc., Auburn Hills, MI, and Toyota Industries Corporation, Aichi, JAPAN have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CHEDE–8 intends to file additional written notifications disclosing all changes in membership.

On December 4, 2019, CHEDE–8 filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 30, 2019 (84 FR 71977).

The last notification was filed with the Department on April 21, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 6, 2020 (85 FR 26988).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–18978 Filed 8–27–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Source Imaging Consortium

Notice is hereby given that, on August 19, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Source Imaging Consortium, Inc. (''Open Source Imaging Consortium'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Brainomix Ltd., Oxford, UNITED KINGDOM, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Open Source Imaging Consortium intends to file additional written notifications disclosing all changes in membership.

On March 20, 2019, Open Source Imaging Consortium filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 12, 2019 (84 FR 14973).

The last notification was filed with the Department on May 18, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 2, 2020 (85 FR 33733).

Suzanne Morris,

Chief, Premerger and Division Statistics Antitrust Division.

[FR Doc. 2020–18983 Filed 8–27–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Institute of Electrical and Electronics Engineers

Notice is hereby given that, on August 4, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Institute of Electrical and Electronics Engineers (''IEEE'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 49 new standards have been initiated and 9 existing standards are being revised. More detail regarding these changes can be found at: *https://standards.ieee.org/about/sasb/sba/june2020.html.*

On February 8, 2015, the IEEE Board of Directors approved an update of the IEEE patent policy for standards development, which became effective on 15 March 2015. The updated policy is available at *http://standards.ieee.org/develop/policies/bylaws/approved-changes.pdf* and, from the effective date, will be available at *http://standards.ieee.org/develop/policies/bylaws/sect6-7.html.*

On September 17, 2004, IEEE filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 3, 2004 (69 FR 64105).

The last notification was filed with the Department on May 27, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 26, 2020 (85 FR 38391).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division, Department of Justice.

[FR Doc. 2020–18982 Filed 8–27–20; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 16–33]

Heavenly Care Pharmacy; Decision and Order

On August 3, 2016, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration issued an Order to Show Cause (''OSC'') to Heavenly Care Pharmacy (hereinafter, Respondent or Respondent Pharmacy), which sought to revoke Respondent's DEA Certificate of Registration FH4377291, at the registered location of 617 9th Ave., Bessemer, Alabama, and to deny any pending or current applications for renewal or modifications of FH4377291. Administrative Law Judge Exhibit (ALJX) 1 (OSC), at 1–2, 7 (citing 21 U.S.C. 823(f), 824(a)(4)). The OSC alleged that Respondent's continued registration is inconsistent with the public interest. *Id.* at 1. Specifically, the OSC alleged that Respondent (1) failed to exercise its corresponding responsibility to assess the legitimacy of prescriptions that it filled in violation of 21 CFR 1306.04(a) and failed to dispense controlled substances within the bounds of the pharmacy profession in violation of 21 CFR 1306.06, *id.* at 2; (2) failed to maintain certain records required under federal and Alabama

state law and have them available for inspection, *id.* at 5–7 (citing 21 CFR 1304.11(a) and (b); 1304.11(e)(1)(iii) and (iv); 1304.11(e)(6); 1304.21(a); and 1305.04(a)); and (3) inaccurately reported its dispensing data to the Alabama Prescription Drug Monitoring Program (PDMP), which the OSC alleged ''clearly constitutes 'such other conduct which may threaten the public health and safety' that counsels against [Respondent's] maintenance of a DEA registration,'' *id.* at 7 (citing 21 U.S.C. 823(f)(5)). The Government also alleged via its Supplemental Prehearing Statement that Respondent provided materially false responses in a registration renewal application filed on September 8, 2016. ALJX 16, at 1.

In a letter from its counsel dated September 7, 2016, Respondent requested a hearing on the allegations. ALJX 2. The matter was placed on the docket of the Office of the Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ). Prehearing proceedings were initiated, ALJX 3, and the Government filed a Prehearing Statement, ALJX 4; however, the case was terminated on October 13, 2016, due to the Respondent's non-compliance with the Chief ALJ's orders, ALJX 3, 5–7. On June 15, 2017, the Acting Administrator of the DEA issued an order remanding the matter to the Office of the Administrative Law Judges for a hearing. ALJX 12. The case was reassigned to ALJ Mark M. Dowd. ALJX 21.

Respondent filed a Prehearing Statement and the Government filed a Supplemental Prehearing Statement on July 19, 2017. ALJX 16 and 17. The ALJ issued an order with a consolidated list of the parties' stipulations on August 2, 2017, ALJX 23, and a hearing was conducted on August 29–31, 2017, in Birmingham, Alabama, ALJX 14. Both the Government and the Respondent filed Posthearing Briefs.

On November 6, 2017, the ALJ issued and served his recommended decision, which included the ALJ's recommendation that I revoke Respondent's registration and deny its pending application for renewal. Recommended Decision (hereinafter, RD), at 61. Neither the Government nor Respondent filed exceptions to the ALJ's RD, and the record was forwarded to me for final agency action.

Having considered the record in its entirety, I agree with the RD that the record established, by substantial evidence, two independent grounds for the revocation of Respondent's registration: (1) Respondent's continued registration is inconsistent with the public interest; and (2) Respondent materially falsified its renewal application. I further agree with the RD that Respondent's acceptance of responsibility is insufficient and that, even if it were sufficient, Respondent did not offer adequate remedial measures.

Accordingly, I conclude that the appropriate sanctions are (1) for Respondent's DEA Registration FH4377291 to be revoked; and (2) for any pending application by Respondent to renew or modify its registration be denied. I make the following findings.

I. Findings of Fact

A. Respondent's DEA Registration

Respondent Heavenly Care Pharmacy holds DEA registration FH4377291, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy at the registered location of 617 9th Ave. N., Bessemer, Alabama 35020. RD, at 7. The registration was set to expire on October 31, 2016, but Respondent submitted a timely renewal application on September 8, 2016.[1] *Id.*

Respondent's answers on the renewal application were certified as true and correct by Santonia Davison, Respondent Pharmacy's owner/proprietor and Pharmacist-in-Charge (PIC) (hereinafter, PIC Davison). Government Exhibit (hereinafter, GX) 26, at 1; Transcript (hereinafter, Tr.) 693. On the renewal application, Respondent answered ''No'' to the question ''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?'' GX 26, at 1; Tr. 214. I find by clear, unequivocal, and convincing evidence that Respondent's answer was false because Respondent acknowledged that it was served the OSC on August 9, 2016. *See* ALJX 2, at 1.

B. The Investigation of Respondent

1. Forgery Investigation

In October 2014, a Diversion Investigator (hereinafter, DI One) and a Birmingham Police Department Sergeant (hereinafter, Police Sergeant) were working a prescription forgery ring, which involved approximately ten pharmacies, including the Respondent Pharmacy.[2] Tr. 130–31, 138–39, 814–16. Prescription pads had been stolen from The University of Alabama Medical Center (UAB) and were being forged to obtain controlled substances. *Id.* at 135, 231–32.

Along with the Police Sergeant, DI One proceeded to the Respondent Pharmacy to obtain hard copies of the forged prescriptions filled there. *Id.* at 131, 234; GX 6. Of the ten pharmacies involved in the investigation, DI One testified that Respondent Pharmacy had the most forged prescriptions filled—at least seven during a two-week time frame. Tr. 138–39, 233–35. While there, PIC Davison notified the Police Sergeant and DI One that one of the forged prescriptions had only been partially filled, and that the individual was expected to return shortly to fill the remainder of the prescription. *Id.* at 133, 816–19. When the subject individual sought to fill the remainder of the prescription, he was arrested by the Police Sergeant and removed to a back room at the pharmacy for questioning. *Id.* at 134, 817–18. Again with PIC Davison's assistance, two other individuals were questioned at the Respondent Pharmacy in connection with the forgery ring that day. *Id.* at 134, 586–87, 817–18.

2. Administrative Inspection

On May 20, 2015, DEA Investigators executed an Administrative Inspection Warrant (AIW) at Respondent. GX 1, at 4; Tr. 30. The lead Diversion Investigator for the audit (hereinafter, DI Two)[3] presented the AIW to PIC Davison. Tr. 30. DI Two was accompanied on the inspection by another diversion investigator, a DEA intelligence analyst, two local police officers, and two Alabama Board of Pharmacy investigators. *Id.* at 30, 31. DI Two testified that when she entered the pharmacy there were papers everywhere ''like someone had turned on a fan in there'' and that there was trash on the counter. *Id.* at 32.

During the inspection, the investigators requested Respondent's ''initial inventory,'' the annual inventory required by the State of Alabama, controlled substance ordering records, controlled substance receipt records, and records accounting for all controlled substances dispensed from the pharmacy, to date. *Id.* at 31–34, 83. DI Two testified that she requested these records for two reasons: (1) To audit the

[1] The status of a registration under an OSC, such as Respondent's, does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019).

[2] DI One has been a DEA Diversion Investigator since July 2012. She was assigned to the Birmingham DEA Office in September 2012. Tr. 129.

[3] DI Two has been a DEA diversion investigator since February 2011. Tr. 24, 25. DI Two is assigned to investigate DEA registrants, and in that capacity, typically inspects ten to twelve pharmacies a year. Tr. 25–26.

number of controlled substances—the drugs entering and leaving the pharmacy; and (2) to review the records for completeness. *Id.* at 34

PIC Davison was unable to produce an initial inventory of the controlled substances at the pharmacy to DI Two. *Id.* at 32–33. During the hearing, she testified that she did not know that she was required to have an initial inventory, *id.* at 543, but conceded that the Pharmacy Manual, which she studied in pharmacy school and used in developing her policies and procedures, contained a detailed explanation of the initial inventory report requirements, *id.* at 700. PIC Davison was also unable to produce the annual inventory required by the state to be completed on January 15, 2015, *id.* at 33, and during the hearing she stated that she could not produce the inventory record because she did not complete the inventory on January 15, 2015, *id.* at 714.

PIC Davison did produce records during the inspection for the ordering, receipt, and dispensation of controlled substances. For Schedule II substances, Respondent ordered drugs using both DEA Form 222s and through an electronic Controlled Substance Ordering System (CSOS). *Id.* at 35, 46–49, 562. DI Two testified that fifteen of Respondent's DEA Form 222s lacked documentation to evidence the receipt of the number of packages received and the date received, Tr. 46–48; GX 3, and that Respondent had failed to record that it had received the ordered drugs for sixteen orders in Respondent's CSOS, Tr. 35–36, 98–99; GX 2. DI Two acknowledged that documentation of receipt would not exist for drugs that were ordered and not received, Tr. 48–49, and that there was no set amount of time in which a pharmacy must record receipt on a DEA Form 222 or in the CSOS, *id.* at 40–42, but expressed doubt that the orders were not received, because they dated back to 2014 and the pharmacist had not written ''VOID'' on the DEA Form 222s, *id.* at 36–37, 43–44, 48–49. PIC Davison confirmed that Respondent Pharmacy had, in fact, received the orders. *Id.* at 92, 564–65.

DI Two testified that she also found the records for Respondent's orders of schedule III–V controlled substances to be incomplete because they did not indicate the date or the amount received. *Id.* at 50; GX 4. On some of the receipt invoices, Respondent had circled the quantity shipped, which DI Two inferred could indicate the amount received was correct, but on other receipt invoices, there were no circled quantities. Tr. 50–51; GX 4. PIC Davison did sign the invoices, which she testified she did to document receipt of the order and confirm that the quantity and date listed on the invoice were correct. Tr. 578; GX 4.

DI Two further testified that, in her experience, it was unusual to find such a large number of record-keeping discrepancies at a new pharmacy, such as Respondent Pharmacy. Tr. 112. She stated that the paperwork at newer pharmacies is generally very compliant and that, in general, it is not until a pharmacy is busier that the record-keeping becomes ''sloppier.'' *Id.* at 112–13.

As part of executing the AIW, DI Two completed a closing inventory (count) of the generic versions of six controlled substances—hydrocodone 10/325, hydrocodone 7.5/325, promethazine with codeine cough syrup, oxycodone 10/325, oxycodone 15, and oxycodone 30. *Id.* at 34, 115, 120–21. Using Respondent's receipt and dispensation records, the DI conducted an audit of Respondent's handling of these six controlled substances. *Id.* at 34. These records included Respondent's DEA Form 222s, CSOS records, schedule III–V receipt invoices, and dispensation records printed by PIC Davison from her electronic system and provided to the investigators. Tr. 55–57, 555–57; GX 27. DI Two stated that for the purposes of the audit, she assumed all drug orders had been received by the pharmacy even though, as described above, Respondent had not documented receipt of all orders. Tr. 53. DI Two's audit found both shortages and overages among the six drugs, including a 22% shortage of oxycodone 10/325 and a 92% overage of hydrocodone 7.5/325. GX 5.[4]

Respondent disputes the accuracy of DI Two's audit. Tr. 551–57. PIC Davison testified that she completed her own closing inventory of the six controlled substances on May 20, 2015, and had a different count than DI Two's for five of the six drugs. Tr. 551–52; GX. 7, at 3. PIC Davison also testified that she believes DI Two's tabulations for the amounts distributed for five of the six drugs were inaccurate, because they were based on an incorrect report that PIC Davison provided at the inspection. Tr. 553–57. PIC Davison stated that she did not know how to run the report in her computer system for the information that DI Two requested, and it was not until July 6, 2015, that PIC Davison ran the ''correct'' report, on which she based her own tabulations.[5] Tr. 555, 561; GX 7, at 3. PIC Davison does not dispute that the July 6 report, which she claims to be the report that should have been used for the audit, was not available to the DEA Investigators during the inspection of Respondent Pharmacy. Tr. 561.

DI Two returned to the Respondent Pharmacy on May 21, 2015, to discuss with PIC Davison each regulatory violation, the audit discrepancies that DI Two discovered, and instructions regarding steps to correct these violations. *Id.* at 62–64, 81, 85, 112.[6] DI Two did not recall any explanation by PIC Davison for the regulatory violations or audit discrepancies discussed. *Id.* at 63–64.

The ALJ found, and I agree, that the testimony of DI Two regarding the execution of the AIW, the audit, and all other aspects of her testimony was fully credible. RD, at 13.

