The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or schedule II controlled substances to the above listed companies.

Dated: January 29, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–02866 Filed 2–20–19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–01]

Ajay S. Ahuja, M.D.; Decision and Order

On May 25, 2017, Administrative Law Judge (ALJ) Charles Wm. Dorman issued the attached Recommended Decision (R.D.).[1] Neither party filed exceptions to the ALJ's Recommended Decision. Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact as modified,[2] conclusions of law, and recommended sanction except as explained below.

Respondent's Registration Status

Respondent is the holder of DEA Certificate of Registration AA3029293, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 825 High Ridge Road, Stamford, Connecticut. Government Exhibit (GX) 1, at 1. Although not alleged in the Order to Show Cause, *see* Administrative Law Judge Exhibit (ALJ Ex.) 1, I also find that the administrative record in this case and this Agency's registration records, of which I take official notice,[3] show that Respondent is the holder of DATA-Waiver Identification Number XA3029293. *See* GX 1, at 1. Respondent's DATA-Waiver authority authorized him to dispense or prescribe schedule III–V narcotic controlled substances which ''have been approved by the Food and Drug Administration . . . specifically for use in maintenance or detoxification treatment'' for up to 275 patients. 21 CFR 1301.28(a) & (b)(1)(iii).

Respondent's registration was due to expire on June 30, 2017. GX 1, at 1. Although the ALJ correctly indicated that the record before him did ''not contain evidence that the Respondent filed an application of renewal,'' R.D., at 2 n.1, the Agency's registration records do indicate, and I take official notice,[4] that Respondent submitted a renewal application on May 9, 2017. Because Respondent has submitted a timely renewal application, I find that Respondent's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i). Moreover, because Respondent's DATA-Waiver authority is contingent on Respondent being a practitioner with a valid DEA registration, *see* 21 U.S.C. 823(g)(2)(A); 21 CFR 1301.28(a), I find that Respondent's DATA-Waiver authority also remained in effect pending issuance of this Decision and Final Order. Thus, this case remains a live controversy, and I have jurisdiction to decide this matter.

Respondent's Corrective Action Plan

After submitting a timely request for a hearing on October 6, 2016, *see* ALJ Ex. 2, Respondent submitted a Corrective Action Plan (CAP) pursuant to 21 U.S.C. 824(c)(2)(C) on October 25, 2016 to the Deputy Assistant Administrator of DEA's Office of Diversion Control. ALJ Ex. 9. As part of his CAP, Respondent promised that he: (1) ''will not order or dispense controlled substances;'' (2) ''will no longer prescribe controlled substances to his family members;'' (3) ''will retain an independent monitor to review and evaluate his practice;'' (4) ''will continue to educate himself on issues related to drug diversion and enroll in related continuing medical education;'' (5) ''will cooperate with DEA in a candid and truthful manner in future communications with DEA;'' and (6) ''will authorize DEA to access all his prescribing records for controlled substances in the Connecticut Prescription Monitoring and Reporting System ('CPMRS').'' *Id.* at 2–3.

On November 4, 2016, the Assistant Administrator of DEA's Diversion Control Division rejected Respondent's CAP and further ''determined there is no potential modification of your [ ]CAP that could or would alter my decision in this regard.'' *See* Exhibit A (Letter from then-Assistant Administrator Louis J. Millione to Respondent (dated November 4, 2016)) to ALJ Ex. 11, at 1. I conclude that the facts set forth in the adopted Recommended Decision demonstrate that the Agency had adequate grounds to deny Respondent's CAP. Thus, I agree with the Agency's denial of Respondent's CAP, and I too reject it.

Pre-Hearing Identification of Documents Used To Impeach a Witness on Cross-Examination

In his Recommended Decision, the ALJ criticized the Government's use of the Respondent's earlier deposition testimony[5] to impeach Respondent during cross-examination because, *inter alia,* ''the Government had not identified the deposition transcript as a document it intended to use prior to the hearing.'' R.D., at 10. I do not adopt the ALJ's suggestion that a party is precluded from using information or a document to impeach a witness during cross-examination unless it is identified prior to the administrative hearing. The APA states that ''[a] party is entitled . . . to conduct such cross-examination as may be required for a full and true disclosure of the facts.'' 5 U.S.C. 556(d). Likewise, Agency precedent has applied this APA standard to hold that ALJs lack the authority to preclude a party from using relevant information to impeach a witness during cross-examination. *See Trinity II,* 83 FR 7304, 7322 n.43 (2018)

[1] All citations to the Recommended Decision are to the slip opinion issued by the ALJ.

[2] I have modified the Recommended Decision by replacing the full name of DEA and state law enforcement officials with their initials. I have indicated where I have made these modifications in the Recommended Decision with brackets.

[3] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

[4] I take official notice of this fact pursuant to the same authority set forth *supra* in footnote 3.

[5] The deposition of Respondent apparently occurred in connection with a civil case brought by the United States Attorney's Office for the District of Connecticut against Respondent. *See* Transcript 61–62, 64, 109–10, 291; *United States* v. *Ahuja,* No. 3:14–CV–1558, 2017 WL 1807561 (D. Conn. May 5, 2017), *aff'd,* 736 F. App'x 20 (2d Cir. 2018).

(''the CALJ lacks the authority to preclude a respondent from using relevant information to impeach a witness during cross-examination'') (citing 5 U.S.C. 556(d)); *Farmacia Yani,* 80 FR 29053, 29063 n.25 (2015) (finding that it was prejudicial error to preclude a respondent from using a document to impeach a witness on cross-examination, even where respondent had failed to present the document to the Government in advance of the hearing). Thus, all parties have the right to use any relevant information to impeach a witness, regardless of whether the party disclosed that information prior to the administrative hearing.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. AA3029293 and DATA-Waiver Identification Number XA3029293, issued to Ajay S. Ahuja, M.D., be, and they hereby are, revoked. I further order that any pending application of Ajay S. Ahuja to renew or modify the above registration, or any pending application of Ajay S. Ahuja for any other registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: February 10, 2019.

Uttam Dhillon,

Acting Administrator.

Paul A. Dean, Esq., for the Government

Ronald W. Chapman II, Esq., and Robert J. Andertz, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Charles Wm. Dorman, Administrative Law Judge.

The Drug Enforcement Administration (''DEA'' or ''Government'') served Ajay S. Ahuja, M.D., (''Respondent'') with an Order to Show Cause (''OSC''), seeking to revoke his DEA Certificate of Registration (''COR''), Number AA3029293. Administrative Law Judge Exhibit (''ALJ-'') 1. In response to the OSC, the Respondent timely requested a hearing before an Administrative Law Judge. ALJ-2. The hearing in this matter was held in Hartford, Connecticut on March 13, 2017.

The issue before the Administrator is whether the record as a whole establishes that the Respondent's COR should be revoked and any pending applications [6] be denied because the Respondent's registration would be inconsistent with the public interest under 21 U.S.C. §§ 824(a)(4) and 823(f).

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

ALLEGATIONS

I. Improper Recordkeeping

1. Between February 2012 and February 2014, the Respondent failed to maintain accurate dispensing records for the following controlled substances, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R. § 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6) [7]: Alprazolam 1 mg tablets (Schedule IV), Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets (Schedule III), Guaifenesin with Codeine Phosphate 10 mg syrup (Schedule V), Testosterone Cypionate 200 mg/mL injectable (Schedule III), and Zolpidem Tartrate ER 12.5 mg tablets (Schedule IV). ALJ-1, at 2-3.

2. Between February 2012 and February 2014, the Respondent was unable to account for the following controlled substances, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R. § 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6): 59 bottles (approximately 5310 tablets) of Alprazolam 1 mg tablets (nearly 10% of total supply), 21 bottles (approximately 630 tablets) of Hydrocodone 10/650 mg tablets (approximately 17.5% of total supply), 58 bottles of Guaifenesin with Codeine Phosphate 10 mg syrup (approximately 27.36% of total supply), 2 vials of Testosterone Cypionate 200 mg/mL injectable (entire supply), and 3 bottles (90 tablets) of Zolpidem Tartrate ER 12.5 mg tablets (entire supply). ALJ-1, at 2-3.

3. Between December 2011 and February 2014, the Respondent failed to maintain a dispensing log in accordance with federal law for the following controlled substances: Alprazolam 1 mg tablets, Hydrocodone 10/650 mg tablets, and Guaifenesin with Codeine Phosphate 10 mg syrup. ALJ-1, at 2-3. Specifically, the Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R. §§ 1304.22(c), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 2-3.

4. Between February 2012 and January 2014, the Respondent failed to maintain controlled substance receipts for the following orders of controlled substances, in violation of 21 U.S.C. § 842(a)(5), 21 C.F.R. §§ 1304.04(a) and 1304.21(a), Conn. Gen. Stat. § 21a-254(c), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6): 17 shipments of Alprazolam 1 mg tablets, 8 shipments of Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets, 7 shipments of Guaifenesin with Codeine Phosphate 10 mg syrup, a shipment of Testosterone Cypionate 200 mg/mL injectable, and a shipment of Zolpidem Tartrate ER 12.5 mg tablets from A&S Medical Solutions, and 10 shipments of Lyrica 75 mg tablets, and 8 shipments of Lyrica 50 mg tablets from J. Knipper & Company, Inc. ALJ-1, at 3-4.