3. July 6, 2015 Meeting

DI One reviewed the results of the AIW at Respondent Pharmacy and invited PIC Davison to attend a meeting on July 6, 2015, at the Birmingham DEA Office with DI One, two of DI One's supervisors, and two investigators from the Alabama Board of Pharmacy, including its Chief Investigator, to discuss bringing the Respondent Pharmacy ''into compliance'' with the relevant regulations and professional standards. Tr. 143–44. The officials contemplated entering into a Memorandum of Agreement (MOA) with Respondent Pharmacy for what was essentially a probationary period in which the DEA would agree not to seek

[4] DI Two explained that a shortage occurs when a pharmacy cannot account for drugs received, *i.e.,* the drug is not in the pharmacy's inventory but there is no record of it being dispensed or otherwise leaving the pharmacy, and an overage reflects the presence of controlled substances in the pharmacy's inventory in excess of the recorded amount received. Tr. 58.

[5] PIC Davison's own tabulations using the July 6 report still showed a shortage for one and overages for three of the six audited drugs. GX 7, at 3. At the hearing, after seeing the July 6 report and PIC Davison's tabulations, DI Two testified that she believed at least one of PIC Davison's tabulations was incorrect. Tr. 823–24.

[6] DI Two testified that after the May 21, 2015 conversation with PIC Davison she had no other interaction with the Respondent Pharmacy. Tr. 65. However, DI Two did learn through DI One that PIC Davison believed that either DI Two or one of the individuals on the day of the AIW took with them a notebook that had the missing records, or improperly kept records from it. *Id.* at 66. DI Two testified that this was not possible, as the alleged notebook had been reviewed multiple times on May 20, 2015. *Id.* at 66. Moreover, DI Two did not believe that a notebook that had been taken from the Respondent Pharmacy contained any missing/incomplete records as DI Two and the other investigators spent five to six hours in the Respondent Pharmacy, and the Respondent Pharmacy was not very large, and DI Two believed that if the record was there, it would have been found. *Id.* at 68. Moreover, DI Two stated that everything taken from the Respondent Pharmacy was recorded in Government Exhibit 1. *Id.* at 69; *see* GX 1.

sanctions as long as the Respondent Pharmacy cooperated with the DEA to bring the Respondent Pharmacy into compliance. *Id.* at 144–45. At some point during the meeting,[7] the officials decided that an MOA would not be appropriate, and that proceedings would be initiated to pursue revocation of the Respondent Pharmacy's registration. *Id.* at 144. DI One explained that this decision was reached because PIC Davison did not concede that the reported violations had occurred, deflected direct questions, and wished to dispose of the matter by simply paying a fine. *Id.* at 145–47.

PIC Davison testified that she learned about the requirement to have an initial inventory during the July 6 meeting and, after the meeting, went to the pharmacy to look through her records and ''see if [she] could find perhaps what they could be looking for.'' *Id.* at 543–44. PIC Davison found a ''Narcotics Sales Report'' generated from Cardinal Health, Respondent Pharmacy's sole pharmaceutical distributor, which listed Respondent's controlled substance purchases from May 1 to May 31, 2014, and which PIC Davison thought was ''as close to what they were explaining to me I should have [for an initial inventory].'' *Id.* at 544–45. PIC Davison then handwrote ''Initial Inventory'' on the report. *Id.* at 545.

The next morning, July 7, 2015, at 1:54 a.m., DI One received an email from PIC Davison explaining that her ''initial inventory'' had been in a three-ring binder that had been ''retrieved'' by one of the DEA Agents during the May 20, 2015, inspection.[8] Tr. 149–50. The email included a two-page attachment, the ''Narcotics Sales Report,'' which PIC Davison purported to be the Respondent Pharmacy's ''initial inventory.'' Tr. 151; GX 7, at 58–59. DI One suspected that the report was produced on the evening of July 6, 2015.[9] Tr. 150–53, 246–48, 253. The ''Narcotics Sales Report'' included a list of the schedule III through V controlled substances procured by the Respondent Pharmacy from Cardinal Health from May 1, 2014, through May 31, 2014. Tr. 151–55; GX 7, at 58–59. The Respondent Pharmacy opened for business on May 26, 2014. Besides perhaps not being a timely report—that is, not created at the time the Respondent Pharmacy began dispensing controlled substances, Tr. 151–156—DI One opined that it was not a fully compliant initial inventory report, as it lacked several other necessary elements. It did not include the initial inventory of schedule I and II controlled substances. It also lacked a specific date and whether it was taken at the open or close of business on that date. *Id.* at 154, 250.

4. DI One's Investigation

Sometime following the July 6, 2015 meeting with PIC Davison, DI One received a call from a local Alabama doctor, (hereinafter, Dr. F.), complaining that the Respondent Pharmacy had filled a prescription and attributed it to him (Dr. F.) in the Alabama Prescription Drug Monitoring Program, PDMP, which the doctor denied prescribing. *Id.* at 157–59. To investigate the matter further, DI One retrieved the PDMP report for the subject prescription and a PDMP report for the Respondent Pharmacy from August 2014-August 2015, revealing all controlled substances dispensed by the Respondent Pharmacy during that period. *Id.* at 159–60; *see* GX 8. DI One further retrieved the original prescription from the Respondent Pharmacy, which identified a different doctor as the prescriber, yet the Respondent Pharmacy label incorrectly identified Dr. F. as the prescriber. Tr. 162–68; see GX. 9.

Using the August 2014-August 2015 PDMP report, DI One located two other instances where the wrong doctor was identified as the prescriber in the subject Respondent Pharmacy PDMP report. *Id.* at 170–71. DI One also found instances where duplicate prescriptions were entered into the PDMP. *Id.* at 172–73; *see* GX 10, at 36. DI One additionally identified a twenty-one day period in which no controlled substance prescriptions were entered into the PDMP by the Respondent Pharmacy, yet nearly 100 prescriptions were filled there during that period. Tr. 174; *see* GX 10, at 36. These discrepancies prompted DI One to retrieve a number of original prescriptions from the Respondent Pharmacy. Tr. 180–81; *see* GX 11–17, 28.

DI One also testified regarding the two administrative subpoenas the DEA issued to Respondent. Tr. 197. The first was issued on February 16, 2016, and requested any documentation on prescriptions for specific patients, specific prescribers, and patients and prescribers that met certain characteristics. GX 18. Respondent replied to this subpoena with a single document describing Respondent's interactions with and knowledge of the patients and prescribers in narrative, summary form. GX 19. The DEA issued a second subpoena on May 6, 2016, requesting ''any and all documents or records (paper or electronic) reflecting efforts by pharmacists at Heavenly Care Pharmacy to exercise their corresponding responsibility to assess the prescriptions for controlled substances they were asked to fill or dispense from March 1, 2013, through December 31, 2015.'' GX 20. The subpoena was delivered to Respondent's counsel along with a letter clarifying that the DEA was not asking Respondent to ''create documents that do not already exist'' but rather was seeking ''contemporaneous documents or records that fit the description provided in the subpoena.'' *Id.; see* Tr. 202. DI One testified that the DEA served the second subpoena because it wanted to be sure that Respondent ''provided any and all documentation regarding patient profiles of dispensing controlled substances to the specific patients and prescribers on the administrative subpoena.'' Tr. 204. Respondent replied to this subpoena with printouts of patient profiles that Respondent kept in its computer system regarding the patients identified by the DEA. GX 22; *see* Tr. 209–10. DI One provided Respondent's responses to the subpoenas to Dr. Alverson to use in her review. Tr. 197.

The ALJ found, and I agree, that, although DI One reported some memory lapse regarding uncritical aspects of the investigation, her testimony was credible in all relevant respects. RD, at 15.

C. Testimony of Dr. Susan Alverson

1. Dr. Alverson's Credentials

Dr. Susan Alverson, a licensed pharmacist for forty-nine years, has been the Executive Secretary for the Alabama Board of Pharmacy for the preceding four years. Dr. Alverson was qualified as an expert in retail pharmacy and the standards for retail pharmacists under both Alabama and federal law and regulations. *Id.* at 309–12. The ALJ found that Dr. Alverson testified convincingly as an expert witness and Respondent conceded Dr. Alverson is a renowned expert. RD, at 20.

2. Auburn University Encounter

Prior to offering her expert opinion testimony, Dr. Alverson testified as a fact witness regarding an encounter she had with PIC Davison approximately

[7] DI One could not remember how long into the meeting the decision was made to move for revocation, and Counsel for the Respondent Pharmacy suggested the meeting only lasted perhaps 90 seconds; however, PIC Davison later suggested the meeting lasted at least 30–40 minutes. Tr. 549.

[8] PIC Davison later explained to DI One that the initial inventory had been picked up by a DEA Agent during the May 20, 2015 audit, and was not discovered by PIC Davison until later that evening. Tr. 258.

[9] The time of the document's creation was suggested to the Government by review of other documents apparently created coincident to the subject document. Tr. 150–56.

one month prior to the hearing. Tr. 313. Dr. Alverson was at Auburn University for a continuing education program. Following the program, Dr. Alverson was approached by PIC Davison, one of Dr. Alverson's former students at Samford University. *Id.* at 313–316. PIC Davison told Dr. Alverson that DEA wanted to ''take [her] license.'' *Id.* at 315–16. PIC Davison began to explain the circumstances of her situation to Dr. Alverson. She explained, in essence, that patients from a nearby pharmacy who appeared to be addicted to prescription drugs had gravitated to her pharmacy. *Id.* PIC Davison suggested she could not ''just cut them off and leave them with no options.'' *Id.* at 317. PIC Davison also voiced her concern to Dr. Alverson about disparate treatment of black patients by the medical/pharmaceutical establishment and law enforcement. *Id.*

On cross-examination, Dr. Alverson conceded PIC Davison's comments may have been less exacting. Dr. Alverson testified that it was possible PIC Davison did not use the word ''addicted'' and may have instead said that the subject patients were receiving the same medication from another pharmacy before coming to Respondent Pharmacy and that ''[w]hatever problems they had when they got to [Respondent Pharmacy], they had those problems before they got to [Respondent Pharmacy].'' *Id.* at 329–30.

Dr. Alverson was unaware of the name of the pharmacist involved in her review of Respondent Pharmacy (and therefore did not immediately connect PIC Davison to Respondent Pharmacy), but as their conversation progressed, Dr. Alverson recognized the circumstances described by PIC Davison as involving the instant investigation. *Id.* PIC Davison then reported that she had read Dr. Alverson's statement on the matter. Dr. Alverson advised PIC Davison to confer with PIC Davison's attorney for advice, and took her leave. *Id.* at 316–17.

The ALJ found, and I agree, that Dr. Alverson testified credibly as a fact witness. RD, at 20.

3. Dr. Alverson's Expert Opinion

Dr. Alverson testified about an Alabama pharmacy's/pharmacist's standard of practice when presented with a controlled substance prescription. *See* Tr. 331–356. Dr. Alverson explained the evolution of the professional responsibilities of pharmacists to the contemporary healthcare team-concept, in which the pharmacist has a ''corresponding responsibility'' to the prescribing physician to make an independent evaluation of each prescription. Tr. 334–35, 347. A pharmacist cannot assume that a prescription is legitimate just because it was written by a physician. *Id.* at 348. The pharmacist acts as the final ''gatekeeper'' in dispensing prescribed medication, with the patient's health and safety of paramount concern. *Id.* at 347–52. The pharmacist must make her own determination that a prescribed drug is safe and appropriate for the patient and look for indicators that the drug was prescribed for illegitimate reasons or outside the norms of the medical profession. *Id.* at 332, 347–48, 377, 474.

Dr. Alverson noted that the State of Alabama had adopted this concept and codified it in several provisions of the Alabama Administrative Code. *See* Tr. 335; GX 25; Ala. Admin. Code 680–X–2–.21. For example, Ala. Admin. Code 680–X–2–.21(2) provides that ''[e]ach new prescription and, where appropriate, refill prescription, should be reviewed for, but not limited to, the following: (a) Therapeutic duplication; (b) drug-disease contraindication where indicated; (c) drug-drug interaction; (d) incorrect dosage/duration; (e) drug allergy interactions; and (f) clinical abuse/misuse.'' Dr. Alverson explained the practical application of these requirements, what is expected of Alabama pharmacists in these regards, and the potential fatal consequences to patients upon the pharmacist's failure to comply with any of these provisions. Tr. 336–40. Dr. Alverson discussed the pharmacist's codified responsibility to develop, document, and maintain patient medication profiles and patient notes, and explained the critical importance of this provision. Tr. 341, 518–23; *see* Ala. Admin. Code 680–X–2–.21(5). In addition to their internal documentation, Dr. Alverson testified that pharmacies in Alabama are required to report each dispensation of a controlled substance to the State's PDMP. Tr. 507–08.

Dr. Alverson explained the various warning signs—''red flags''—of diversion or abuse of which a pharmacist must be cognizant to protect the safety of the patient and community. These included: Doctor-shopping; pharmacy-shopping; the doctor and practice specialty; [10] over-prescribing or duplication of pain medication; traveling long distances to obtain or fill prescriptions; drug combinations susceptible to abuse, *e.g.,* a combination of pain medication with anxiety medication and a muscle relaxant, which is informally referred to as a ''cocktail,'' and well-known as evidence of abuse or diversion; among others. Tr. 348–52, 401. In the face of these red flags, a pharmacist is expected to investigate the matter, to either satisfy her concerns or, failing that, to decline to fill the prescription. Tr. 352, 391. Dr. Alverson explained the investigation would include steps such as interviewing the patient, calling the prescribing physician, reviewing the patient's records in the PDMP, and checking the Alabama Medical Board's website to determine the prescribing physician's registration status, location, and specialty. Tr. 378–381. If the pharmacist fills the prescription, the pharmacist is obliged to document the results of her investigation in the electronic patient notes or on the prescription and the documentation should always be contemporaneous. Tr. 353, 361, 378. These notes are used upon a patient's return to the pharmacy to demonstrate to the pharmacist or to the next pharmacist that red flags have been investigated and resolved, and to demonstrate that the pharmacist is practicing their due diligence. Tr. 353, 520.

Dr. Alverson discussed how pharmacists must use the professional judgment that they develop from education and training. *Id.* at 345. She explained that accredited pharmacy schools offer a class in pharmacy law covering both state and federal law and lessons on pharmacists' responsibilities under the law are integrated into the curriculum of other classes. *Id.* at 346. In order to obtain a pharmacy license, one must pass both a clinical examination, as well as a law exam, which covers both state and federal law. *Id.* Dr. Alverson testified that the corresponding responsibility of a pharmacist is included in the law exam and taught under the pharmacy school curriculum. *Id.* at 347. Dr. Alverson also emphasized that the Alabama Code of Professional Conduct requires a pharmacist to stay abreast of developments in the field, including patterns of abuse and diversion. *Id.* at 343–44; GX 24; Ala. Admin. Code 680–X–2–.22.

In her testimony, Dr. Alverson reacted to the comments made to her at Auburn University by PIC Davison a month prior to the hearing to the effect the subject patients had already been on the subject medications when they reached the Respondent Pharmacy, and had

[10] Dr. Alverson testified that it is important to know the doctor's specialty to determine if a prescription is appropriate. She used the example of an oncologist prescribing higher doses of pain medication to end-stage/hospice patients. Tr. 351. As a counter example, she explained that she would question the appropriateness of a dentist prescribing 30 days of a pain medication for a tooth pull. Tr. 349.

already developed addiction problems. Dr. Alverson deemed that rationale inconsistent with a pharmacist's responsibility, and suggested appropriate responses: Counsel the patient to see a different doctor, refer them to treatment programs, and refuse to fill such prescriptions. Tr. 447–48. Dr. Alverson also dismissed a suggestion that Respondent Pharmacy's responsibilities to investigate red flags were in some way lessened when the prescription was a transfer from another pharmacy—noting that a pharmacy should review transfer prescriptions the same as any new patient prescription. *Id.* at 453.

Dr. Alverson reviewed a number of documents provided by the DEA including patient records from Respondent Pharmacy, corresponding prescriptions from those patients, and a record Respondent Pharmacy produced in response to a DEA subpoena. Dr. Alverson also reviewed records from the Alabama PDMP. She noted that from November 10, 2014, until December 1, 2014, the Respondent Pharmacy made no reports of dispensing controlled substances to the PDMP, despite the presence of original prescriptions evidencing the filling of controlled substances during that period. *Id.* at 393–95. On cross-examination, Dr. Alverson conceded that the pharmaceutical knowledge base was ever-growing and the professional standards ever-evolving, but confirmed that she evaluated the Respondent Pharmacy based upon the standards in place at the time of the dispensations. *Id.* at 460–73.

a. Patient M.A. (Male) [11]

For the first patient discussed, male M.A., Dr. Alverson noted that the patient arrived at Respondent Pharmacy in December 2014 with prescriptions for a risky combination of drugs, but that none of the records included any patient notes by PIC Davison, as would be expected in light of the red flags revealed by the prescriptions. *Id.* at 359–68, 382, 494; GX 11, 22. The medications prescribed to M.A. included both hydrocodone and oxycodone, which are two opioid pain medications and respiratory depressants that ''potentiate'' each other, or magnify the other's effects. Tr. 369. These medications were coupled with carisoprodol, a muscle relaxant, which further acts to depress respiration. *Id.* at 368–70. Dr. Alverson testified that a responsible pharmacist would have investigated why this combination of drugs, all of which cause respiratory depression and work the same way, were prescribed and would have declined to dispense the drugs unless satisfied that she could dispense them safely. *Id.* at 377.

Dr. Alverson noted that M.A.'s dose of pain medication (oxycodone) was doubled from 60 tablets to 120 tablets over a thirty-day period, when the best practice is to increase by no more than 25% at a time. *Id.* at 383–84. The increase also troubled Dr. Alverson, because the oxycodone was prescribed for breakthrough pain but was being prescribed at the level for a maintenance pain drug, *id.* at 386; and then, in June 2015, the doctor switched which pain medication was for maintenance and which was for breakthrough pain, *id.* at 386–390. Dr. Alverson testified that this switch was a red flag for abuse because it indicated the doctor ''didn't really care about providing legitimate medical treatment.'' *Id.* at 390. In June 2015, the patient was also prescribed zolpidem, a fourth respiratory depressant. *Id.* at 385. In addition, patient M.A. continued to receive repeated refills of carisoprodol despite a Food and Drug Administration (FDA) approval saying that the drug should not be used for more than three weeks. *Id.* at 370.

Dr. Alverson opined the prescribing pattern for M.A. was inconsistent with accepted pharmaceutical standards and posed a danger to the patient. *Id.* at 379, 502–03. She stated that in addition to an investigation at the initial prescription (of which there was no record), Respondent Pharmacy should have done further investigations based on the increased quantities and number of drugs prescribed. *Id.* at 391. Dr. Alverson found no indication in the records before her, which included copies of the front and back of the original hard-copy prescription and the patient's profile from Respondent's electronic system, that an appropriate, timely investigation was ever performed by the Respondent Pharmacy regarding the above-noted red flags. *Id.* at 392, 500, 504. Dr. Alverson testified that the prescriptions should not have been filled without investigation, and that even if the pharmacist had completed an investigation and just failed to document the investigation, the lack of documentation is itself a violation of the standard of care in Alabama. *Id.* at 502–504.

b. Patient C.W.[12]

The next patient discussed, C.W., had controlled substances prescribed by two different doctors—a red flag—as well as pain medication coupled with a muscle relaxant and benzodiazepine, or in Dr. Alverson's words a drug ''cocktail,'' as discussed above. *Id.* at 393, 396–98; GX 10, 12, 22. Despite the red flags, Dr. Alverson found no evidence that any investigation was undertaken by the Respondent Pharmacy, which Dr. Alverson stated was contrary to what was expected of a pharmacist acting in the usual course of the retail pharmacy profession in Alabama. Tr. 399–400.

The physician later added promethazine and codeine cough syrup to C.W.'s prescriptions, an additional controlled substance with a high street value. *Id.* at 401; GX 22, at 23. The patient also received an unusual increase in medication amounts and there was a three-month gap in treatment. Dr. Alverson noted no investigation evident by the Respondent Pharmacy into these, and other, red flags and said that without investigation and documentation a pharmacist within

[11] The parties stipulated that Respondent filled the following prescriptions for controlled substances for patient M.A. (male): on December 1, 2014, 30 tablets of carisoprodol 350mg and 120 tablets of hydrocodone-acetaminophen 10–325 mg; on December 8, 2014, 60 tablets of oxycodone 15mg; on January 6, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, and 120 tablets of hydrocodone-acetaminophen 10–325mg; on February 9, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, and 120 tablets of hydrocodone-acetaminophen 10–325mg; on March 9, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, 120 tablets of hydrocodone-acetaminophen 10–325mg, and 30 tablets of zolpidem 10mg; on April 13, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, 120 tablets of hydrocodone-acetaminophen 10–325mg, and 30 tablets of zolpidem 10mg; on May 11, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, 120 tablets of hydrocodone-acetaminophen 10–325mg, and 30 tablets of zolpidem 10mg; on June 8, 2015, 120 tablets of oxycodone 15mg, 120 tablets of hydrocodone-acetaminophen 10–325mg, and 30 tablets of zolpidem 10mg; on July 13, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, and 120 tablets of hydrocodone-acetaminophen; on August 17, 2015, 30 tablets of carisoprodol 350mg, 120 tablets of oxycodone 15mg, and 120 tablets of hydrocodone-acetaminophen. RD, at 3–4.

[12] The parties stipulated Respondent filled the following prescriptions for controlled substances for patient C.W. On December 5, 2014, 30 tablets of carisoprodol 350mg; on December 9, 2014, 31 tablets of alprazolam 2mg and 60 tablets of oxycodone 30mg; on January 16, 2015, 180ml of promethazine-codeine syrup; on February 18, 2015, 90 tablets of oxycodone 30mg, 100 tablets of hydrocodone-acetaminophen 10–325mg, and 30 tablets of alprazolam 2mg; on March 18, 2015, 30 tablets of alprazolam 2mg and 30 tablets of carisoprodol 350mg; on June 15, 2015, 30 tablets of carisoprodol 350mg, 30 tablets of alprazolam 2mg, another 30 tablets of alprazolam 2mg, 100 tablets of hydrocodone-acetaminophen, and 100 tablets of oxycodone 30mg; on June 16, 2015, 180ml of promethazine-codeine syrup; on July 15, 2015, 30 tablets of carisoprodol 350mg, 30 tablets of alprazolam 2mg, 100 tablets of hydrocodone-acetaminophen, and 100 tablets of oxycodone 30mg; on August 18, 2015, 30 tablets of carisoprodol 350mg, 60 tablets of alprazolam 2mg, 100 tablets of hydrocodone-acetaminophen, and 100 tablets of oxycodone 30mg. RD, at 4.

the usual course of professional practice could not continue to fill prescriptions for C.W. Tr. 402–05.

c. Patient D.B.[13]

The third patient discussed, D.B., was prescribed 180 tablets of methadone-10 milligrams and 90 tablets of carisoprodol-350 milligrams by two different doctors. Tr. 413–14; GX 13, 22, 25.[14] Dr. Alverson explained the heightened danger caused by methadone, as methadone creates its own form of sleep apnea and is responsible for a disproportionate number of deaths among the synthetic opioids, especially when prescribed in conjunction with another respiratory depressant, as was done for this patient. Tr. 414–15. Alprazolam, a benzodiazepine, was later added to this patient's prescription creating the red flag drug ''cocktail.'' *Id.* at 418–19. Dr. Alverson noted that as of September 1, 2016, alprazolam became the subject of a ''black box'' warning issued by the FDA, putting all pharmacists on notice of the heightened risk of fatal consequences when combining the drug with an opioid. *Id.* at 418–19, 495. Although the ''black box'' warning was issued after the subject prescription was filled, Dr. Alverson noted that the dangerous combination of alprazolam and opioids was well-known within the pharmacy community in 2014. *Id.* at 420. Despite the danger of D.B.'s prescriptions, no investigation by the Respondent Pharmacy was evident in the records reviewed by Dr. Alverson. *Id.* at 420–21.

d. Prescriptions Issued by Dr. U.I.[15]

Dr. Alverson then reviewed three prescriptions issued to three different patients by the same doctor, Dr. U.I., for the benzodiazepine/opioid/muscle relaxant ''cocktail.'' Tr. 421; GX 14. She noted that it was ''strange'' to see a physician write this combination of drugs repeatedly for a variety of patients and was indicative of a problem because the ''cocktail'' is rarely prescribed for legitimate medical reasons. Tr. 421–22. Dr. Alverson also found it highly suspicious that two of the three patients shared the same last name and lived at the same address, suggesting they were related. *Id.* at 422. She stated that it would be extraordinarily rare for two people living at the same address to receive this combination of drugs for legitimate medical purposes. *Id.* at 424. Dr. Alverson opined that after the second cohabitant presented a prescription for this cocktail, Respondent Pharmacy should have declined to fill the prescription and that a pharmacist could not fill the prescription consistent with their professional responsibilities.

e. Prescriptions Issued by Dr. S.H.[16]

Dr. Alverson also reviewed several opioid prescriptions issued by the same doctor, Dr. S.H., to three separate patients, which were filled at the Respondent Pharmacy within minutes of each other, suggesting the patients arrived together. Tr. 427–28; GX 15. Dr. Alverson described this circumstance as suspicious, in that, three patients from different parts of the area would be highly unlikely to appear together at the same pharmacy at the same time, unless they were involved in diversion. Tr. 429–33.

f. Patient A.C.[17]

Dr. Alverson's review of patient A.C.'s records revealed a patient who was prescribed opioids by multiple doctors and filled at multiple pharmacies within a 30-day period, which was suggestive of doctor-shopping and pharmacy-shopping. Tr. 434–38; GX 16, 28. Dr. Alverson noted that a review of the PDMP by the pharmacist would have disclosed these suspicious circumstances. For example, if PIC Davison had reviewed the PDMP before dispensing a prescription of hydrocodone to A.C. on September 24, 2015, she would have seen that A.C. had five different prescriptions for hydrocodone in the previous month. Tr. 438; GX 28. Dr. Alverson stated that, under the circumstances, the prescriptions should not have been filled, and the prescribing doctors and the police should have been notified. Tr. 439–440.

g. Patient R.D.[18]

The Respondent Pharmacy filled opioid prescriptions for patient R.D., which turned out to be forgeries. The filled prescriptions included a month's supply of hydrocodone and a month's supply of oxycodone, which Respondent Pharmacy filled within a week of each other. *Id.* at 441; GX 17. Dr. Alverson testified that there is no ''logical reason'' narcotics would be prescribed in this way and that an Alabama pharmacist acting in the bounds of her profession would be expected to investigate the prescriptions by calling the prescriber and checking the PDMP. Tr. at 441; *see also,* GX 31, at 26. Dr. Alverson conducted a brief investigation of the prescriptions by accessing the Alabama Medical Board website, which revealed the prescribing doctor to be an OB–GYN. Tr. at 444–45. Patient R.D. was a man. *Id.* at 445.

D. Testimony of Dr. Santonia Davison

PIC Davison was born in Bessemer, Alabama, attended the local high school, graduated from Miles College with a B.S. in biology, and then graduated from Samford University with a Doctorate of Pharmacy in 2011. Tr. 530–31. PIC Davison began her pharmacy career at CVS Pharmacy, where she ultimately worked at all 43

[13] The parties stipulated that Respondent filled the following prescriptions for controlled substances for patient D.B.: On December 2, 2014, 180 tablets of methadone 10mg and 90 tablets of carisoprodol 350mg; on December 29, 2014, 180 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on January 20, 2015, 90 tablets of Lyrica 100mg; on January 26, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on February 23, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, 90 tablets of alprazolam 2mg, and 90 tablets; on March 20, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, 90 tablets of alprazolam 2mg, and 90 tablets of Lyrica 100mg; on April 20, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on May 11, 2015, 90 tablets of Lyrica 100mg; on May 18, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on June 5, 2015, 90 tablets of Lyrica 100mg; on June 15, 2015, 210 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on July 7, 2015, 150 tablets of methadone 10mg, 90 tablets of carisoprodol 350mg, and 90 tablets of alprazolam 2mg; on August 4, 2015, 90 tablets of Lyrica 100mg; on August 10, 2015, 90 tablets of carisoprodol 350mg and 90 tablets of alprazolam 2mg; on August 12, 2015, 180 tablets of methadone 10mg. RD, at 4–5.