5. Between December 2011 and February 2014, the Respondent failed to separate his Schedule III-V controlled substance records from his non-controlled substance records, in violation of 21 C.F.R. § 1304.04(f)(2), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4.

6. The Respondent failed to perform and maintain a biennial inventory of controlled substances, in violation of 21 U.S.C. § 827(a)(1), 21 CFR § 1304.11(c), Conn. Gen. Stat. § 21a-254(h), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4.

7. The Respondent failed to report to the Connecticut State Commissioner of Consumer Protection that he was engaging in dispensing drugs, and failed to biennially notify the Commissioner of his intent to continue to dispense drugs, in violation of Conn. Gen. Stat. §§ 20-14f and 21a-317 and 21 C.F.R. § 1306.03(a)(1). ALJ-1, at 5.

[6] The Respondent's COR will expire by its terms on June 30, 2017. ALJ-1, at 1. The record does not contain any evidence that the Respondent filed an application for renewal. *See* 21 C.F.R. § 1301.36(i); *Richard J. Settles, D.O.,* 81 FR 64940, 64940-42, (2016).

[7] In the OSC and Government's Prehearing Statement, many of the Government's citations to the Connecticut statutes and regulations were incorrect. *See* ALJ-1; ALJ-13, at 12. This issue was addressed during the December 5, 2016 Prehearing Conference, and in my Prehearing Order, issued the same day, and the Government was ordered to prepare copies of the Connecticut statutes and regulations it intended to rely upon. ALJ-20, at 2. In its Supplemental Prehearing Statement, the Government provided an updated list and copies of the correct Connecticut statutes and regulations. ALJ-30, at 12, attach. A. Accordingly, the Respondent was put on notice of the Connecticut statutes and regulations that the Government alleged the Respondent violated. I refer to these updated statutes and regulations in this Recommended Decision.

II. Improper Prescribing to Himself & Family Members

8. Between 2012 and 2014, the Respondent issued controlled substance prescriptions to himself and his family members for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 5-6.

III. Improper Prescribing to Patients

9. The Respondent issued controlled substance prescriptions to patients for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 6-10.

a. Specifically, on at least 20 occasions between May 2012 and November 2014, the Respondent issued multiple overlapping prescriptions for controlled substances to his patients, which made it possible for these patients to receive early refills of controlled substances and facilitated potential diversion of those controlled substances. ALJ-1, at 6-7.

b. On at least 35 occasions involving at least eight of the Respondent's patients between July 2010 and November 2014, the Respondent issued prescriptions to those patients without any documentation of those prescriptions, or any bases for the prescriptions, in the patient's record, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 7-8.

c. On at least 9 occasions involving at least three of the Respondent's patients between April 2011 [8] and March 2014, the Respondent dispensed controlled substances to those patients from his office supply without any documentation of those dispenses, or any bases for those dispenses, in the patient's records, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. §§ 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 8.

d. On at least 26 occasions involving at least seven of the Respondent's patients between April 2011 and October 2014 the Respondent issued prescriptions to those patients without sufficient documentation of those prescriptions, or any bases for the prescriptions, in the patient's records, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c)(d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 9.

e. On at least 45 occasions involving at least seven patients between May 2010 and March 2014, the Respondent dispensed controlled substance prescriptions from his office supply without sufficient documentation of those dispenses, or sufficient documentation of the bases for them, in the patient's records, in violation of Conn. Gen. Stat. § 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c)(d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 10.

IV. Failure to Maintain Adequate Security

10. The Respondent failed to maintain adequate security for the controlled substances in his possession, in violation of 21 C.F.R. § 1301.75(b) and Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-326-1(d). ALJ-1, at 11.

V. Other Conduct Threatening the Public Health and Safety (Factor Five)

11. Additionally, the Respondent engaged in conduct which may threaten the public health and safety, in violation of 21 U.S.C. C.F.R. § 823(f)(5). ALJ-1, at 11.

WITNESSES

I. The Government's Witnesses

The Government presented its case through the testimony of five witnesses. First, the Government presented the testimony of [R.M.], Director of the Drug Control Division of the State of Connecticut. Tr. 15-32. [R.M.] has held his current position for under a year, and he was previously a Connecticut Drug Control Agent. Tr. 15-16. [R.M.] testified concerning his background, training, and previous experience. Tr. 16. Along with DEA Diversion Investigator [N.C.], [R.M.] was involved in the removal of controlled substances from the Respondent's clinic. Tr. 18. Additionally, [R.M.] testified about the nature and workings of Connecticut's Prescription Monitoring Program (''PMP'') and that physicians who dispense controlled substances are required to report that dispensing to the Connecticut PMP. Tr. 17-18. I find [R.M.]'s testimony to be thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

Second, the Government presented the testimony of DEA Diversion Investigator [N.C.]. Tr. 33-48. [N.C.] has been stationed at the DEA Camden Resident Office in Maple Shade, New Jersey since November 28, 2016, but was previously stationed at the DEA Hartford Resident Office in Rocky Hill, Connecticut. Tr. 33-34. [N.C.] testified concerning his background, training, and experience as a diversion investigator for the DEA. Tr. 34. [N.C.] testified that his Group Supervisor, [L.L.], directed him to assist the State of Connecticut in retrieving controlled substances from the Respondent's clinic. Tr. 35. [N.C.] testified that he went with [R.M.] to the Respondent's clinic to pick-up the Respondent's expired controlled substances. Tr. 36-37. I find [N.C.]'s testimony to be thorough and internally consistent. Therefore, I merit [N.C.]'s testimony as credible in this Recommended Decision.

Third, the Government presented the testimony of [P.L.], who was a Drug Control Agent with the Connecticut Department of Consumer Protection. Tr. 49-78. [P.L.] is currently a pharmacist with the Food and Drug Administration, a position she has held since January 2017. Tr. 49. [P.L.] worked with the State of Connecticut Drug Division during the course of the investigation into the Respondent. Tr. 49. [P.L.] testified as to how the investigation into the Respondent began and about how she contacted Diversion Investigator [M.J.] to assist with the investigation. Tr. 51-52. In January 2014, [P.L.] went with [M.J.] to the Respondent's clinic to ask the Respondent some questions. Tr. 55. [P.L.] testified about her interactions with the Respondent during this visit, specifically, statements the Respondent made concerning why the investigators were asking the Respondent about alprazolam, as he did not believe that it was a diverted or abused substance. Tr. 55. [P.L.] and [M.J.] went back to the Respondent's clinic in February 2014 to execute an Administrative Inspection Warrant (''AIW''). Tr. 59. Additionally, [P.L.] testified about the security measures in place for controlled substances at the Respondent's clinic during both of her visits, and how these measures violated Connecticut state regulations. Tr. 64-65. Finally, [P.L.] testified concerning an e-mail correspondence that she had with the Respondent, in which he requested assistance with his expired controlled substances. Tr. 63. I find [P.L.]'s testimony to be thorough, detailed, and internally consistent. Therefore, I merit

[8] Paragraph 9(c) of the OSC lists the inclusive dates as February 2012 and March 2014. ALJ-1 at 8. Subparagraph 9(c)(ii) of the OSC, however, lists the dates as April 2011 and March 2014. ALJ-1, at 8. Further, the Respondent stipulated to the dates of April 2011 and March 2014. ALJ-32, at 6, para. 42. Thus, the Respondent was on notice that the inclusive dates for this allegation were April 2011 and March 2014.

it as credible in this Recommended Decision.

Fourth, the Government presented the testimony of DEA Diversion Investigator [M.J.]. Tr. 79-140. [M.J.] testified that she has held her position for six years, and discussed her background and thirteen-week training at the DEA Training Academy at Quantico. Tr. 80. [M.J.] initially became involved in the investigation into the Respondent when she was requested to assist the Connecticut Drug Control Division in their investigation of the Respondent. Tr. 80-81. [M.J.] testified about how she and [P.L.] pulled PMP records for the Respondent. Tr. 81-82.