[14] On cross-examination, Dr. Alverson conceded that her concern regarding prescriptions from two separate doctors would be alleviated by learning that they were partners at the same clinic. Tr. 514–15.

[15] The parties stipulated that Respondent filled the following prescriptions from Dr. U.I.: On April 28, 2015, 90 tablets of carisoprodol 350mg, 120 tablets of hydrocodone-acetaminophen 10–325mg, and 60 tablets of alprazolam 1mg to [female] M.A.; on April 30, 2015, 60 tablets of carisoprodol 350mg, 90 tablets of hydrocodone-acetaminophen 10–325mg, and 60 tablets of alprazolam 1mg to T.K.; on May 1, 2015, 30 tablets of zolpidem tartrate 10mg, 30 tablets of lorazepam 1mg, 60 tablets of hydrocodone-acetaminophen 10–325mg, and 60 tablets of carisoprodol 350mg to J.K. RD, at 5.

[16] The parties stipulated that on August 13, 2015, Respondent dispensed 84 tablets of oxycodone 15mg to patient T.M., 112 tablets of oxycodone 30mg to patient P.I., and 112 tablets of oxycodone 30mg to patient J.C. based on prescriptions issued by Dr. S.H. RD, at 5.

[17] The parties stipulated that on September 23 and 24, 2015, Respondent dispensed 30 tablets of carisoprodol 350mg and 30 tablets of hydrocodone-acetaminophen 7.5–325mg to A.C. RD, at 5.

[18] The parties stipulated that Respondent that on October 11, 2014, Respondent dispensed 90 tablets of oxycodone 30mg to R.D., and on October 6, 2014, Respondent dispensed 120 tablets of hydrocodone-acetaminophen 10–325mg and 90 tablets of alprazolam 2mg to R.D. RD, at 5–6.

stores within the district. *Id.* at 532. The CVS stores shared the same policies and procedures and computer programs. *Id.* at 535–36. Their pharmacy computer program performed many pharmacist functions automatically, including a ''medication conflict check,'' a drug interaction check, and a therapeutic duplication check. *Id.* at 536. When the program recognized a problem with a prescription, the interactive program required the pharmacist to check a box designating how the pharmacist resolved the issue, such as, ''review of patient history,'' ''medication review,'' and ''prescriber consult,'' before the system would permit a prescription to be filled. The CVS software also allowed the pharmacists to make patient notes and automatically reported each prescription dispensed to the PDMP. *Id.* at 541. PIC Davison reported that although the combination of an opioid and a benzodiazepine would trigger an alert for ''therapeutic duplication,'' CVS had no official policy restricting the filling of that drug combination between 2011 and 2013. *Id.* at 538.

PIC Davison left CVS in 2013 in preparation for opening her own pharmacy. *Id.* at 538. She opened Respondent Pharmacy, Heavenly Care Pharmacy, on May 26, 2014, as the Pharmacist-in-Charge. *Id.* at 539, 693. PIC Davison developed the policies and procedures for the pharmacy by borrowing from ''care pharmacy'' association and from CVS. *Id.* at 540. She purchased her pharmacy software system from Abacus. *Id.* Although similar to the CVS software, PIC Davison testified the Abacus software became unreliable in automatically reporting dispensed prescriptions to the PDMP. *Id.* at 541. After discussions with DEA officials regarding missing PDMP data, which included a three-week lapse in reporting to the PDMP, PIC Davison began manually reporting to the PDMP. *Id.* at 541–42, 619, 753–55. PIC Davison explained that the Respondent Pharmacy also submitted a file to the PDMP that included data from the time the pharmacy opened. *Id.* at 753–55.

PIC Davison described her understanding of her record-keeping responsibilities as an ongoing process, prompted by the visits to her pharmacy by DEA. *Id.* at 558–60, 812. PIC Davison conceded that she had not properly documented the ordering and receipt of controlled substances to the pharmacy through inadvertence, computer issues, prioritizing patient consultation over record-keeping, and procrastination. *Id.* at 560–80, 675, 689–92. PIC Davison apologized for her ''lack of documentation [causing] all of this uproar.'' *Id.* at 691.

PIC Davison's testimony then addressed the specific prescriptions the Government identified in the Order to Show Cause and the ''red flags'' on those prescriptions that Dr. Alverson discussed in her testimony. *See* Tr. 591–671. PIC Davison described her personal interactions with the subject patients. PIC Davison testified that she was certain or ''pretty sure'' that she had contacted the prescribing physicians for all patients other than patient R.D. (the patient who presented the forged prescription). *Id.* at 608–09, 620–28, 630–31, 635, 640, 651, 659, 666, 670, 751. PIC Davison described her discussions with the doctors in her testimony but was largely unable to produce any contemporaneous documentation of those discussions.[19] *Id.;* GX 19, 22 (Respondent's responses to Government subpoenas requesting the documentation). For some of the patients, she conceded that no documentation existed and that she made a mistake not to document her investigations. *Id.* at 602, 608–09. For other patients, PIC Davison testified that the documentation would have been written on the original prescription, usually on the first fill script, but that those prescriptions were seized by the DEA, and were not offered into evidence. *Id.* at 634–35, 637–38, 641, 663–64, 673.[20] PIC Davison stated she now records her notes both on the original prescription and electronically in her patient notes. *Id.* at 674.

PIC Davison testified that she checked the PDMP before filling prescriptions for some, but not all, of the subject patients.[21] For male patient M.A., PIC Davison could not recall if she had searched the PDMP prior to filling his prescriptions, but when shown the record of her PDMP searches, which she had produced for the hearing, conceded the record showed she did not conduct a search. *Id.* at 744–45; RX 1, at 39 and 40. PIC Davison also said that she did not check the PDMP before filling the forged prescription for patient R.D. Tr. 795. PIC Davison affirmatively testified that she checked the PDMP for patients C.W., A.C., and one of Dr. S.H.'s patients, patient T.M. Tr. 609, 652, 658, 670. On cross examination, the DEA attorney questioned PIC Davison on her decisions to fill certain prescriptions for C.W. and A.C. after having viewed their prescription history in the PDMP. For C.W., PIC Davison testified that she did not recall seeing on the PDMP report that C.W. had received ten months of alprazolam in the prior five months. She explained that perhaps there was a software error, or that she had only reviewed the previous 30 days of the patient's history, or maybe that she just did not notice it. *Id.* at 764–66. For Patient A.C., PIC Davison testified that she had checked the PDMP report on A.C. on July 14, 2015, and had declined to fill one of A.C's pain medication prescriptions, because it was too early for a refill according to the PDMP. *Id.* at 670. PIC Davison also stated that the Government may have improperly attributed PDMP data to patient A.C., because the PDMP report used by the Government compiled data from patient profiles with the same name and birthdate but with four different street addresses in Bessemer, Alabama. *Id.* at 788–91.

As to the two patients with the same last name, living at the same address, PIC Davison did not recognize that coincidence as being concerning, as family members often see the same physician, but stated that after her interactions with DI Two, she now knows it is something a pharmacy should explore. *Id.* at 640–47; *see* Tr. 421; GX 14. Regarding the three patients who apparently came to the pharmacy together with similar prescriptions, yet from different parts of the area, PIC Davison explained that two of the three patients, P.I. and T.M., carpooled, because P.I. had an arm amputation. Tr. 650. PIC Davison stated that both lived in Jasper, Alabama. *Id.* at 665.[22] P.I. and T.M. had difficulty finding their prescribed medications, which were available at the Respondent Pharmacy. *Id.* at 651. The third of the trio, J.C., was a local individual, who frequented a commercial cleaning business a few doors down from the Respondent Pharmacy. *Id.* at 665–67. For these reasons, the appearance of these three individuals arriving at the Respondent Pharmacy at the same time did not raise any concerns for PIC Davison. *Id.* at 668–69; *see id.* at 427–28; GX 15. PIC Davison explained that she ''figured that perhaps the doctor [at the pain

[19] There was a handwritten note on one of patient C.W.'s prescriptions documenting PIC Davison's discussion with the doctor regarding a missing dosage on a prescription. Tr. 612; *see* GX 12, at 17.

[20] This testimony was permitted over the Government's objection that it was not properly noticed within the Respondent Pharmacy's Prehearing Notices. Tr. 663. However, the ALJ determined that Respondent Pharmacy's Prehearing statements provided adequate notice that this was part of its defense. Tr. 663; ALJX 17, at Ex. A 2, 15; GX 19, 47.

[21] PIC Davison stated on cross that ''at first, I wasn't using the PDMP because it wasn't being reported daily.'' Tr. 758.

[22] However, according to the scripts in evidence, P.I. lived in Jasper at the time her script was filled, while T.M. lived in Quinton. GX 15.

management clinic] scheduled them all the same day.'' [23] Tr. 669.

PIC Davison testified that she gave less scrutiny to prescriptions from pain management clinics, because she thought they had procedures to detect abuse and diversion, such as pill counts and urine analysis. *Id.* at 653–54, 784–85. Similarly, PIC Davison acknowledged she did not scrutinize transfers from other pharmacies as she did new patients. She reported that she had confidence that prescriptions filled at other pharmacies were proper, explaining that all pharmacists are under the same obligation and liability to perform their jobs as she. *Id.* at 628. PIC Davison said she now scrutinizes transfers as she would a new patient. *Id.* at 629.

The ALJ found that PIC Davison's testimony lacked credibility. RD, at 58. He stated that ''[i]n testifying as to factual matters regarding the initial inventory, the timing and extent of her purported investigations, and documentation of her investigations, [PIC] Davison's testimony was marked with a level of equivocation, implausibility, and inconsistency . . . .'' *Id.* I concur.

E. Allegations That Respondent Filled Prescriptions Without Investigating and Resolving Red Flags

The Government alleged that Respondent filled prescriptions that displayed red flags of abuse and diversion without resolving those red flags in violation of the pharmacist's corresponding responsibility to assess the legitimacy of the prescription. To support its allegations, the Government presented hard copies of prescriptions; copies of Respondent's electronic profiles for these patients; and the expert testimony of Dr. Alverson regarding the red flags presented by the patients' prescriptions. Respondent disputes the allegations and argues that she upheld her corresponding responsibility to assess the legitimacy of all of the subject prescriptions. In defense of these allegations, PIC Davison testified at the hearing regarding the due diligence that she conducted on the prescriptions and presented written summaries of her investigations in response to a Government subpoena and in a prehearing statement.[24]

As Dr. Alverson explained in her expert testimony regarding the standards of practice for an Alabama pharmacist, which is summarized in further detail *supra* at I.C.3, pharmacists are required under Alabama law to review each prescription for, among other things, therapeutic duplication, drug-drug interactions, incorrect dose/duration, and clinical abuse/misuse of medications. Ala. Admin. Code 680–X–2–.21. The law also requires pharmacists to maintain patient medication profiles, which includes the pharmacists' comments on consultation with the patient. *Id.*

Dr. Alverson identified various red flags that pharmacists are trained to be aware of to identify suspicious and unlawful prescriptions, which include patients traveling significant or unusual distances, patterns from prescribers who repeatedly issue prescriptions or groupings of prescriptions for drugs susceptible to abuse or misuse (''pattern prescribing''), doctor or pharmacy shopping, different family members who receive substantially similar prescriptions, prescribers issuing prescriptions for large quantities of narcotics or other controlled substances, and prescriptions that are therapeutically duplicative or other combinations that do not make clinical sense with each other or do not make sense for the patient. Dr. Alverson testified that, at the time the subject prescriptions were filled, an Alabama pharmacist would be expected to know about the red flags she identified and emphasized that the Alabama Code of Professional Conduct requires a pharmacist to stay abreast of developments in the field, including patterns of abuse and diversion. *Id.* at 343–44; GX 24; Ala. Admin. Code 680–X–2–.22. She further testified that when such red flags are present, Alabama pharmacists, acting in the normal course of their professional practice and in fulfillment of their corresponding responsibility, will investigate the circumstances, document their investigation, and decline to fill the prescription if they cannot resolve the red flags. Pharmacists will generally document the investigation as part of the ''comments'' maintained within the patient profiles the pharmacist is required by law to maintain, but they can also put the documentation on the prescriptions themselves.

The Government and Respondent Pharmacy presented conflicting testimony on two overarching factual matters relevant to Respondent's investigation and resolution of red flags, or lack thereof, for the prescriptions at issue. First, Respondent claims to have conducted due diligence investigations for all of the prescriptions at issue, but the Government suggests that any reported investigation by Respondent Pharmacy occurred after the fact, following the initiation of the Agency investigation. The Government supported this allegation by eliciting testimony demonstrating how the Respondent Pharmacy's explanations changed in reaction to the Government's filings. The Government subpoenaed certain of Respondent Pharmacy's patient records in February 2016 and May 2016, including any records Respondent Pharmacy held regarding the subject prescriptions. GX 18; Tr. 721. Respondent Pharmacy did not provide any records with contemporaneous documentation of investigations for any of the subject prescriptions in response, instead providing a single document describing its due diligence as to these patients in narrative form and the relevant patient profiles (the profiles required by Alabama law) none of which contained pharmacist comments. *See* GX 19; GX 22; Tr. 723. The Respondent Pharmacy's due diligence, described in Government Exhibit 19, were mostly in summary form, and except for one prescribing physician, did not include calls to the prescribing doctor as part of its due diligence. In fact, for a number of patients, PIC Davison reported, ''I cannot remember anything about this patient.'' GX 19.

The Government noted that following the Respondent Pharmacy's review of Dr. Alverson's report, the Respondent Pharmacy bolstered its claimed due diligence in its Prehearing statement to include steps described by Dr. Alverson

[23] Based on the copies of the prescriptions, which were submitted into evidence and stipulated by the parties to be true and correct copies, the prescriptions for P.I. and T.M were issued on the same day, July 30, 2015. The prescription for J.C. was issued the following day, July 31, 2015. The three patients did not bring the prescriptions to Respondent Pharmacy to be filled until August 13, 2015, approximately two weeks after the prescriptions were issued. GX 15.