[M.J.] also testified about her meeting with the Respondent in January 2014 and some of the advisements that she and [P.L.] provided the Respondent with regards to the Respondent's recordkeeping and security practices. Tr. 84-86. Additionally, [M.J.] testified about statements the Respondent made questioning why she and [P.L.] were investigating the Respondent's benzodiazepine prescriptions because he did not believe they were being diverted or abused. Tr. 87. [M.J.] also testified about the events that took place on February 21, 2014, when she, along with [P.L.], another diversion investigator, and two Connecticut police officers, served the Respondent with an AIW. Tr. 94. I find [M.J.]'s testimony to be thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.[9]

Finally, the Government presented the testimony of Adam Perrin, M.D. (''Dr. Perrin''). Tr. 141-209. Dr. Perrin was accepted as an expert, without objection, in the field of clinical medicine in the State of Connecticut with respect to prescribing controlled substances. Tr. 149, 153. Dr. Perrin is currently employed by the University of Connecticut School of Medicine and specializes in family medicine and primary care sports medicine. Tr. 141, 143. He also maintains a medical license in the State of Connecticut, a Certificate of Added Qualification in Primary Care Sports Medicine, a Certificate from the American College of Medical Quality, and is Board Certified in Family Medicine. Tr. 143-44. Additionally, Dr. Perrin does team physician work for Wesleyan University, and consulting work for the Livanta Organization, where he conducts peer reviews of cases and determines the appropriateness of a patient's discharge and whether the patient was at the necessary level of care. Tr. 142.

Dr. Perrin testified that he has taken continuing medical education courses in the areas of controlled substances and pain management, most recently through the Connecticut State Medical Society. Tr. 144. He also testified that he has experience treating patients with controlled substances, specifically opiates, dealt with addictive issues of patients, and is familiar with the risks of prescribing controlled substances. Tr. 146-47. He testified that he is familiar with the standards of care in the State of Connecticut and is ''familiar with how doctors should conduct themselves in Connecticut while prescribing controlled substances for a legitimate medical purpose.'' Tr. 148. This body of knowledge is based on Dr. Perrin's experience as a physician and as a teacher of physicians. Tr. 147.

Dr. Perrin testified about Suboxone, what it is and what it is used for. Tr. 153-55. Dr. Perrin reviewed the Ahuja family patient file, Government Exhibit 11, as well as prescriptions written by Dr. Ahuja to his family members to determine whether the records revealed any therapeutic duplication of controlled substances. Tr. 157-59. Additionally, Dr. Perrin reviewed copies of prescriptions written by the Respondent and was asked to compare those prescriptions to the patient files for members of the Respondent's family to determine if the prescriptions were documented in those patient files. Tr. 159-63.

Dr. Perrin reviewed the Stipulations of Fact, ALJ-32, and was asked his opinion with respect to the standard of care. Tr. 164-82. Specifically, Dr. Perrin discussed the potential harm of overlapping prescriptions, Tr. 165, 178, and why having inadequate or no documentation in a patient's file would fall below the standard of care in Connecticut. Tr. 166, 202-04.

I find Dr. Perrin's testimony to be thorough, detailed, and internally consistent. Therefore, I merit is as credible in this Recommended Decision.[10]

II. The Respondent's Witness

The Respondent presented his case through his own testimony. Tr. 210-303. The Respondent testified concerning his background, medical education and training. Tr. 211-14. The Respondent also testified as to how he began treating Suboxone patients and the nature of his treatment of these patients. Tr. 216-24. He testified that currently about 80% of his medical practice is devoted to treatment of Suboxone patients. Tr. 217. The Respondent also testified about his treatment of patient D.M., and about a prescription he wrote to this patient for Percocet. Tr. 225-26. Additionally, the Respondent testified about the security measures present in his clinic, including an alarm system, and where he stored his controlled substances. Tr. 227-34. The Respondent also testified as to his interactions with [M.J.] and [P.L.] during their investigation in 2014. Tr. 238, 254-56.

Throughout his testimony on direct examination, the Respondent testified about his changing opinions with regards to what controlled substances are being abused and diverted, Tr. 238-39, and various patient behaviors that present red flags. Tr. 240-42. His opinions changed after he took medical education courses which changed the way he practiced medicine and prescribed controlled substances. Tr. 239-51. The Respondent also testified that during a course he took in January 2017 he learned the importance of documenting the treatment he provided to his patients. Tr. 246.

While the Respondent testified with confidence and clarity during direct examination, his testimony on cross examination was somewhat combative, confusing, and evasive. For example, when the Respondent was asked to compare the content of the OSC with the facts he had stipulated to, he was unable to do so. Tr. 259-63. When the Respondent was asked if his testimony on several issues was different at the hearing than at an earlier deposition, and when showed the transcript of the deposition, the Respondent was unable to recall. Tr. 279-92. When asked twice

[9] I found [M.J.]'s testimony to be disingenuous concerning her knowledge of the DEA policy concerning the use of DEA Form 82, and whether the form included an advisement to a practitioner of the right to counsel at the time of an inspection. Given her experience and the ''hundreds'' of times she has used DEA Form 82, that portion of her testimony was not credible. Nevertheless, that testimony concerned only a peripheral issue in this case, and it does not detract from the credibility of the remainder of her testimony. Tr. 112-14, 137-38.

[10] I note that Dr. Perrin mistakenly testified that Suboxone is a Schedule II controlled substances, when it is actually Schedule III. Tr. 154. I also found Dr. Perrin's testimony concerning the reason that he would not write prescriptions for himself or for family members to be less than convincing. Specifically, he testified that there is no law or regulation in Connecticut that prevents a doctor from writing a prescription for himself or for family members, but, based on guidance from the American Medical Association (''AMA''), it would be considered an ethical violation to do so. Tr. 194. He further testified that few physicians are aware of the AMA guidelines. Tr. 196-97. He then testified that he would not write such prescriptions because he would be worried about his own license and what his peers might think. Tr. 196, 205. Dr. Perrin finally testified he would not write such prescriptions as a matter of personal philosophy. Tr. 205-06. These two minor areas of Dr. Perrin's testimony, do not undermine my assessment that, overall, his testimony is credible and merits significant weight.

when his office associate, Dr. Jacobson, left the Respondent's medical practice, the Respondent gave rambling answers, but he did not answer the question of when Dr. Jacobson left. In addition, when badgered as to the number of Suboxone patients that he treats, the Respondent eventually did not even give an approximate number. Tr. 275-79.

While combativeness, confusion and evasiveness tend to undermine the credibility of a witness, here the combativeness, confusion and evasiveness concerned issues of little significance. For example, having the Respondent agree that the factual allegations contained in the OSC matched many of the facts to which the Respondent had already stipulated was meaningless. The two documents speak for themselves. Further, the Government's use of the Respondent's earlier deposition testimony was a meaningless exercise for several reasons. First, the Government had not identified the deposition transcript as a document it intended to use prior to the hearing. Second, the issues the Government questioned the Respondent about, based upon his deposition testimony, do not relate to the allegations contained in the OSC, except for the disposition of some cough syrup, where the Respondent admitted he took some home. Tr. 291, 298. Third, it had minimal impeachment value. Finally, as the Respondent noted, the exact number of Suboxone patients the Respondent treats, so long as it is less than the number he is allowed to treat, is of no consequence to this decision. Accordingly, when accessing the Respondent's credibility, I find that the clear and confident manner in which the Respondent testified on direct examination outweighs the manner in which he testified on cross examination. Further, when comparing his testimony to that of other witnesses, I find that it was generally consistent with that of the Government's witnesses. Thus, I find the Respondent's testimony credible on all relevant factual issues. I, however, find it less credible than that of other witnesses in one area.

The Respondent testified that he did not recall telling [M.J.] and [P.L.] that benzodiazepines are not commonly diverted or abused. Tr. 282. [P.L.] testified that the Respondent did not understand why she was concerned about alprazolam, which is a benzodiazepine, because he did not think it was diverted or abused. Tr. 55. [M.J.] also testified that she heard the Respondent make a similar statement. Tr. 87. The Respondent testified that he told [M.J.] and [P.L.] that oxycodone was more addictive than a benzodiazepine. Tr. 253, 282. Given the Respondent's acknowledgement of discussing the topic and his inability to recall if he made the statement reported by both [M.J.] and [P.L.], I credit their testimonies on this issue.

The parties stipulated to the authenticity of all of the Government's exhibits, accordingly, all of the Government's exhibits were admitted into evidence. Tr. 8. Additionally, the parties stipulated to the authenticity of Respondent Exhibits A, C-J, accordingly, these exhibits were also entered into evidence. Tr. 9.

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

STIPULATIONS OF FACT [11]

The Government and the Respondent stipulated the following facts (''Stip. of Fact''):

1. Respondent is registered with the DEA as a practitioner to handle Controlled Substances in Schedules II–V under DEA COR AA3029293 at 825 High Ridge Road, Stamford, Connecticut 06905-1904.

2. Respondent is presently licensed in Connecticut as a medical doctor (M.D.) with medical license 25539.

3. On February 21, 2014, DEA executed an Administrative Inspection Warrant at Respondent's medical practice. During the execution of the warrant, DEA and state drug control agents reviewed documentation of Respondent's recordkeeping practices related to his obligations under the Controlled Substances Act (CSA), its regulations, and state law.

Recordkeeping Violations

4. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Alprazolam 1 mg tablets, a Schedule IV controlled substance, and was unable to account for 59 bottles (approximately 5310 tablets) of Alprazolam 1 mg tablets received from his supplier.

5. Between February 2012 and February 2014, Respondent failed to maintain a dispensing log for Alprazolam 1 mg tablets in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

6. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Hydrocodone Bitartrate with Acetaminophen 10/650 mg (Hydrocodone 10/650 mg) tablets, a Schedule III controlled substance, and was unable to account for 21 bottles (approximately 630 tablets) of Hydrocodone 10/650 mg tablets received from his supplier.

7. Between January 2012 and February 2014, Respondent failed to maintain a dispensing log for Hydrocodone 10/650 mg tablets in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

8. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Guaifenesin with Codeine Phosphate 10 mg syrup, a Schedule V controlled substance, and was unable to account for 58 bottles of Guaifenesin with Codeine Phosphate 10 mg syrup received from his supplier.

9. Between December 2011 and February 2014, Respondent failed to maintain a dispensing log for Guafenesin with Codeine Phosphate 10 mg syrup in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

10. Between May 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Testosterone Cypionate 200 mg/mL injectable, a Schedule III Controlled Substance and was unable to account for 2 vials of Testosterone Cypionate 200 mg/mL injectable received from his supplier.

11. Between August 2013 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Zolpidem Tartrate ER 12.5 mg tablets, a Schedule IV controlled substance, and was unable to account for 3 bottles (90 tablets) of Zolpidem Tartrate ER 12.5 mg tablets received from his supplier.

12. Between February 2012 and November 2013, Respondent ordered 17 shipments of Alprazolam 1 mg tablets from A&S Medical Solutions. Respondent failed to maintain

[11] These stipulations of fact are numbered the same manner as those found in ALJ-32, and also correspond to the references made to a specific stipulation mentioned in the transcript.

controlled substance receipt records for any of these shipments.

13. Between February 2012 and November 2013, Respondent ordered 8 shipments of Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for any of these shipments.

14. Between February 2012 and November 2013, Respondent ordered 7 shipments of Guaifenesin with Codeine Phosphate 10 mg syrup from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for any of these shipments.

15. Between February 2012 and January 2014, Respondent ordered a shipment of Testosterone Cypionate 200 mg/mL injectable from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for this shipment.

16. Between February 2012 and January 2014, Respondent ordered a shipment of Zolpidem Tartrate ER 12.5 mg tablets from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for this shipment.

17. Between February 2012 and January 2014, Respondent ordered 10 shipments of Lyrica 75 mg tablets, a Schedule V controlled substance, from J. Knipper & Company, Inc. Respondent failed to maintain controlled substance receipt records for these shipments.

18. Between February 2012 and January 2014, Respondent ordered 8 shipments of Lyrica 50 mg tablets, a Schedule V controlled substance, from J. Knipper & Company, Inc. Respondent failed to maintain controlled substance receipt records for these shipments.

19. Between December 2011 and February 2014, Respondent failed to separate Schedule III–V controlled substance records from his non-controlled substance records. Specifically, Respondent's Schedule III–V dispensing logs included dispensing logs for Azithromycin, which is not a controlled substance.

20. Respondent failed to perform and maintain a biennial inventory of controlled substances.

21. Respondent failed to report to the State Commissioner of Consumer Protection that he was engaged in dispensing drugs, and Respondent failed to biennially notify the Commissioner of his intent to continue to dispense drugs.

Improper Prescribing to Family Members

22. After the execution of the administrative warrant, DEA issued Respondent two successive administrative subpoenas for copies of patient records for several individuals to whom Respondent had issued controlled substances prescriptions, including Respondent and several family members.

23. On December 18, 2014, pursuant to an administrative subpoena, Respondent provided DEA with a copy of, among others, patient records for himself and certain family members, including N.A., U.A., and G.A.

24. On at least two occasions between December 2012 and December 2014, Respondent either issued, or dispensed, overlapping prescriptions of controlled substances constituting early fills for himself (alprazolam 1 mg, Schedule IV) and a family member, N.A., (zolpidem tartrate 10 mg).

25. On at least seven additional occasions, between February and September 2014, Respondent either issued a controlled substance prescription to himself (lorazepam, Schedule IV) or dispensed controlled substances to himself (guaifenesin with codeine, Schedule V; alprazolam 1 mg, Schedule IV) with inadequate documentation in the medical record.

26. On at least five additional occasions, between February and October 2014, Respondent issued his family member, N.A., prescriptions for a variety of controlled substances (including Lunesta 3 mg, Schedule IV; zolpidem tartrate 10 mg, Schedule IV; alprazolam 1 mg, Schedule IV) with inadequate documentation in the medical record.

27. On at least one additional occasion, between April and December 2014, Respondent issued a controlled substance prescription (hydrocodone 10 mg/acetaminophen 650 mg (Lorcet), formerly Schedule III) to family member, G.A., and inadequately documented that prescription and the basis for it in G.A.'s medical record.

Improper Prescribing to Patients

28. On December 18, 2014 and July 31, 2015, pursuant to DEA administrative subpoenas, Respondent provided DEA with a copy of patient records for certain patients, including J.C., J.Cu., W.L., L.M., R.P., M.R., A.S., J.T., and J.V.

29. On ten occasions between May and November 2012, Respondent issued multiple overlapping prescriptions for alprazolam 1 mg (Schedule IV) to his patient, J.Cu., within days of issuing previous prescriptions to J.Cu. for the same controlled substance. For example, in the course of 199 days in which, by Respondent's instructions, J.Cu. should not have consumed more than 597 dosage units of Alprazolam 1 mg, Respondent prescribed J.Cu. 1870 dosage units of Alprazolam 1 mg.

30. On five occasions between October and November 2014, Respondent issued multiple overlapping prescriptions for controlled substances (Tramadol 50 mg (Schedule IV), Methylphenidate 20 mg (Schedule II), and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient, J.T., within days of issuing previous prescriptions to J.T. for the same controlled substances. In the course of 28 days in which, by Respondent's limited instructions, J.T. should not have consumed more than 84 dosage units of Tramadol 50 mg, Respondent prescribed or dispensed to J.T. 540 dosage units of Tramadol. Likewise, Respondent issued J.T. a prescription for 90 tablets of Methylphenidate 20 mg for a thirty day supply. Six days later Respondent issued J.T. two additional prescriptions for a total of 90 additional tablets of Methylphenidate. On November 15, 2014, Respondent issued J.T. a prescription for 30 tablets of Dextroamphetamine/Amphetamine 20 mg, a 15 day supply. Three days later, Respondent issued J.T. another prescription for 45 additional tablets of the same controlled substance.

31. On four occasions between June and October 2012, Respondent issued multiple overlapping prescriptions for alprazolam 1 mg to his patient, A.S., within days of issuing a previous prescription to A.S. for the same controlled substance. In the course of 133 days in which, by Respondent's limited instructions, A.S. should not have consumed more than 399 dosage units of Alprazolam 1 mg, Respondent prescribed or dispensed to A.S. at least 780 dosage units of Alprazolam 1 mg.

32. On one occasion in October 2012, Respondent issued an overlapping prescription for alprazolam 1 mg (Schedule IV) to his patient, M.R., within days of issuing a previous prescription to M.R. for the same controlled substance. In the course of 28 days in which, by Respondent's instructions, M.R. should have consumed 42 dosage units of Alprazolam 1 mg, Respondent prescribed M.R. 150 dosage units of Alprazolam 1 mg during that time frame.

33. On eight occasions between October and November 2014, Respondent issued controlled substance prescriptions (including Tramadol 50 mg (Schedule IV), methylphenidate 20 mg (Schedule II), and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient J.T. without any documentation of those

prescriptions, or the bases for them, in the patient's medical record.

34. On seven occasions between July 2010 and July 2014, Respondent issued controlled substance prescriptions (Diazepam 5 and 10 mg (Schedule IV)) to his patient L.M. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

35. On six occasions between May 2012 and March 2013, Respondent issued controlled substance prescriptions (including dextroamphetamine/amphetamine 20 mg and alprazolam 1 mg) to his patient W.L. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

36. On four occasions between May 2012 and February 2013, Respondent issued controlled substance prescriptions (including alprazolam 1 mg and phenobarbital 60 mg—both Schedule IV) to his patient J.Cu. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

37. On four occasions between May 2011 and November 2013, Respondent issued controlled substance prescriptions (Hydrocodone 7.5 mg/Ibuprofen 200 mg (Schedule III)) to his patient R.P. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

38. On four occasions between November 2011 and March 2014, Respondent issued controlled substance prescriptions (alprazolam 1 mg (Schedule IV) and Oxycodone 10 mg/Acetaminophen 325 mg (Schedule III)) to his patient M.R. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

39. On at least one occasion in December 2013, Respondent issued a prescription for alprazolam 1 mg (Schedule IV) to his patient J.C. without any documentation of that prescription, or the basis for it, in the patient's medical record.

40. On at least one occasion in October 2012, Respondent issued a prescription for alprazolam 1 mg (Schedule IV) to his patient A.S. without any documentation of that prescription, or the basis for it, in the patient's medical record.