[24] In addition to the testimony and evidence described below regarding the subject prescriptions, PIC Davison also supplied testimony and medical articles related to correlations between race and prescribing of controlled substances. *See* Tr. 679–686; RX 2. PIC Davison testified that these articles demonstrated that the medical establishment was less likely to prescribe opioid pain medications to Black patients. Tr. 684–86. In the course of her testimony and in Respondent's Prehearing Statement, PIC Davison stated some of the patients with prescriptions at issue in this case are Black, some white, and did not provide testimony on the race of others. *See, e.g.,* ALJX 17, Ex. A. PIC Davison testified, however, that the information in the articles did not influence the scrutiny she applied to prescriptions for controlled substances and that she engaged in the same level of scrutiny regardless of the race of the patient. Tr. 798–801. PIC Davison stated that she does not consider the race of the patient when determining whether an investigation is necessary when presented with prescriptions for controlled substances; therefore, I conclude that this evidence is irrelevant to the allegations that PIC Davison failed to properly investigate and document her investigation into any red flags presented by the subject prescriptions.

as necessary due diligence. Govt Posthearing, at 22–24; Tr. 728–39, 778–81.

Respondent Pharmacy categorically denies this allegation and detailed investigations on several of the subject patients in PIC Davison's testimony. Respondent Pharmacy argues that its claims of extensive, timely investigations were uncontroverted and should be accepted as credible. The ALJ, however, found, and I agree, that PIC Davison's testimony was ''sometimes implausible and inconsistent'' and described her testimony of one patient investigation as ''misleading and equivocating.'' RD, at 58.

I agree with the ALJ's finding that it is more believable than not that Respondent Pharmacy's investigations were not as timely or extensive as PIC Davison testified. RD, at 48. *See Wilbur-Ellis Co.* v. *M/V Captayannis ''S'',* 451 F.2d 973, 974 (9th Cir. 1971) (the court is not bound to accept uncontroverted testimony at face value if it is improbable, unreasonable, or otherwise questionable) (citing *Quock Ting* v. *United States,* 140 U.S. 417, 420–21 (1891)); *Koivunen* v. *States Line,* 371 F.2d 781, 783 (9th Cir. 1967) (evidence of witnesses, especially those who have a biased or prejudiced interest in the result of the trial in which they testify, need not be accepted at face value). Respondent Pharmacy has provided no documentary evidence in support of its claims of timely investigation. Furthermore, as the ALJ found, the propensity of the subject prescription forgery ring to concentrate their efforts at Respondent Pharmacy strongly suggests that the criminal diversion community had identified Respondent Pharmacy ''as a location where investigation was minimal and diversion would likely be successful.'' RD, at 48. *See* Tr. 431 (testimony from Dr. Alverson that patients seeking legitimate pain management do not tend to travel in groups, but that those not seeking legitimate pain management do, because they learn which pharmacies will fill their prescriptions).

As to the second preliminary matter, Respondent Pharmacy alleged in its Prehearing Statement that PIC Davison noted the results of her investigations on the initial prescriptions of the patients (first fill prescriptions), however, these prescriptions were seized by DEA, and while they were not listed as evidence, they were not returned to her. *See* ALJX 17, Ex. A, at 2, 15. At the hearing, however, PIC Davison was less certain about recording the results of her patient investigations on the initial prescriptions and only conditionally indicated that *if* she recorded her investigation, it would have been on the initial prescription, or in her patient notes. Tr. 634–35, 637–38, 663–64, 673, 805.

The Government did not offer all of the subject ''missing'' first fill prescriptions into evidence. In past cases, this Agency has applied the ''adverse inference rule'' against parties that failed to produce records. *See, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10,876, 10,890 (2018) pet. for rev. denied, 789 F. App'x 724 (11th Cir. 2019). As the D.C. Circuit explained, ''[s]imply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.3d 1329, 1336 (D.C. Cir. 1972). *See also Huthnance* v. *District of Columbia,* 722 F.2d 371, 378 (D.C. Cir. 2013). In this case, however, I agree with the ALJ that the Respondent Pharmacy's conditional assertion of favorable evidence under the sole control of the Government is insufficient to justify an adverse inference. RD, at 43 (citing *Beau Bashers,* 76 FR 194,401, 19,404 (2011); *UAW* v. *NLRB,* 459 F.2d at 1335–39). The credibility of Respondent's conditional assertions of favorable evidence is also drawn into question by the first fill prescriptions the Government did produce, none of which contained documentation of Respondent's alleged investigations. Furthermore, PIC Davison failed to produce any prescriptions with documentation of an investigation for any prescription filled at Respondent Pharmacy—documentation that she was required to make as an Alabama pharmacist—and conceded that she failed to document the results of her investigation for several of the subject prescriptions, relying instead on her memory.

1. Prescriptions for Patients M.A., C.W., and D.B.

The Government alleged that from December 2014 through August 2015, Respondent filled prescriptions for patients M.A. (male), C.W., and D.B. for large quantities of narcotics, in combinations reflecting therapeutic duplication, in combinations known to be susceptible to abuse or diversion, and unlikely to be issued for legitimate medical purposes by prescribers operating within the bounds of their profession. The Government further alleged that Respondent filled these prescriptions without appropriate investigation, documentation, and resolution of these circumstances in violation of its corresponding responsibility. ALJX 1, at 3.

In regard to patient M.A. (male), Dr. Alverson testified that his prescriptions presented multiple red flags: Therapeutic duplication; a rapid increase in the quantity of a prescribed opioid; the prescriber switching which drug was for maintenance and which for breakthrough pain; and repeated refills of a drug contrary to FDA approval. Dr. Alverson opined the prescribing pattern for M.A. was inconsistent with accepted pharmaceutical standards and posed a danger to the patient. Tr. 379, 502–03. She further found no contemporaneous documentation on the record that PIC Davison had conducted any investigation of the red flags.[25] PIC Davison acknowledged at the hearing that she did not document her investigation, but testified that she determined the prescriptions were appropriate based on conversations with the patient and the prescribing physician which revealed M.A. was a delivery driver who suffered from chronic back pain.[26] *Id.* at 593–96.

For patient C.W., Dr. Alverson testified that the patient's prescriptions presented several red flags including controlled substances prescribed by different doctors, the combination of an opiate and a benzodiazepine or ''drug cocktail'' popular with drug abusers, an unusual increase in medication amounts, and a three-month gap in treatment. *Id.* at 393, 396–98, 401–404. PDMP data for C.W. that Respondent Pharmacy submitted into evidence also revealed red flags including that C.W. had frequented multiple pharmacies and received 10 months of alprazolam in the five months prior to transferring his prescription to Respondent Pharmacy. Tr. 761–62; RX 1, at 14–16. Despite the evidence of red flags, there was no evidence that Respondent

[25] In its Prehearing Statement, Respondent wrote that any documentation for PIC Davison's investigation of patient M.A. (male) would be on the original fill prescription. The Government introduced the original fill prescription into evidence. It contained no documentation by PIC Davison. *See* GX 11.

[26] In its Prehearing Statement, Respondent stated that PIC Davison had contacted the prescribing physician to confirm the diagnosis and validity of the prescription and to discuss safety and possible therapeutic duplication. GX 47, at 4. During the hearing, however, PIC Davison's testimony on this matter wavered. She testified that she spoke with the prescribing physician on the phone regarding M.A.'s consecutive therapies and ''why Soma was prescribed with two different narcotics,'' Tr. 727–28, but later admitted that she could only specifically recall calling the doctor to discuss a change in the prescription from extended-release to immediate-release oxycodone, Tr. 751.

Pharmacy undertook any investigation. PIC Davison said she conducted due diligence on C.W.'s prescriptions by talking with the patient, who told her he was a factory worker doing repetitive actions, and that she was ''pretty sure'' she called the prescribing doctor before filling C.W.'s prescriptions for the first time. Tr. 608. PIC Davison also suggested that the PDMP report she viewed in December 2014, when C.W. came to Respondent Pharmacy, could have looked different than the one she offered into evidence at the hearing, but she offered no evidence to support her claim. *Id.* at 763–66.

For patient D.B., Dr. Alverson testified that the patient's prescriptions evinced several red flags including doctor shopping and the opioid/benzodiazepine ''cocktail.'' *Supra* I.C.3.c. PIC Davison discussed the investigation she conducted on patient D.B., but yet again conceded she failed to properly document it. Tr. 620–28, 630. PIC Davison testified that she was not suspicious that D.B. paid for her carisoprodol prescription with cash, while her other prescriptions were covered by insurance or Medicare. Tr. 768–69, 810; RX 1, at 27.

For both C.W. and D.B., PIC Davison argued that at the time the subject prescriptions were filled, 2014–15, the opioid/benzodiazepine drug combination was not known to be a red flag and that a reasonable pharmacist at the time would not necessarily be suspicious of prescriptions with that drug combination. To support her argument, PIC Davison submitted evidence that the U.S. Department of Health and Human Services (HHS) issued guidelines in March 2016 regarding the risks of opioid pain medications, after the subject prescriptions were issued. *See* RX 2, at 9. However, Dr. Alverson, who Respondent conceded was a renowned expert in the field, testified that while HHS did not issue those guidelines or add a ''black box'' [27] warning to benzodiazepines that they should not be combined with an opioid until 2016, the dangers of the ''cocktail,'' and its propensity for abuse, were well known in the pharmacy community in 2014. Tr. 420, 494. She further testified that when reviewing the subject prescriptions, she applied the standards of professional practice that were applicable at the time of the dispensations. *Id.* at 460–73. I credit Dr. Alverson's testimony on this matter and find that, at the time Respondent Pharmacy dispensed the subject prescriptions to C.W. and D.B., an Alabama pharmacist should have been aware of the risks posed by an opioid/alprazolam drug combination.

Based on the evidence in the record, I find that Respondent filled prescriptions for patients M.A. (male), C.W., and D.B. that raised red flags and that PIC Davison knew or should have known that the prescriptions raised red flags.[28] I further find that, even if these red flags were resolvable, there was no credible evidence that Respondent addressed or resolved them before filling the prescriptions. I cannot, and do not, place any weight on PIC Davison's testimony that she resolved the red flags, because she produced no contemporaneous documentary evidence to support her claim that she attempted to and, in fact, did resolve them before filling the prescriptions and because the ALJ found, and I agree, that her testimony on this matter was not credible. *See* RD, at 56.

2. Prescriptions Issued by Dr. U.I.

From April 2015 to August 2015, Respondent Pharmacy filled prescriptions issued by prescriber U.I. RD, at 5. The Government alleged that three patients of Dr. U.I. ''presented prescriptions that indicated a pattern of prescribing the same combinations of controlled substances to patient after patient, combinations including large quantities of narcotics and combinations known to be susceptible to abuse or diversion and unlikely to be issued for legitimate purposes by prescribers operating within the bounds of their profession.'' ALJX 1, at 4. The Government additionally alleged that ''these patterned prescriptions were presented by patients who shared the same home address and last name, issued within one date of one another.'' *Id.* The Government further alleged that Respondent filled the prescriptions with red flags from Dr. U.I. to numerous patients without appropriate investigation, documentation, and resolution of the alleged red flags. *Id.*

To support these allegations, the Government submitted prescriptions into evidence from Dr. U.I. for patients M.A. (female), T.K, and J.K. GX 14. Dr. Alverson testified that these prescriptions showed red flags. Tr. 421. All three patients were prescribed a combination of an opioid, benzodiazepine, and a muscle relaxant—a drug ''cocktail'' known to be susceptible to diversion and abuse—and a red flag in and of itself. Dr. Alverson testified that a pattern of prescriptions from a prescriber for this ''cocktail'' is also a red flag because the ''cocktail'' is rarely prescribed for legitimate medical reasons and further, that it would be extraordinarily rare for two people living at the same address to receive this ''cocktail'' for legitimate purposes. Tr. 421–22.

PIC Davison testified that she was ''pretty sure'' she had investigated the prescriptions from Dr. U.I. by calling the doctor, Tr. 635–43,[29] but she did not claim to have conducted any due diligence on prescriptions from Dr. U.I. in either her response to the Government's subpoena, GX 19, or in the Prehearing statement, where she summarized the due diligence she conducted on the subject prescriptions, GX 47, at 8. During the hearing, PIC Davison stated that two patients sharing an address and receiving similar controlled substances ''would raise a flag,'' but also testified that at the time she did not think it was a red flag for two patients with the same last name, living at the same address, to receive prescriptions for the same doctor, because, in her experience, family members often see the same physician. She conceded, however, that she learned this circumstance should be investigated by pharmacies during her discussions with DI One. Tr. 645–47.

Based on the evidence in the record, I find that Respondent filled prescriptions from prescriber U.I. that raised red flags that PIC Davison knew or should have known that the prescriptions raised red flags. I further find that, even if these red flags were resolvable, there was no credible evidence that Respondent addressed or resolved them before filling the

[27] Dr. Alverson testified that a ''black box'' warning is a type warning that is required to be placed on the package insert for certain drugs and is formatted with a black border around that text. Tr. 419.

[28] In a prehearing statement, Respondent argued that M.A., C.W., and D.B. had the same or similar prescriptions filled at other area pharmacies before or after they were patients at Respondent Pharmacy and that this demonstrates the ''common prescribing practices amongst the physicians in the area.'' GX 47, at 5–7. Respondent supported this argument with data from the PDMP that it presented as evidence during the hearing. RX 1, at 1–17, 43–58. The best that this evidence shows, however, is that the red flags presented by M.A., C.W., and D.B.'s prescriptions may be resolvable with proper investigation. At worst, it shows that in some cases the patients had to go to several pharmacies to receive the same combination of drugs they received from Respondent Pharmacy. I will not fully explore this argument because Respondent seems to have abandoned it by failing to elicit testimony at the hearing and not discussing it in its Posthearing brief.

[29] PIC Davison testified that she would have written any documentation of her investigations on the first fill script of the patients M.A. (female) and T.K. but that the DEA had taken those scripts and not submitted them into evidence. Tr. 638–42. As discussed, *supra,* I do not give weight to PIC Davison's testimony on this matter. The Government did submit copies of the front and back of the first fill script from patient J.K., which did not contain any documentation of an investigation by Respondent. GX 14 at 5–6.

prescriptions. I cannot, and do not, place any weight on PIC Davison's testimony that she resolved the red flags because she produced no contemporaneous documentary evidence to support her claim that she attempted to and, in fact, did resolve them before filling the prescriptions and because the ALJ found that the testimony was not credible. *See* RD, at 56.