41. On five occasions between June 2012 and April 2013, Respondent dispensed controlled substances (alprazolam 1 mg (Schedule IV) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient A.S. without any documentation of those dispenses, or their bases, in the patient's medical record.

42. On two occasions between April 2011 and March 2014, Respondent dispensed controlled substances (alprazolam 1 mg (Schedule IV) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient W.L. without any documentation of those dispenses, or their bases, in the patient's medical record.

43. On two occasions between February 2012 and October 2012, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient J.V. without any documentation of those dispenses, or their bases, in the patient's medical record.

44. On ten occasions between September 2013 and March 2014, Respondent issued controlled substance prescriptions (dextroamphetamine/amphetamine 20 mg and 30 mg (Schedule II) and alprazolam 1 mg (Schedule IV)) to his patient J.C. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

45. On six occasions between April 2011 and March 2014, Respondent issued controlled substance prescriptions (dextroamphetamine/amphetamine 20 mg) to his patient W.L. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

46. On at least two occasions between May 2012 and February 2013, Respondent issued controlled substance prescriptions (phenobarbital 60 mg (Schedule IV) and alprazolam 1 mg (Schedule IV)) to his patient J.Cu. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

47. On at least two occasions between February 2013 and July 2013, Respondent issued controlled substance prescriptions (diazepam 10 mg (Schedule IV)) to his patient L.M. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

48. On at least two occasions between April 2012 and October 2012, Respondent issued controlled substance prescriptions (hydrocodone 10 mg/acetaminophen 325 mg (Schedule III) and on at least two occasions between April 2012 and October 2012, Respondent issued controlled substance prescriptions (hydrocodone 7.5 mg/ibuprofen 200 mg (Schedule III) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) to his patient R.P. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

49. On at least two occasions between May 2012 and October 2012, Respondent issued controlled substance prescriptions (oxycodone 7.5 mg/ibuprofen 200 mg (Schedule III) and alprazolam 1 mg (Schedule IV)) to his patient M.R. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

50. On two occasions in October 2014, Respondent issued controlled substance prescriptions (methylphenidate 20 mg (Schedule II) and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient J.T. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

51. On 12 occasions between May and November 2012, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III) and alprazolam 1 mg (Schedule IV)) from his office supply to his patient J.Cu. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

52. On 12 occasions between May 2010 and July 2013, Respondent dispensed a controlled substance (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient J.V. with insufficient documentation of those dispenses, or the bases for them, in the patient's record.

53. On nine occasions between May 2011 and November 2013, Respondent dispensed controlled substances (hydrocodone 7.5 mg/ibuprofen 200 mg (Schedule III), hydrocodone 7.5 mg/acetaminophen 650 mg, and guaifenesin with codeine (Schedule V)) from his office supply to his patient R.P. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

54. On seven occasions between April 2011 and July 2013, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg and alprazolam 1 mg) from his office supply to his patient W.L. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

55. On two occasions between June 2013 and March 2014, Respondent dispensed a controlled substance (alprazolam 1 mg (Schedule IV)) from his office supply to his patient M.R. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

56. On at least two occasions between October 2012 and April 2013,

Respondent dispensed a controlled substance (alprazolam 1 mg) from his office supply to his patient A.S. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

57. On at least one occasion between September 2013 and March 2014, Respondent dispensed a controlled substance (alprazolam 1 mg (Schedule IV)) from his office supply to his patient J.C. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

Accordingly, the Respondent stipulated to a majority of the facts alleged by the Government in the OSC. However, the Respondent did not stipulate to the factual allegations: concerning prescribing to himself and his family members; concerning his failure to maintain adequate security; and concerning his other conduct which may have threatened the public health and safety.

FINDINGS OF FACT [12]

I. Respondent's Background

1. The Respondent was born and raised in New Delhi, India. Tr. 211. As a child, the Respondent spoke Hindi, Punjabi, and a little English at home with his family. Tr. 211.

2. The Respondent earned his college degree in 1971 from the College of Sciences in New Delhi. Tr. 211. Subsequently, the Respondent went to medical school at the Maulana Azad Medical College in New Delhi, and graduated in 1977. Tr. 211-12.

3. In April of 1979, the Respondent came to the United States. Tr. 212.

4. Once in the United States, the Respondent took a three-month course to prepare to take the Educational Commission for Foreign Medical Graduates exam, to have his medical degree recognized in the United Sates. Tr. 212. The Respondent passed this exam in July of 1979. Tr. 213.

5. In July 1980, the Respondent began an internship at LaGuardia Hospital in Forest Hills, New York. Tr. 213.

6. After his internship, the Respondent finished his residency at Andover Hospital in 1984. Tr. 213. The Respondent specialized in internal medicine. Tr. 213.

7. The Respondent was licensed to practice medicine in the State of Connecticut in January 1985. Tr. 214.

8. After being licensed, the Respondent worked at a ''walk-in'' medical clinic in Danbury, Connecticut. Tr. 214.

9. In 1988, the Respondent opened the Immediate Medical Care Center, which he still owns and where he maintains his medical practice. Tr. 215.

II. The 2014 Investigation

10. [P.L.] began investigating the Respondent after she received information from a probation officer who had concerns about the Respondent's prescribing habits. Tr. 51. [P.L.] ran a report using Connecticut's prescription monitoring and reporting system (''PMP'') to review the Respondent's prescribing habits and she identified prescriptions suggestive of ''early refills or duplicate therapy.'' Tr. 51. [P.L.] also contacted the DEA, [M.J.], because of the controlled substances involved. Tr. 52, 81. At this point, it was a joint investigation between the DEA and the State of Connecticut. Tr. 52-53.

11. Pharmacies in Connecticut are required to submit information into the PMP when they fill a prescription. Tr. 73. In addition, when a doctor dispenses a controlled substance, the doctor is required to report that event to the PMP within 24 hours. Tr. 18, 30-31. When [P.L.] ran the Respondent's PMP, it should have shown ''all prescriptions that have been filled by pharmacies uploaded into the PMP under [the Respondent] as the prescriber,'' as well as any controlled substances the Respondent had dispensed and reported. Tr. 73-74. Administering a controlled substance directly to the patient would not show up on the PMP, but dispensing the substance to the patient to take home would show up on the PMP—if properly reported. Tr. 75-76.

12. [P.L.] and [M.J.] went through the Respondent's PMP report and then collected copies of prescriptions the Respondent had written from the pharmacies that filled the prescriptions. Tr. 51, 54, 62-63.

13. [M.J.] also pulled data from the Automation of Reports and Consolidated Orders System (''ARCOS''). Tr. 83. ARCOS is a DEA system where manufacturers and distributors report purchases of specific controlled substances by a registrant. Tr. 83-84.

14. Although the ARCOS records indicated that the Respondent had obtained controlled substances, the PMP report did not indicate that he had dispensed any. Tr. 81, 139.

15. On the morning of January 31, 2014, [M.J.] and [P.L.] arrived, unannounced, at the Respondent's clinic to speak with him. Tr. 55-56, 83, 117. When they arrived, the only other employee at the Respondent's clinic was his secretary. Tr. 77. Because the Respondent was busy with patients, he asked [M.J.] and [P.L.] if they could talk later that day when another physician would be in the office to see patients. Tr. 55, 117, 254-55. When [M.J.] and [P.L.] came back later in the day on January 31, 2014, another physician was present. Tr. 78.

16. When [P.L.] and [M.J.] returned to the Respondent's office on January 31, 2014, they asked the Respondent if he prescribed to his family members. Tr. 55, 86. The Respondent indicated he mostly did not, ''because he did not want to take the responsibility if something went wrong.'' Tr. 55-56; *see also* Tr. 70, 87. When [P.L.] showed the Respondent the prescriptions written for family members, the Respondent verified that he wrote the prescriptions. Tr. 56. When [M.J.] and [P.L.] asked the Respondent if he had copies of patient files for his family members the Respondent said he did not. Tr. 56, 87.

17. On January 31, 2014, [M.J.] and [P.L.] advised the Respondent of the requirement to conduct a biennial inventory and about the security of controlled substances. Tr. 84-85, 118.

18. On January 31, 2014, [M.J.] and [P.L.] asked the Respondent to sign an agreement stating that he would no longer treat his family members, but he refused to do so. Tr. 56.

19. The Respondent refused to allow [M.J.] and [P.L.] to conduct an audit of the controlled substances he had in his clinic on January 31, 2014, and he denied their request to conduct an inspection. Tr. 56, 87, 93-94, 117.

20. On January 31, 2014, the Respondent told [M.J.] and [P.L.] that he was not aware that alprazolam, a benzodiazepine, was being abused or diverted. Tr. 55, 87; *see also* Tr. 238, 253, 268-69.

21. On February 21, 2014, [M.J.], [P.L.], DI [J.H.], and two Stanford police officers, arrived at the Respondent's clinic to execute an Administrative Investigation Warrant (''AIW'') in order to collect records and to perform a count of the Respondent's controlled substances. Tr. 59-60, 94.