3. Prescriptions Issued by Dr. S.H.

On August 13, 2015, Respondent filled three different prescriptions for oxycodone presented by three different patients from Dr. S.H. in Moody, Alabama. RD, at 5. The Government alleged the patients traveled unusual distances to obtain and fill the prescriptions, and that the timing of the prescription fills indicates the patients may have traveled together, and that despite these circumstances, Respondent ''filled the prescriptions without appropriate investigation, documentation, and resolution of these circumstances.'' ALJX 1, at 4.

The Government presented testimony at the hearing that Moody, Alabama, where the prescribing physician was located, is on the southeast-side of Birmingham and approximately a 40-minute drive from Respondent Pharmacy; that Jasper, Alabama, where one of the patients resided, is on the north-side of Birmingham and approximately a 50-minute drive from Respondent Pharmacy; and that Quinton, Alabama, where a second patient resided, is proximate to Jasper. Tr. 428–29. The third patient resided in Bessemer, Alabama, the same city as Respondent Pharmacy. The Government presented prescriptions from the patients with dispensing labels showing they were filled at Respondent Pharmacy within minutes of one another. GX 15. Dr. Alverson testified that it is a red flag for patients from three different cities to visit the same doctor in a fourth city ''quite a distance from where they live,'' to receive prescriptions from that prescriber for the same controlled substance, and then to take those prescriptions to the same pharmacy at the same time (and at a pharmacy that is distant from the residence of two of the three patients). Tr. 429–32. She further testified that patients seeking legitimate pain management care do not tend to travel in groups, but that it is a common practice for patients abusing or diverting drugs to do so, because ''patients who are seeking drugs usually learn pretty quickly the physicians that will write those prescriptions for them, and they learn which pharmacies will fill those prescriptions . . . . With no questions asked.'' *Id.* at 431–32.

PIC Davison testified that she ''sort of, but not really'' found it suspicious that the three patients from Dr. S.H. arrived at her pharmacy at the same time because she ''figured that perhaps the doctor scheduled them all the same day'' and the two patients from Jasper and Quinton carpooled (one was an amputee without transportation) and the third was a local resident, who frequented a cleaner by the pharmacy. Tr. 667–69; GX 47, at 9. She stated that the two patients who carpooled came to her pharmacy because they were unable to find another pharmacy with their medication (oxycodone) in stock. Tr. 650–58; GX 47, at 8–9. PIC Davison further testified that she investigated the prescriptions by calling the pain management clinic where Dr. S.H. worked to validate the prescriptions and checking the PDMP, Tr. 651–53, 658–59, but she equivocated on whether or not she documented her investigations, which she asserted would have been on prescriptions the DEA had seized and not returned, Tr. 662–66. PIC Davison conceded that she generally conducted less due diligence on prescriptions from pain clinics like the subject prescriptions. Tr. 654.

Based on the evidence in the record, I find that Respondent filled prescriptions from prescriber S.H. that raised red flags and that PIC Davison knew or should have known that the prescriptions raised red flags. Carpooling explains why two of the patients arrived at the same time, but it does not explain the unusual distances they traveled or why the third patient arrived at the pharmacy with them. PIC Davison's explanation that she was not suspicious of them all arriving together, because she assumed the doctor had seen the patients on the same day also lacks credibility—Respondent Pharmacy filled the prescriptions approximately two weeks after they were prescribed.[30] I further find that, even if these red flags were resolvable, there was no credible evidence that Respondent addressed or resolved them before filling the prescriptions. I cannot, and do not, place any weight on PIC Davison's testimony that she resolved the red flags because she produced no contemporaneous documentary evidence to support her claim that she attempted to and, in fact, did resolve them before filling the prescriptions and because the ALJ found that the testimony was not credible. *See* RD, at 56.

4. Patient A.C.

On September 23 and 24, 2015, Respondent filled prescriptions for patient A.C. for 30 tablets of carisoprodol 350 mg, identified as a 7-day supply, and 30 tablets of hydrocodone-acetaminophen 7.5–325mg, identified as a 4-day supply. RD, at 5. The Government alleged that patient A.C. ''presented prescriptions for a high volume of narcotics for a small period of time'' and were ''non-periodic in nature'' and ''presented prescriptions from two different doctors in the prior month.'' ALJX 1, at 4–5. The Government further alleged that investigation of these circumstances would have revealed that A.C. ''had presented numerous prescriptions from different prescribers to different pharmacies,'' but that Respondent had filled A.C.'s prescriptions without appropriate investigation, documentation, and resolution of the circumstances. *Id.*

Dr. Alverson testified that A.C.'s prescriptions had several red flags. She stated that A.C.'s records were suggestive of doctor and pharmacy shopping and that if PIC Davison had reviewed the PDMP data before dispensing the prescription of hydrocodone to A.C. on September 24, 2015, PIC Davison would have seen that A.C. had filled five different prescriptions for hydrocodone in the previous month. Tr. 434–38, GX 16 and 28. Dr. Alverson testified that the red flags for A.C.'s prescriptions were so egregious that, in her opinion, an Alabama pharmacist acting in accordance with appropriate professional standards could not resolve them. Tr. 440.

PIC Davison argues that the subject prescription was appropriately dispensed based on the investigation she conducted. PIC Davison spoke in detail regarding information she learned directly from A.C.; however, her testimony regarding the rest of her investigation was inconsistent. PIC Davison testified that she had called a Dr. S. to verify A.C.'s prescriptions, but the prescriptions at issue were prescribed by a different doctor, Dr. C. Tr. 670, *see* GX 16. Then on cross examination, PIC Davison implied that she had spoken with Dr. C.[31] Tr. 792. Additionally, during the hearing, PIC Davison speculated the Government and

[30] The three patients' prescriptions were written on July 29 and 30, 2015. The patients had the prescriptions filled at Respondent Pharmacy on August 13, 2015. *See* GX 15.

[31] When asked if she would fill the subject prescription today, PIC Davison replied ''I know after talking with Dr. [C.] then, yes, I would've filled it.''

Dr. Alverson may have improperly attributed PDMP data to patient A.C. because the PDMP report used by the Government compiled data from patient profiles with the same name and birthdate but with four different street addresses in Bessemer, Alabama. Tr. 788–91. Yet, PIC Davison also testified that she declined to fill a prescription for A.C. in July of 2015 based on the same PDMP data. Tr. 670.

Based on the evidence in the record, I find that Respondent filled prescriptions for patient A.C. that raised red flags and that PIC Davison knew or should have known that the prescriptions raised red flags. I further find that, even if these red flags were resolvable—and there was credible testimony from Dr. Alverson that they were not—there was no credible evidence that Respondent addressed or resolved them before filling the prescriptions. I cannot, and do not, place any weight on PIC Davison's testimony that she resolved the red flags, because she produced no contemporaneous documentary evidence to support her claim that she attempted to and, in fact, did resolve them before filling the prescriptions and because her testimony was inconsistent and the ALJ found that it was not credible. RD, at 56.

5. Patient R.D.

On October 11, 2014, Respondent filled a prescription for a narcotic for Patient R.D. The Government alleged the patient presented this prescription days after filling another prescription for a large volume of narcotics and that the prescriber specialized in obstetrics and gynecology (an unusual fact since R.D. was a male) and that despite these circumstances, Respondent ''filled the prescription without appropriate investigation, documentation, and resolution of these circumstances.'' ALJX 1, at 5. The Government also presented testimony that the prescription was a forgery. *See* Tr. 142.

Dr. Alverson testified that it is a red flag that Patient R.D. received a month's supply of a narcotic within a week of receiving a month's supply of another narcotic and that an Alabama pharmacist would be expected to investigate and resolve the red flag before filling the second (the October 11) prescription. Tr. at 441. Dr. Alverson further testified that a brief investigation would have revealed that the ''prescribing doctor'' was an obstetric gynecologist—another red flag as Patient R.D. is male. *Id.* at 445. PIC Davison conceded at the hearing that she had not conducted any investigation before filling Patient R.D.'s October 11, 2104 prescription. Tr. 795–96.

Based on the evidence in the record, I find that Respondent filled a prescription for patient R.D. that raised red flags and that PIC Davison knew or should have known that the prescription raised red flags. I further find that Respondent did not investigate or resolve the red flags—which were unresolvable as the prescription was a forgery—before filling the prescription.

In sum, I find that between October 2014 and September 2015, Respondent filled prescriptions that presented red flags that an Alabama pharmacist acting in the usual course of her professional practice and in fulfillment of her corresponding responsibility should have recognized, investigated, documented, and resolved prior to filling the prescriptions. I further find that Respondent did not conduct proper investigations of these prescriptions before filling them and did not document the results of any investigation she did conduct as is standard practice for an Alabama pharmacist and required by Ala. Admin. Code 680–X–2–.21.

II. Discussion

The Government alleged that the Respondent Pharmacy's registration should be revoked because the Respondent Pharmacy has materially falsified its renewal application and has 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 allegations that Respondent Pharmacy provided false and material responses in the renewal application for registration and that it violated federal and state laws relating to controlled substances when it improperly filled prescriptions and failed to properly maintain certain records.[32]

A. Materially False Statement in Renewal Application

The Government's allegation that Respondent Pharmacy materially falsified its renewal application arose with the Respondent Pharmacy's application to renew its registration during the pendency of this action. In the renewal application, Respondent Pharmacy answered ''No'' to the question: ''[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending?'' GX 26, at 1. The Government alleged that Respondent materially falsified its renewal application on the basis of its ''No'' response to the above question.[33]

Pursuant to 21 U.S.C. 824(a)(1), a registration ''may be suspended or revoked . . . upon a finding that the registrant (1) has materially falsified any application filed pursuant to or required by subchapter or subchapter II of this chapter . . . .'' There is no question that Respondent knew or should have known that it submitted a registration renewal application with a false response to the question asking if the applicant had an action pending to have a federal controlled substance registration revoked. *Supra* I.A. Respondent, however, argued that its false response to that question was not material and therefore cannot serve as a ground to revoke its registration. First, Respondent argued that DEA had issued the OSC and was obviously aware that there was a pending revocation of Respondent's registration. Resp Posthearing, at 6. Second, Respondent argued that, even if DEA were deceived, ''that deception would not have had an effect on the renewal, which in this case was automatic.'' *Id.* I reject Respondent's arguments, as the ALJ did, for the reasons that follow. *See* RD, at 28–29.

Respondent's submission of a renewal application containing a false response to a liability question is material, because such false information is ''predictably capable of affecting, *i.e.,* ha[s] a natural tendency to affect, the

[32] In Respondent's Prehearing statement and in the prehearing conversation she had with Dr. Alverson, PIC Davison implied that DEA may not have treated her fairly based on her race, Tr. 329; Resp Prehearing, at 23, but Respondent did not actively pursue this issue as a defense during the hearing, Tr. 686–87. Before the hearing, the ALJ advised the parties that if the issue was pursued, he would consider it within the context of ''unequal treatment'' by the Agency and asked Respondent's counsel if he planned to pursue a defense of unfair or unequal treatment by the Agency. Tr. 19. Respondent Counsel responded that he agreed with the ALJ that the legal issue presented would be one of disparate impact but stated that he would not know if Respondent would pursue disparate impact as a defense until after hearing the testimony at the hearing. Tr. 20–21. After the hearing, Respondent filed a Posthearing Brief with the ALJ that presented Respondent's arguments and defenses against the Government's case. Respondent did not allege unequal treatment in that brief. Because Respondent did not pursue the defense at hearing or in its Posthearing Brief, I consider Respondent to have abandoned the defense and will not consider it in my decision.

[33] This allegation does not appear in the Order to Show Cause because it did not arise until after the OSC was issued. The Government did, however, clearly include the allegation in its Supplemental Prehearing Statement, Respondent did not challenge the timeliness of the allegation, *see, e.g.,* Resp Prehearing Statement, and the allegation was fully litigated during the hearing, *see* RD, at 25. The ALJ found Respondent received sufficient notice of the allegation, and the allegation was properly before him. *Id.* at 26. I concur.

official decision.'' *Kungys* v. *United States,* 485 U.S. 759, 771 (1988). All of the form's liability questions implicate at least one of the factors I am required to consider in carrying out my registration-related responsibilities under 21 U.S.C. 823(f). Respondent's false response to liability question number two is material because of this question's connection to the second, third, and fourth factors listed in section 824(f) and, therefore, my ability to carry out my statutory responsibilities. 21 U.S.C. 823(f). Thus, I reject Respondent's argument that ''the omission was not material because it had no capacity to affect the official decision.'' Resp Post Hearing, at 6.

I also reject Respondent's argument that ''not only could the failure to alert the DEA what the DEA was doing possibly deceive the DEA, but even if it could, then that deception would not have had an effect on the renewal, which in this case was automatic.'' [34] *Id.* First, having an ''effect on the renewal'' plays no role in the assessment of ''materiality.'' As Respondent acknowledges in its Post Hearing Brief, the Supreme Court made this clear decades ago when it stated that ''[i]t has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation.'' *Kungys,* 485 U.S. at 771 [emphases in original]. Second, while some Agency decisions mention deception,[35] they mention it in the context of determining the appropriate sanction, not in determining whether a falsity is material. I decline Respondent's suggestion that I disregard Supreme Court precedent by injecting the notion of deception into my assessment of materiality.

Respondent additionally argues that an existing registration is renewed automatically, thereby precluding any affirmative finding of materiality. Respondent misreads 21 CFR 1301.36(i).[36] Nothing in it grants a registrant the automatic renewal of its registration. The renewal of Respondent's registration is not ''automatic,'' and I disagree with Respondent that 21 CFR 1301.36(i) is relevant to whether or not Respondent's false submission is material.

For the reasons stated above, I find that Respondent's false response on its renewal application is material, which is an independent ground for revocation pursuant to section 824(a)(1).

B. Public Interest Factors

Section 304(a) of the Controlled Substances Act 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'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 separately. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5488 (2019); *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).

In the adjudication of a revocation of a DEA registration, the Government has the burden of proving that the requirements of revocation 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, given the totality of the facts and circumstances on the record, revoking registration would not be appropriate. *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. 824(f) seeks the revocation of the Respondent Pharmacy's registration based primarily on conduct most aptly considered under Public Interest Factors Two and Four.[37] The Government also alleged certain ''other conduct which threatens the public health and safety,'' which is properly considered under Factor Five. I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). I further find that Respondent failed to provide sufficient evidence to rebut the Government's *prima facie* case.

[34] Respondent's argument that DEA's acceptance of its renewal application is ''automatic'' is baseless and I reject it. *Infra.*

[35] *See e.g., Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,808 (2015) (lack of intent to deceive can be a ''relevant consideration []'').

[36] 21 CFR 1301.36(i) states, in part, that ''[i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order . . . .''

[37] There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent Pharmacy's DEA registration (Factor One). However, the fact that a state has not acted against a registrant's license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *E.g., Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62,316, 62,340 (2012); *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,730 (2009). Likewise, the record contains no evidence that the Respondent Pharmacy, its owner, or any pharmacist or key employee of pharmacy has been convicted of (or charged with) a crime related to controlled substances (Factor Three). 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. *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 (10th Cir. 2011). 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.*

Specifically, I find that the record contains substantial evidence that Respondent's Pharmacist-in-Charge, PIC Davison, violated her corresponding responsibility when she dispensed multiple prescriptions. I also find there is substantial evidence on the record that Respondent violated multiple federal and state recordkeeping requirements.

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

Evidence is considered under Public Interest Factors Two and Four when it reflects a registrant's compliance (or non-compliance) with laws related to controlled substances and registrant's experience dispensing controlled substances. Established violations of the Controlled Substances Act, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable when considering if a registration is consistent with the public interest. As DEA has held in the past, 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)). Under Agency precedent, ''[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). Agency precedent has also consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, LLC,* 69 FR 63,178, 63,181 (2004); *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988).[38]

In this case, the Government alleged and presented evidence that the Respondent Pharmacy's pharmacist, in violation of 21 CFR 1306.04(a), failed to exercise her corresponding responsibility to assess the legitimacy of numerous controlled substance prescriptions she filled. ALJX 1, at 2–5. The Government also alleged that, in violation of 21 CFR 1306.06, the Respondent Pharmacy's pharmacist failed to dispense those same prescriptions for controlled substances within the lawful bounds of the pharmacy profession. *Id.* Additionally, the Government alleged and presented evidence that the Respondent Pharmacy failed to maintain an initial inventory required under federal law pursuant to 21 CFR 1304.11, or an initial inventory and an annual inventory required under Alabama law pursuant to Ala. Admin. Code 680–X–3–.08. ALJX 1, at 5 and 6. The Government also alleged and presented evidence that the Respondent Pharmacy failed to notate whether individual controlled substances that it ordered were actually received, and if so, on what date they were received, in the CSOS, on DEA Form 222s, and on its invoices. *Id.* at 6. Perhaps as a result of those alleged recordkeeping violations, the Government also alleged that an audit revealed ''significant discrepancies'' in the amounts of certain controlled substances at the pharmacy compared with the amounts the Respondent Pharmacy's records indicated should have been present. *Id.* Finally, the Government alleged and presented evidence that the Respondent Pharmacy inaccurately reported certain information to the Alabama PDMP, undermining the purpose of that database. *Id.* at 7. These allegations and the evidence of record are addressed below.

a. 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.'').

[38] The Order to Show Cause alleged that ''Respondent'' violated its corresponding responsibility. It is undisputed that Respondent is owned and operated by Santonia Davison, who is also Respondent's pharmacist-in-charge and Respondent's only pharmacist. Thus, for purposes of finding and attributing liability in this case, I find that the actions and inactions of Respondent's Owner and PIC were the actions and inactions of Respondent.

Here, the Government does not claim that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Rather, the Government argues that Respondent violated the corresponding responsibility rule when she dispensed controlled substance prescriptions while ''repeatedly ignor[ing] obvious and apparent signs of abuse and diversion—signs that a professional pharmacist, operating in the bounds of the profession with eyes open to such indicia, would detect and resolve.'' Govt Posthearing, at 37.

As I found above, Respondent dispensed prescriptions for controlled substances without resolving red flags presented by the prescriptions, including the red flags of drug cocktails, multiple customers filling prescriptions from the same prescriber for the same drugs (''pattern prescribing''), customers with the same last name and street address presenting the same prescriptions within a short period of time, traveling unusual distances, doctor shopping, pharmacy shopping, therapeutic duplication, and unusual increases in drug quantities. Prior Agency decisions have 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. *See, e.g., Zion Clinic Pharmacy,* 83 FR at 10,898 (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; two short-acting opiates prescribed together; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59,504, 59,507, 59,512–14 (2014) (unusually large quantity of a controlled substance; pattern prescribing; drug cocktails); *Holiday CVS,* 77 FR at 62,317–22 (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); *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 prescriptions). The Government also presented credible testimony that PIC Davison knew, or should have known, there were red flags on the prescriptions at the time they were dispensed. Alabama law requires pharmacists to review all new prescriptions, and refill prescriptions where appropriate, for, among other things, therapeutic duplication, drug-disease contraindication, incorrect dosage/duration, and clinical abuse/misuse. Ala Admin. Code 680–X–2–.21. Dr. Alverson testified that an Alabama pharmacist is trained to and should have recognized the red flags on the subject prescriptions, which included red flags explicitly named in Alabama law, and that an Alabama pharmacist exercising her corresponding responsibility and acting in the usual course of professional practice will not dispense controlled substances without investigating, documenting the investigation, and resolving any red flags. Furthermore, PIC Davison's comments to Dr. Alverson that the subject patients were receiving the same controlled substances from another pharmacy before they came to Respondent Pharmacy and ''[w]hatever problems they had when they got to [Respondent Pharmacy], they had those problems before they got to [Respondent Pharmacy]'' reflects an abdication of PIC Davison's corresponding responsibility.

Accordingly, I find the Government has proven by substantial evidence that Respondent filled prescriptions for controlled substances that it knew were not prescribed for legitimate medical purposes, or was willfully blind to such, in violation of its corresponding responsibility under 21 CFR 1306.04(a) and outside the usual course of its professional practice in violation of 21 CFR 1306.06.

In its Posthearing Brief, Respondent contended that the evidence produced during the hearing ''demonstrated that the prescriptions at issue were neither per-se unreasonable or issued without an appropriate investigation'' [39] and that Respondent, therefore, did not violate its corresponding responsibility. Resp Posthearing, at 1. I disagree. First, as discussed *supra,* PIC Davison's testimony regarding the extent of her investigations on the subject prescriptions lacked credibility and was unsupported by any documentation. Second, it was Dr. Alverson's expert testimony that some of the subject prescriptions—those with combinations of oxycodone, hydrocodone, and alprazolam, all prescribed in high doses—were sufficiently dangerous that they ''on their face were invalid.'' Tr. 487. Dr. Alverson also testified that there were red flags on patient A.C.'s prescriptions that, in her expert opinion, were unresolvable and were, in fact, so egregious that if presented with the prescription, she not only would have declined to fill it, she would have notified the police. *Id.* at 439–40. PIC Davison's decisions to dispense these prescriptions despite the unresolvable red flags indicate that she either did not conduct the thorough investigation she claims to have conducted or was willfully blind to the results of her own investigation. It is also uncontroverted that Respondent conducted no investigation before filling forged prescriptions for patient R.D.

Finally, Respondent has argued that the Government's case must fail because the Government did not produce any of the subject physicians, or physicians' representatives, to rebut PIC Davison's testimony that she had contacted the prescribing physicians to verify the subject prescriptions were legitimate and medically necessary given the conditions of the patients. Resp Posthearing, at 2. Respondent did not elaborate on its argument or cite any legal precedent for it, and it is contrary to Agency decisions. *See, e.g., Zion Clinic Pharmacy,* 83 FR at 10,899. Accordingly, I reject it.[40]

b. 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

[39] In its Posthearing Brief, Respondent seemed to agree with the Government that the subject prescriptions had red flags, but it is difficult to make a blanket statement on Respondent's acknowledgement of the red flags identified by Dr. Alverson because PIC Davison's testimony at the hearing was equivocal. For example, she described two patients from the same household presenting substantially similar prescriptions from the same prescriber as a circumstance that ''would raise a flag'' but then said that she did not find the circumstances suspicious because it was common for family members to see the same doctor. Tr. 646–47. In its Posthearing Brief, however, Respondent did not contest any of the red flags identified by Dr. Alverson. Instead, Respondent only argued that PIC Davison had properly investigated all subject prescriptions by calling the issuing physicians to verify the validity and medical necessity of the prescription.

[40] Furthermore, as discussed *supra* at I.E., I do not place any weight on PIC Davison's testimony that she adequately investigated and resolved the red flags on the subject prescriptions because she produced no contemporaneous documentary evidence to support her claim and because the ALJ found, and I agree, that the testimony was not credible.

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 violated multiple federal regulations and Alabama state laws related to the maintenance of records. The CSA requires registrants like Respondent to ''maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of,'' 21 U.S.C. 827(a), in accordance with and with such relevant information as required by the CSA implementing regulations, 21 U.S.C. 827(b). The State of Alabama also imposes separate recordkeeping requirements on pharmacies.

i. Inventories

Registrant pharmacies are required to make an initial inventory of controlled substances ''on hand'' on the date they first engage in dispensing of controlled substances. 21 CFR 1304.11(b). ''In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.'' *Id.* The initial inventory must be available for at least two years from the date of the inventory for inspection and copying by the DEA. 21 CFR 1304.04(a).

DI Two requested the Respondent Pharmacy's initial inventory during the May 20, 2015 administrative inspection. PIC Davison was unable to produce the initial inventory and conceded at the hearing that she did not know she was supposed to have an initial inventory. *Supra* I.B.2. After the July 6, 2015 meeting with the DEA, PIC Davison emailed DI One and representatives of the Alabama Board of Pharmacy a computer-generated record, entitled ''Narcotic Sales Report,'' which included a list of the schedule III through V controlled substances procured by Respondent Pharmacy from Cardinal Health, the pharmacy's sole pharmaceutical distributer, from May 1, 2014 through May 31, 2014. GX 7, at 58–59. PIC Davison wrote ''Initial Inventory'' at the top of the report before faxing it.

PIC Davison's *post hoc* attempts to create an initial inventory do not meet the requirements of 21 CFR 1304.11(b). Even assuming the ''Narcotic Sales Report'' record was in the pharmacy during the May 20, 2015 inspection as PIC Davison claims (a claim which is refuted by DI Two whose testimony the ALJ found credible), there is no evidence that the report was created when the Respondent Pharmacy commenced dispensing controlled substances, and PIC Davison testified that she did not mark the report as an ''initial inventory'' until after the July 6, 2015 meeting with the DEA. The report also does not meet the requirements for an initial inventory because it does not have a specific date or a notation of whether it was taken on the open or close of business on that date. I find, therefore, that there is substantial evidence that Respondent Pharmacy violated 21 CFR 1304.11(b) by failing to create and maintain a record of an initial inventory.

Alabama state law, like under federal law, also required Respondent to conduct an inventory on the ''date it first engages in dispensing of controlled substances.'' Ala. Admin. Code 680–x–3–.08(3). After the initial inventory, Respondent was required to conduct an annual inventory of controlled substances on or around January 15 of each calendar year. Ala Admin. Code 680–X–3–.08(1). The inventories must be signed and dated and indicate whether they were taken as of the close or opening of business. Ala. Admin. Code 680–x–3–.08(4).

Respondent did not produce either the initial or the January 15 inventory required by state law at the May 20, 2015 inspection, *supra* I.B.2, and PIC Davison conceded during the hearing that she did not conduct an inventory on or about January 15, 2015, as required by state law, Tr. 714. I therefore find that there is substantial evidence that Respondent did not conduct the required inventories in violation of 680–x–3–.08 of the Alabama Administrative Code.

ii. Allegations Respondent Violated Regulations Related to Schedule II Orders

The Government alleged that Respondent violated DEA recordkeeping regulations for ordering schedule II controlled substances in both its paper and electronic ordering systems. ALJX 1, at 6. Specifically, the Government alleged that on sixteen electronic records of controlled substances ordered by Respondent through the CSOS between March 24, 2015 and May 19, 2015, Respondent did not indicate that the orders were received and that on fifteen records of controlled substances ordered by Respondent on DEA Form 222s from November 13, 2014 to March 10, 2015, Respondent did not notate whether the orders were received. *Id.* (citing 21 CFR 1305.13(e) and 1305.22(g)).

As support for the allegation that Respondent did not properly maintain DEA Form 222s, the Government submitted copies of 15 ''purchaser's Copy 3'' of order forms Respondent submitted to its distributer. GX 3. Under DEA's regulations, ''[t]he purchaser must 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.'' 21 CFR 1305.13(e). PIC Davison testified that she received the fifteen orders, *supra* I.B.2., but the DEA Form 222s for the orders do not have a record of the date received or the number of items received, GX 3. Respondent thus violated 21 CFR 1305.13(e).

As support for the allegation that Respondent did not properly maintain records or receipt of orders made electronically in the CSOS, the Government submitted print-outs of Respondent's CSOS orders from March 13, 2015 to May 19, 2015. GX 2. Sixteen of the twenty orders are not recorded as ''Received.'' *Id.* Under DEA regulation 21 CFR 1305.22(g), ''[w]hen a purchaser receives a shipment [of controlled substances from an electronic order], the purchaser must create a record of the quantity of each item received and the date received'' and ''the record must be electronically linked to the original order and archived.'' PIC Davison testified that Respondent Pharmacy received the sixteen orders not recorded as ''Received,'' *supra* I.B.2, but the CSOS does not have a record of the date received or the number of items received, GX 3. Respondent thus violated 21 CFR 1305.22(g).

iii. Allegation Respondent Violated Schedule III–V Orders Recordkeeping Requirements

Under 21 CFR 1304.22(a)(2)(iv) and (c), Respondent Pharmacy was required to maintain a record of each order of controlled substances that included the date of receipt, the quantity acquired, and the name, address, and registration number of the person from whom the substances were acquired. The Government alleged that Respondent violated this requirement by failing to record the date and amount of controlled substances ''actually

received.'' ALJX 1, at 6 (citing 21 CFR 1304.21(d)). To support this allegation, the Government submitted 64 invoices for orders of schedule III–V controlled substances from Respondent Pharmacy.[41] GX 4. The invoices all listed the name, address and registration number of the person from whom the substances were acquired and the quantity of substances and date shipped. On some of the receipt invoices, Respondent had circled the quantity shipped, which DI Two inferred could indicate the amount received was correct, but on other receipt invoices, there were no circled quantities. Tr. 50–51; GX 4. PIC Davison did sign the invoices, which she testified she did to document receipt of the order and confirm that the quantity and date listed on the invoice were correct. Tr. 578; GX 4.