22. [M.J.] served the Respondent with the warrant on February 21, 2014, and he was not cooperative initially. Tr. 60, 94-95. [J.H.], one of the police officers, and the Respondent's secretary, encouraged the Respondent to comply with the warrant. Tr. 60, 94-95.

23. On February 21, 2014, [M.J.] attempted to conduct an audit of the Respondent's controlled substances, but was unable to do so because there was

[12] The extensive and detailed stipulations of fact essentially establish the factual bases for most of the allegations contained in the OSC. It is, therefore, unnecessary to make additional findings of fact based upon my independent review of documentary evidence and my evaluation of the credible testimony, where those findings would essentially duplicate the stipulations of fact.

no biennial inventory. Tr. 96. Instead, [M.J.] performed a closing count and the investigators collected what records they were able to from the Respondent, including some dispensing logs and what the Respondent called his medication log. Tr. 96-97.

III. Recordkeeping & PMP Requirements

24. There were recordkeeping issues in the Respondent's practice prior to February 2014. Tr. 224.

25. After reviewing the documents that [M.J.] and [P.L.] were able to obtain during the execution of the AIW on February 21, 2014, they were able to identify some problem patients, review their data, and request their records. Tr. 102-03.

26. Prior to April 2014, the Respondent had never logged onto the PMP system. Tr. 102. Although there is nothing in the Code of Federal Regulations (''CFR'') that specifically requires a physician to check the PMP records, Tr. 103, federal law requires a practitioner to comply with state law.[13] Tr. 103.

27. In Connecticut, a practitioner is required to notify the state of his intent to dispense controlled substances. Conn. Gen. Stat. § 20-14f; Tr. 19.

28. After the Respondent stopped dispensing controlled substances, he no longer had an obligation to report that he intended to dispense controlled substances. Tr. 25.

29. Respondent Exhibit D is a ''Record of Surrender or Disposal'' issued by the State of Connecticut—Department of Consumer Protection, Drug Control Division. RE-D. The record is signed by the Respondent, [R.M.], and [N.C.], and it documents the controlled substances that were received from the Respondent's clinic on March 4, 2016. Tr. 21, 40; RE-D.

30. Even if the Respondent is no longer dispensing controlled substances, it would still be considered a state violation in 2017 if the Respondent failed to report dispensing controlled substance to the state that occurred in 2014. Tr. 29.

IV. Security

31. The purpose of requiring that a storage cabinet be substantially secure is to prevent the theft or diversion of controlled substances. Tr. 123.

32. The Respondent stored all of his controlled and non-controlled substances in the same location.[14] Tr. 57.

33. Prior to [M.J.] and [P.L.]'s arrival at the Respondent's office on January 31, 2014, the Respondent kept his controlled substances in an unlocked closet, with a louvered door, located in a locked unused patient care room. Tr. 57-58, 65-66, 85-86, 229, 232, 301-03.

34. The Respondent stored unused medical equipment, valued at approximately $150,000, in the unused locked examination room, where he also stored his controlled substances. Tr. 229-30.

35. On February 21, 2014, the controlled substances were in the same unlocked closet as they were when [M.J.] and [P.L.] visited the Respondent on January 31, 2014. Tr. 60-61, 95, 232.

36. The Respondent did not order any additional controlled substances after the investigators came to visit him. Tr. 231.

37. The Respondent ''set up a lock in the closet'' because the investigators asked him to do so. Tr. 231-32; *see also* Tr. 36, 40.

38. When [R.M.] came to the Respondent's clinic on March 4, 2016, he does not remember if the Respondent's controlled substances were locked in a cabinet. Tr. 22.

39. When [R.M.] and [N.C.] arrived at the Respondent's clinic on March 4, 2016, to retrieve the Respondent's expired controlled substances, the closet where the controlled substances were stored was not locked. Tr. 36-37, 41. The door to the unused examination room was closed, but [N.C.] does not recall if it was locked. Tr. 42, 46-47.

40. The Respondent denies that he failed to maintain adequate security of the controlled substances in his possession. Tr. 268; 301.

V. Prescribing to Self and Family

41. Concerning the allegation of therapeutic duplication, the Respondent knew that the patient would not take the two medications at the same time because the patient was his own son, N.A. Tr. 266-67. N.A. came to the Respondent and told him that the medication he was currently taking was not working and asked the Respondent if he could prescribe something else. Tr. 267. N.A. lived with the Respondent. Tr. 267.

42. The Respondent wrote prescriptions for controlled substances to either himself or to family members, N.A. or U.A., at least 14 times between June 2012 and December 2014 without any documentation of those prescriptions or any bases for those prescriptions in any medical records. Tr. 56, 87, 161-63, 267-68; GE-11, GE-13-23, GE-25-31.

43. Government Exhibit 8 is a prescription for Percocet written by the Respondent to patient D.M. on November 23, 2013. Tr. 92, 225; GE-8. D.M. is the Respondent's patient. Tr. 225. When the pharmacy filled this prescription, it was issued to the Respondent, rather than to D.M. Tr. 92; GE-8.

44. D.M.'s patient file does not contain an entry on November 23, 2013. Tr. 93.

45. The prescription written to D.M. is for Percocet, which contains oxycodone. Tr. 226; GE-8. The Respondent cannot take oxycodone. Tr. 226-27.

VI. Dr. Perrin's Testimony

46. Physicians who write prescriptions and dispense controlled substances in Connecticut are subject to regulatory review. Tr. 153.

47. Dr. Perrin's testimony regarding inadequate documentation was based on his review of the patient files of the Respondent's patients, to include those of the Respondent's family. Tr. 156, 201-02.

48. Suboxone is a synthetic opioid-based medication that is primarily used to treat patients who are addicted to opioids. Tr. 154, 198.[15]

49. Alprazolam is a Schedule IV controlled substance and is classified as a benzodiazepine. Tr. 154.

50. According to Centers for Disease Control and Prevention guidance, prescribing opioids and benzodiazepines in conjunction with each other ''should be avoided because the combination can be potentially very dangerous in terms of overdose and addictive potential.'' Tr. 155. The rationale being that ''[w]hen you combine those two substances, they can be significantly over-sedating'' and put the patient at a ''higher risk for overdose.'' Tr. 199.

51. Government Exhibit 18 is a prescription for Lunesta, indicating five refills, issued by the Respondent to N.A.

[13] In determining whether the continued registration is in the public interest, federal law requires the consideration of the respondent's compliance with applicable state, federal, or local laws related to controlled substances. 21 U.S.C. § 823(f)(4) (''Factor Four''). The DEA has found that a respondent's failure to report various dispensings to the state's PMP, in violation of that state's law, was a violation under Factor Four. *See Keith Ky Ly, D.O.,* 80 Fed. Reg. 29025, 29035 (2015).

[14] At the hearing, [P.L.] testified that storing controlled and non-controlled substances in the same location was a separate violation of regulations. Tr. 57. This allegation, however, was never raised in the OSC or in any of the Government's prehearing or post-hearing filings. *See* ALJ-1; ALJ-13; ALJ-30. Therefore, I give no weight to this testimony.

[15] Although Dr. Perrin testified that Suboxone is a Schedule II substance, Tr. 154, it is in fact listed in Schedule III. 21 C.F.R. § 1308.13(e)(2)(i).

on February 24, 2014. GE-18; Tr. 157. Lunesta is a sedative hypnotic agent that is used to treat insomnia. Tr. 156-57.

52. Government Exhibit 19 is a prescription for Ambien, with five refills, issued by the Respondent to N.A. on March 5, 2014. GE-19; Tr. 157. Ambien is also a sedative hypnotic used to treat insomnia. Tr. 156-57.

53. Government Exhibit 19 is an overlapping prescription with Government Exhibit 18. Tr. 157.

54. The combination of prescriptions Lunesta and Ambien constitutes therapeutic duplication. Tr. 157.

55. In the Respondent's patient file for N.A., there is a notation, dated March 5, 2014, that ''Luntesta doesn't help changed to Ambien 10 mg #30.'' GE-11, at 7. In Dr. Perrin's opinion, this notation is not sufficient to justify the therapeutic duplication. Tr. 158-59. Therapeutic duplication can be dangerous if one prescription is not discontinued in favor of the other. Tr. 159. Dr. Perrin explained that ''[i]t has to be carefully explained not to mix'' and that ''[i]deally we like to dispose of the prior prescription'' and have that noted in the patient file. Tr. 159.

56. The Respondent's practice of issuing overlapping prescriptions of controlled substances for himself, a family member, and other patients fell below the standard of care in Connecticut. Tr. 164-65, 169-73, 203-04; Stip. of Fact 24, 29-32. Issuing ''overlapping prescriptions . . . could pose potential harm if taken simultaneously for . . . those who don't know to take it properly.'' Tr. 165. Additionally, ''it's a cumulative effect of too much of a potentially sedating medication that also has addictive potential.'' Tr. 165.

57. Overlapping prescriptions increase the potential for diversion because of the additional controlled substances floating around. Tr. 207.

58. Issuing early refills is not a legitimate medical practice in the State of Connecticut. Tr. 165.

59. There is no law or regulation in the State of Connecticut that prohibits a doctor from self-proscribing. Tr. 194, 206. According to the American Medical Association (''AMA''), however, it is considered an ''ethical violation'' to self-prescribe controlled substances. Tr. 166, 194. The AMA ethical rules do not automatically set the standard of care. Tr. 194. Additionally, there are exceptions in the AMA rule to self-prescribing, including short-term treatment or minor problems. Tr. 195.

60. The Respondent's practice of issuing a controlled substance prescription to himself or his family members, or dispensing a controlled substance to himself or his family members, however, without adequate documentation in the medical record is below the standard of care in the State of Connecticut. Stip. of Fact 25-27; Tr. 166. With any prescription of a controlled substance, it is ''important to provide adequate documentation as to the precise reason for why [the] particular substance is indicated.'' Tr. 166. There needs to be ''an appropriate diagnosis that underlies the prescribing of said substance, and [there] has to be documentation that's beyond cursory to substantiate the choice of prescribing said substance.'' Tr. 166.

61. Where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance there is no legitimate medical purpose for the prescription.[16] Tr. 202. Thus, the Respondent's practice of issuing controlled substance prescriptions or dispensing controlled substances from his office supply, to patients without adequate documentation, or bases for the prescription or dispensing in the patient's medical record fell below the standard of care in the State of Connecticut and were not issued or dispensed for a legitimate medical purpose. Tr. 167-69, 173, 179-81; Stip. of Fact 25-27, 33-57.

VII. Acceptance of Responsibility

62. The Respondent admitted to most of the factual allegations contained in the COR, but he refused to answer the questions regarding whether his actions were either below the standard of care or outside the course of professional practice. Tr. 264-66; *see also* Stip. of Fact 4-57.

63. The Respondent denied that he had issued overlapping prescriptions to N.A. in a manner that constituted therapeutic duplication. Tr. 267.

64. The Respondent denied that he failed to maintain adequate security of his controlled substances, as alleged in paragraph 10 of the OSC. Tr. 268. The Respondent admitted to most of factual allegations contained in paragraph 10 of the OSC, but he denies that the room where the controlled substances were kept in an unlocked closet was unlocked. Tr. 302-03.

65. The Respondent denies that he made any statement suggesting that his ''dispensing of 'benzos' was not worthy of DEA investigation, particularly given how other doctors in [his] community were distributing Schedule II controlled substances,'' as alleged in paragraph 11(a) of the OCS. ALJ-1, at 11; Tr. 268-69.

66. The Respondent denies the allegations contained in paragraph 11(b) of the OSC, alleging that he attempted to mislead the DEA during its investigation. Tr. 269.

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

ANALYSIS

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

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

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

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

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

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. § 823(f) (2012).

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

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the

[16] While Dr. Perrin's testimony on this issue focused on Stip. of Fact 30, I find the reasoning applicable to situations where there is inadequate documentation of the need to prescribe a controlled substance.

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

I. The Government's Position

Here, the Government seeks to revoke the Respondent's COR based on Factors Two, Four, and Five. Post-Hearing Brief on Behalf of the Government (''Gov't Brief'').[17] ALJ-37 at 19-22. With regard to Factors Two and Four, the Government argues that the Respondent's ''repeated failure to comply with Federal and State laws relating to the prescribing, dispensing, and recordkeeping of controlled substances strongly militate in favor of revocation . . . .'' *Id.* at 19. The Government notes that the Respondent: dispensed overlapping prescriptions at least 22 times; issued prescriptions to family members at least 27 times without adequate medical documentation in their medical records; issued 35 prescriptions for controlled substances to non-family members without any medical documentation; dispensed controlled substances at least 9 times to non-family members without any medical documentation, and an additional 71 times without adequate documentation. *Id.* at 20-21. The Government contends that these prescriptions and the dispensing of controlled substances were not for legitimate medical purposes, and were outside the usual course of professional treatment. *Id.* at 19.

The Government also points to the numerous recordkeeping violations that the Respondent committed. Those violations resulted in the Respondent being unable to account for thousands of dosages of controlled substances. *Id.* at 21. The Government notes that ''careless recordkeeping is sufficient grounds unto itself for the Administrator to revoke Respondent's COR.'' *Id.*

With respect to Factor Five, the Government argues that the Respondent's lack of candor supports revocation. *Id.* at 22. Specifically, the Government argues that the Respondent's initial denial of having any family medical files, and then his later producing them, suggests that the Respondent created the files ''to thwart DEA's investigation.'' *Id.* The Government also argues that the Respondent was less than candid during his testimony on cross-examination, when he ''was forced to admit that he had previously testified differently.'' *Id.* at 23.

The Government also contends that the Respondent has not accepted responsibility for his conduct, and therefore any remediation he has taken is irrelevant. *Id.* at 23-26. In addition, the Government seeks an adverse inference that the Respondent did not accept responsibility for his actions based upon the Respondent's refusal to answer questions of whether his actions fell below the standard of care or were outside the course of professional practice. *Id.* at 26-27. Finally, the Government also argues that even if the Respondent had accepted responsibility his actions were so egregious that revocation of his COR would be appropriate in this case. *Id.* at 27-28.[18]

II. The Respondent's Position

In the Respondent's Proposed Findings of Fact and Conclusions of Law[19] (''Resp't Brief''), the Respondent argues that the public interest factors, when viewed in their totality, weigh in favor of his continued registration. ALJ-38, at 17. Initially, the Respondent argues that the Government's failure to present any evidence of action by the State of Connecticut against his medical license or evidence of any conviction of the Respondent weigh in favor of his continued registration. *Id.* at 17-18. Further, while the Respondent acknowledges past dispensing issues, he notes that he no longer dispenses controlled substances and he voluntarily surrendered all of his controlled substances. *Id.* at 18. He argues that such action ''supports a finding that his continued registration is consistent with the public interest at this time.'' *Id.* at 18.

The Respondent also contends that the Government failed to meet its burden of proof with respect to: paragraph 7(b) of the OSC concerning his issuance of overlapping prescriptions to a family member in a manner that constituted therapeutic duplication; paragraph 7(c) of the OCS, concerning writing a prescription for oxycodone to himself;[20] and paragraph 10 of the OSC concerning whether he maintained adequate security of his controlled substances. ALJ-38, at 19-22. With respect to Factor Five, the Respondent contends that he did not engage in other misconduct that may threaten the public health and safety. *Id.* at 22-25. Specifically, he contends that the statements he made to [M.J.] and [P.L.] comparing the relative dangers of schedule II controlled substances when compared to schedule IV controlled substances does not ''rise to the level of creating even a possible threat to public health and safety.'' *Id.* at 23. The Respondent also denies the allegations contained in paragraph 11(b) of the OSC, because the testimony does not support a conclusion that the Respondent told the investigators that he did not write prescriptions to family members.[21]

The Respondent asserts that through his testimony, and by entering into 57 stipulations of fact, he has accepted responsibility for his actions. ALJ-38, at 25-27. The Respondent also asserts that his refusal to answer questions about whether his actions fell below the level of care or were outside the usual course of professional practice does not negate his acceptance of responsibility. *Id.* at 26. He argues that the few questions he declined to answer called for legal conclusions, but that he unequivocally accepted responsibility for his actions. *Id.* Finally, the Respondent notes that he has taken the following remedial measures: the Respondent has taken numerous continuing medical education

[17] The Post-Hearing Brief on Behalf of the Government has been marked as ALJ-37.

[18] The Government did not address two significant issues in its Post Hearing Brief. First, the Government provided no analysis to support its allegation that the Respondent had failed to maintain adequate security of his controlled substances. Second, the Government's brief is silent concerning its allegation, under Factor Five, that the Respondent's *statement* to DEA investigators that he did not understand why they were concerned about ''benzos'' constitutes conduct which may threaten the public health and safety.

[19] The Respondent's Proposed Findings of Fact and Conclusions of Law have been marked as ALJ-38.

[20] Paragraph 7(c) of the OSC does not mention any specific controlled substance; rather it alleges that the Respondent issued prescriptions for controlled substances to himself and family members without any documentation of those prescriptions being placed in his medical record or the records of family members. Of note, at the hearing, the Respondent testified that the facts alleged in paragraph 7(c) of the OSC are true. Tr. 267-68.

[21] The Resp't Brief does not address the allegation, also contained in paragraph 11(b), that the Respondent told the investigators that he did not have any patient files for his family members, but then later provided those records. ALJ-1, at 11.

courses; the Respondent has incorporated what he learned in the courses into his current daily medical practice; the Respondent has discontinued dispensing controlled substances; and the Respondent no longer prescribes or dispenses controlled substances to himself or family members. *Id.* at 27–30. Accordingly, the Respondent argues that, due to his acceptance of responsibility and the remedial actions he has taken, revocation of his COR is not appropriate at this time. *Id.* at 31.