I find that PIC Davison's signature on the invoices was insufficient to meet the record requirements of 21 CFR 1304.22(a)(2)(iv) and that, therefore, Respondent violated the regulation. The regulation requires registrants to record the date of receipt and quantity acquired. The invoices from Respondent Pharmacy do contain the date and quantity *shipped* but they do not list the date r*eceived,* and the regulation and the Pharmacy Manual, which was introduced at the hearing and which PIC Davison testified she used to develop her policies and procedures, clearly state that the registrant must ''record[] the date the drugs were received and confirm that the order is accurate.'' GX 50. While the regulation does not specify the manner in which the registrant must make the notations in the record, Respondent Pharmacy failed to meet this requirement because it did not record the date of receipt on the invoices in any manner and can only argue that it confirmed the accuracy of the order on the invoices where the quantities were circled.

iv. 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 I & Superior Pharmacy II,* 81 FR 31,310, 31,341 (2016); *see also Hills Pharmacy,* 81 FR at 49,843–45 (considering allegations of overages and shortages).

The audit of six oft-diverted controlled substances at the Respondent Pharmacy revealed dramatic discrepancies with both shortages and overages of drugs. The Respondent Pharmacy conceded most of the discrepancies, but explained that they resulted from her unfamiliarity with her drug supplier's computer software and the wrong inventory list being mistakenly downloaded at the time of the audit. This explanation provides no defense. The Respondent Pharmacy is obliged to ''maintain, on a current basis, a complete and accurate record of each controlled substance,'' 21 CFR 1304.21(a), and to make its records readily available for review by DEA, s*ee* 21 CFR 1304.04(a). Additionally, even Respondent's own ''self-audit,'' which PIC Davison testified she made using an inventory report she did not produce during the DEA audit, contained discrepancies for four of the six audited controlled substances.

I find, therefore, there is substantial evidence to support the allegation that Respondent Pharmacy failed to keep a current and accurate record of controlled substances, pursuant to 21 CFR 1304.21(a).

v. Twenty-One Day Absence of PDMP Inputs

Under Alabama state law, a licensed pharmacy is required to report each dispensation of a controlled substance to the Alabama Prescription Drug Monitoring Program. Ala. Code § 20–2–213; Tr. 507–08. Dr. Alverson testified that from November 10, 2014, until December 1, 2014, the Respondent Pharmacy made no reports of dispensing controlled substances to the PDMP, despite the presence of original prescriptions evidencing the filling of controlled substances during that period. Tr. 393–95. *See* Tr. 174; GX 10, at 36; GX 12; GX 22, at 23.

PIC Davison explained that she ''guessed'' this lapse was due to a software glitch in Respondent Pharmacy's computer system. Tr. 754. This provides no defense for Respondent Pharmacy's failure to report for three weeks and its failure to make any corrective measures until prompted to do so by the Alabama Board of Pharmacy.[42] Respondent Pharmacy has a legal responsibility to report each controlled substance dispensation. In his Recommended Decision, the ALJ noted that the long lapse begs the questions: ''why did the lapse go on for so long; why did the Respondent Pharmacy not quickly correct the lapse? It suggests the Respondent Pharmacy was not checking the PDMP frequently.'' RD, at 56.

Accordingly, I find that Respondent Pharmacy failed to submit records to the PDMP in violation of Alabama law.

2. Factor Five

Under Factor Five, the Administrator is authorized to consider ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). This factor encompasses ''conduct which creates a probable or possible threat (and not only an actual [threat]) to public health and safety.'' *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,401 n.2 (2011). The Government argues that Respondent Pharmacy's inaccurate reporting to the Alabama Prescription Drug Monitoring Program and the confusion that the inaccurate reporting caused threatened public safety and weigh in favor of revocation under Factor Five.

The record reveals that the Respondent Pharmacy did submit incorrect information to the Alabama PDMP on several occasions. DI One had received a call from a local doctor, Dr. F., complaining that the Respondent Pharmacy had filled a prescription and attributed it to Dr. F. on the PDMP, which this doctor had not prescribed. Tr. 157–60; GX 8. DI One retrieved the original prescription from the Respondent Pharmacy, which identified

[41] The Government submitted copies of 69 invoices but conceded at the hearing and in the Government's Posthearing Brief that only 64 of the invoices contained orders for controlled substances. Govt Posthearing, at 3.

[42] It is not clear from PIC Davison's testimony when or how she learned of the three week gap in reporting, but her testimony strongly implies she did not know about it until she was alerted by the Alabama Board of Pharmacy. ''Q [from DEA Attorney Hill]: 'When were you alerted to the fact that you had stopped reporting any controlled substances to PDMP?' A [from PIC Davison]: 'I cannot tell you at this point. I've had numerous run-ins with the Board of Pharmacy, you guys from several cases. I can't actively tell you that particular date, but when we did learn about it, we submitted the file.''' Tr. 755.

a different doctor as prescriber, yet the pharmacy label incorrectly identified Dr. F. as the prescriber. Tr. 162–68. DI One also found instances where duplicate prescriptions were entered into the PDMP by the Respondent Pharmacy and where Respondent Pharmacy had input prescriptions under a prescriber DEA number with insufficient digits. *Id.* at 172–73; *see* GX 10, at 36 and 40. But there is also evidence in the record that the PDMP is subject to error, delayed reporting, and correction. Dr. Alverson testified that a pharmacy cannot correct a PDMP entry itself and must contact the PDMP staff with the correction. Tr. 412, 506. She further testified that the pharmacy is under no obligation to ensure the correction was made, Tr. 507, and DI One testified that she did not, as part of her investigation, contact the PDMP to determine if Respondent Pharmacy had submitted corrected information for any of the incorrect entries, Tr. 272.

The Government concedes that stray errors in PDMP reports would not render a registration inconsistent with the public interest and argues only that such errors should be considered to ''threaten the public health safety'' under Factor Five when they are ''sufficiently persistent and widespread that they are credibly said to impede regulatory investigations.'' Govt Posthearing, at 47 n.23. The Government has failed to meet the standard it set for itself. While I agree with the Administrative Law Judge's assessment that errors within the PDMP compromise the important role the program plays in the state in preventing the abuse and diversion of controlled substances, RD, at 56, the handful of PDMP submission errors by Respondent Pharmacy that are supported by evidence on the record were not so widespread or egregious in this case that they threatened the public health and safety.

The Government has demonstrated that Respondent's *omissions* to the PDMP were sufficiently persistent and widespread that they could pose a threat to public health and safety, but in this case, those failures were a violation of state law and were considered under Factor Four. Because Factor Five only implicates ''such other conduct,'' it necessarily follows that conduct considered in Factors One through Four may not be considered under Factor Five. *Holiday CVS,* 77 FR at 62,345. Accordingly, Factor Five does not weigh for or against revocation.

3. Summary of the Public Interest Factors

As found above, Respondent Pharmacy filled controlled substance prescriptions for nearly a dozen patients in violation of its corresponding responsibility and outside the usual course of professional practice. 21 CFR 1306.04, 1306.06. It also violated numerous federal and state record keeping regulations related to controlled substances. Thus, I conclude that Respondent 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's continued registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that 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 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 23848, 23853 (2007)). DEA cases have repeatedly found that when a registrant has committed acts inconsistent with the public interest, ''the Respondent is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Holiday CVS,* 77 FR at 62,339 (internal quotations omitted). *See, also, Hoxie* v. *DEA,* 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 held to undermine 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).[43]

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.''). Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Linda Sue Cheek, M.D.,* 76 FR 66,972, 66,973 (2011).

Here, the ALJ recommended that I find that Respondent did not ''meet[] the evidence with an acceptance of responsibility.'' RD, at 57. PIC Davison testified during the hearing that she took responsibility for many of the established violations but her acceptance was equivocal, did not cover the full scope of her violations, and lacked credibility. PIC Davison acknowledged many of her recordkeeping failures but did not acknowledge the impropriety of a single dispensing of a controlled substance at issue in this case.[44] Dr. Alverson's fact testimony, which the ALJ found credible, also belied PIC Davison's acceptance of responsibility at the hearing. Just a month before the hearing, PIC Davison was eschewing her

[43] Here, the Respondent Pharmacy testified that there were five instances, out of the 69 alleged invoice violations for orders of schedule III–V controlled substances, in which the Government had mistakenly included non-controlled substances. The Government credibly explained the cause of the charging error and amended the charges accordingly. The ALJ did not consider this legal challenge by the Respondent as compromising her potential acceptance of responsibility, RD, at 58, and neither will I.

[44] The closest PIC Davison came to acknowledging that she improperly filled a prescription was to say that if presented with female M.A.'s prescription today she would *perhaps* not fill it based on 2016 guidelines on the dangers of opioid and benzodiazepine combinations, but Dr. Alverson testified that the danger was widely known in the pharmacy community when PIC Davison filled female M.A.'s prescription. See Tr. 420, 773–75.

professional responsibility telling Dr. Alverson that whatever problems her patients had with controlled substances, they already had those problems when they arrived at her pharmacy.

PIC Davison also failed to recognize the real harm that could result to her patients and the public from her violations and minimized the severity of her misconduct. She seemed more concerned with preventing another DEA investigation than preventing diversion repeatedly testifying that she was sorry her violations ''caused all this uproar.'' Tr. 691–92.

Additionally, the ALJ found that PIC Davison was not fully candid during the investigation and hearing, which tends to rebut any acceptance of responsibility. The ALJ stated that ''[i]n testifying as to factual matters regarding the initial inventory, the timing and extent of her purported investigations, and documentation of her investigations, PIC Davison's testimony was marked with a level of equivocation, implausibility, and inconsistently that profoundly undermined her efforts to diminish her culpability.'' RD, at 58. For example, Respondent conceded that it failed to properly document PIC Davison's due diligence investigations as to some of the subject patients, while suggesting to have properly documented her investigation as to other patients; however, the ALJ specifically found that PIC Davison's testimony regarding her documentation of investigations was not always credible. *Id.* Finally, PIC Davison's false statements on her registration renewal application, which were made during the pendency of the instant matter, undermine any claims of contrition and her argument that she can be trusted with the responsibilities of a registration.

In Respondent's favor, PIC Davison testified that she has undertaken corrective measures to prevent the reoccurrence of violations of her regulatory and professional responsibilities. She has instituted new policies to remedy Respondent Pharmacy's numerous recordkeeping violations including contemporaneous electronic notations of communications with physicians, up to date ordering processes for all controlled substances, and manual input of PDMP information to avoid errors. The ALJ also found that PIC Davison's in-hearing ''impromptu evaluation of patient cases demonstrated that she was fully aware of her responsibilities to investigate suspicious prescriptions, and the steps she reported she would take to investigate largely mirrored those recommended by Dr. Alverson.'' RD, at 60. The ALJ was skeptical, however, that PIC Davison ''would consistently honor her commitment to regulatory compliance . . . in light of her conflicting priorities.'' *Id.* (referencing PIC Davison's repeated statements that she prioritized patient consultation over documentation and other legal requirements). He also referred to her remedial measures as ''dilatory.'' *Id.* at 58. I am similarly skeptical that PIC Davison will consistently comply with her new recordkeeping procedures. The record demonstrates that for some of the established recordkeeping violations, such as the improperly documented paper and electronic orders of schedule II substances, PIC Davison was aware of and capable of fulfilling her obligations, but she chose not to prioritize compliance. ''Past performance is the best predictor of future performance,'' *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1998); and the ALJ found, and I agree, that the allegations sustained on the record in this matter ''exhibit a near deliberate policy to de-prioritize the Respondent Pharmacy's record-keeping and corresponding prescription investigation responsibilities,'' RD, at 60.

The ALJ recommended that ''the record supports the imposition of a sanction.'' RD, at 58. I agree that is the appropriate result on the record in this case.

Respondent has not presented sufficient mitigating evidence to assure me that it can be entrusted with the responsibility carried by a DEA registration. As the ALJ noted in his Recommended Decision ''[t]he Respondent Pharmacy's case is characterized by non-compliance *ab initio.* The Respondent Pharmacy opened for business without a demonstrated commitment to regulatory compliance, both in [PIC] Davison's corresponding responsibility and its record-keeping, and only appears to have become compliant with the prospect of losing its registration.'' RD, at 59. The evidence shows that PIC Davison committed extensive violations of federal and state recordkeeping requirements, filled prescriptions that were not issued for a legitimate medical purpose in violation of her corresponding responsibility, and, perhaps most egregiously, continued to fill prescriptions lacking a legitimate medical purpose even after multiple discussions with DEA and state pharmacy board officials regarding her regulatory noncompliance. She also continued to violate federal law after the initiation of the proceedings to revoke her registration by submitting false statements on her registration renewal and falsification on an application for registration cannot be tolerated. *Peter A. Ahles, M.D.,* 71 FR at 50,099; *Hoxie,* 419 F.3d at 483.

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. I agree with the ALJ's conclusion that ''the Agency's interest in general deterrence is . . . best served here by the revocation of the Respondent Pharmacy's COR.'' RD, at 60. Based on the number and variety of the established violations in this case, a sanction less than revocation would send a message to the regulated community that ''due diligence is not a required condition precedent to operating as a registrant.'' *Zion Clinic Pharmacy,* 83 FR at 10,903.

The ALJ recommended revocation as the appropriate sanction. RD, at 60. A balancing of the statutory public interest factors, coupled with consideration of the Respondent Pharmacy's failure to accept full responsibility, the absence of record evidence of timely and committed remedial measures to guard against recurrence, and the Agency's interest in deterrence, supports the conclusion that the Respondent Pharmacy should not continue to be entrusted with a registration. The Respondent Pharmacy's false statements within its registration renewal application also supply an independent ground for revocation pursuant to section 824(a)(1). Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

IV. 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 FH4377291 issued to Heavenly Care 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 Heavenly Care Pharmacy to renew or modify this registration. This order is effective September 28, 2020.

Timothy J. Shea,

Acting Administrator.

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