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

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Connecticut. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by a relevant state licensing board or professional disciplinary authority. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20011, 20018 (2011). Rather, a state medical board's decision to allow a doctor to practice medicine is not dispositive as to whether the doctor's DEA registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 n.16 (2009).

The Respondent argues that the lack of state board action weighs against revocation. ALJ-38, at 17-18. Agency precedent, however, establishes that where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011) (''The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'') Accordingly, Factor One does not weigh for or against revocation in this matter.

As to Factor Three, there is no evidence that Respondent has been convicted of an offense under either federal or Connecticut law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.,* 75 Fed. Reg 49956, 49973 (2010), *pet. for rev. denied, MacKay v. DEA,* 664 F.3d 808, 822 (10th Cir. 2011). The Agency has, 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.* Accordingly, Factor Three neither weighs for or against revocation in this case.

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

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

Here, the Government alleges that revocation of the Respondent's COR is appropriate under Factors Two and Four for four reasons: (1) improper recordkeeping; (2) improper prescribing to himself and family members; (3) improper prescribing to patients; and (4) failure to maintain adequate security. ALJ-1, 13, 30, 37.

I. Improper Recordkeeping

Registrants are required to keep certain records and inventories of their controlled substances. *Paul H. Volkman, M.D.,* 73 FR 30630, 30644 (2008). Among those requirements, registrants are to: (1) maintain adequate dispensing records and logs, see 21 CFR 1304.21(a) and 1304.22(c); (2) maintain receipt records for all controlled substances received, see 21 CFR 1304.04(a) and 1304.21(a); (3) maintain records of controlled substances listed in Schedules III–V, separate from other records, see 21 CFR 1304.04(f)(2); and (4) perform and maintain a biennial inventory, see 21 CFR 1304.11(c). Such recordkeeping is one of the central features of the Controlled Substances Act (''CSA'') because ''a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Superior Pharmacy I & Superior Pharmacy II,* 81 FR 31310, 31337 (2016) (quoting *Volkman,* 73 FR at 30644). The Supreme Court has noted that ''[t]he CSA and its implementing regulations set forth strict requirements regarding . . . recordkeeping.'' *Gonzales v. Raich,* 545 U.S. 1, 14 (2005). However, the DEA has also held that, where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required. *See Terese, Inc., D/B/A Peach Orchard Drugs,* 76 FR 46843, 46848 (2011).

First, the Government alleged that the Respondent failed to maintain accurate dispensing records and logs, in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.21(a) and 1304.22(c), and Conn. Agencies Regs. § 21a–326–1(d)(2), (6). ALJ-1, at 2–3. The Respondent, however, stipulated to numerous facts that establish by a preponderance of the evidence that he repeatedly failed to maintain accurate dispensing records and logs. Stip. of Fact 4-11. Accordingly, the Government's allegations that the Respondent failed to maintain accurate dispensing records and logs, as alleged in paragraphs 4(b), 4(d), and 4(f) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Second, the Government alleged that the Respondent failed to maintain controlled substance receipts for orders of controlled substances, in violation of 21 U.S.C. 842(a)(5), 21 CFR 1304.04(a) and 1304.21(a), Conn. Gen. Stat. § 21a-254(c), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 3-4. Here, too, the Respondent stipulated to numerous facts that established by a preponderance of the evidence that he repeatedly failed to maintain controlled substance receipts for orders of controlled substances that he received in his office. Stip. of Fact 12–18. Accordingly, the Government's allegations that the Respondent failed to maintain controlled substance receipts

for orders of controlled substances, as alleged in paragraphs 4(i)–4(o) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Third, the Government alleged that the Respondent failed to maintain records of controlled substances listed in Schedules III–V, separate from other records, in violation of 21 CFR 1304.04(f)(2), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4. With respect to this allegation, the Respondent stipulated that he had failed to keep his records of his Schedules III–V controlled substances separate from his records of other controlled substances. Stip. of Fact 19. This factual stipulation establishes by a preponderance of the evidence that the Respondent failed to maintain records of controlled substances, listed in Schedules III–V, separate from other records. Accordingly, that allegation, as set forth in paragraph 4(p) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration.

Fourth, the Government alleged that the Respondent failed to perform and maintain a biennial inventory of his controlled substances, in violation of 21 U.S.C. 827(a)(1), 21 CFR 1304.11(c), Conn. Gen. Stat. § 21a-254(h), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4. The Respondent stipulated to the fact that he failed to perform and maintain a biennial inventory of his controlled substances. Stip. of Fact 20. This stipulation satisfies the preponderance of evidence standard to prove that the Respondent did not perform or maintain a biennial inventory as he was required to do. Accordingly, the Government's allegation that the Respondent failed to perform and maintain a biennial of his controlled substances, as alleged in paragraph 4(q) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration

Fifth, the Government alleged that as a result of the Respondent's poor record keeping he was unable to account for significant quantities of several different controlled substances he received from his supplier, in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 2-3. The Respondent conceded that these allegations were true. Stip. of Fact 4, 6, 8, 10, 11. These stipulations satisfy the preponderance of evidence standard to prove that the Respondent was unable to account for significant quantities of his controlled substances. Accordingly, the Government's allegations that the Respondent was unable to account for quantities of controlled substances he received from his supplier, as alleged in paragraphs 4(a), 4(c), 4(e), 4(g), and 4(h) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Finally, the last recordkeeping violation the Government alleged was that the Respondent failed to report to the Connecticut State Commissioner of Consumer Protection that he was dispensing drugs, and that the Respondent failed to biennially notify the Commissioner of his intent to continue to dispense drugs, in violation of Conn. Gen. Stat. §§ 20-14f and 21a-317, and 21 CFR 1306.03(a)(1). ALJ-1, at 5. The Respondent stipulated to these facts. Stip. of Fact 21. This stipulation meets the evidentiary standard of preponderance of the evidence. Accordingly, the Government's allegation that the Respondent failed to report to the Commissioner that he was dispensing drugs and intended to continue to do so, as alleged in paragraphs 4(r) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration.

II. Improper Prescribing to Himself & Family Members

Under federal regulations, ''[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The prescription requirement prevents ''doctors from peddling to patients who crave the drugs for . . . prohibited uses.'' *George C. Aycock, M.D.,* 74 FR 17529, 17541 (2009) (citing *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006)). Accordingly, ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription[,] . . . and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' 21 CFR 1306.04(a).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act in the usual course of professional practice and to issue a prescription for a legitimate medical purpose. *Fiaz Afzal, M.D.,* 79 FR 61651, 61653 (2014); *see also Samuel Mintlow, M.D.,* 80 FR 3630, 3648 (2015) (citing *United States v. Moore,* 423 U.S. 122, 142–43 (1975)). The CSA ''generally looks to State law and standards of medical practice to determine whether a doctor and patient have established (and are maintaining) a bona fide doctor-patient relationship.'' *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010).

Here, the Government alleged that the Respondent repeatedly issued controlled substance prescriptions to himself and his family members for other than legitimate medical purposes and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 CFR 1306.04(a). ALJ-1, at 5-6. Specifically, the Government alleged in the OSC: [7(a)] that the Respondent either issued or dispensed overlapping prescriptions of controlled substances to himself and a family member, N.A., constituting early refills; [7(b)] that the Respondent issued to N.A. overlapping prescriptions for controlled substances that are similar or have similar effects on the body, constituting therapeutic duplication; [7(c)] that the Respondent issued to himself, and his family members N.A. and U.A., prescriptions for controlled substances without any documentation of those prescriptions or the bases for them in the medical records; [7(d)] that the Respondent either issued a prescription or dispended controlled substances to himself without adequate documentation in the medical record; [7(e)] that the Respondent issued prescriptions to N.A. for a variety of controlled substances without adequate documentation in the medical record; and [7(f)] that the Respondent issued a controlled substance prescription to a family member G.A. and inadequately documented that prescription or the basis for it in G.A.'s medical record. ALJ-1, at 5–6.

Regarding the allegations in paragraph 7(a) of the OSC, the Respondent stipulated to the factual allegations that he issued overlapping prescriptions of controlled substances to himself and a family member, N.A., constituting early refills. Stip. of Fact 24. Similarly, regarding the allegations in paragraphs 7(d), 7(e), and 7(f), the Respondent stipulated to the factual allegations that he issued a prescription or dispensed controlled substances to himself, or to family members, N.A. and G.A., without adequate documentation in the medical record. Stip. of Fact 25-27.

There are, however, two allegations that the Respondent disputes. Specifically, the Respondent contests the allegations contained in paragraph 7(b) of the OSC. That paragraph alleges that the Respondent issued overlapping prescriptions for controlled substances

to a family member, N.A. It further alleges that those prescriptions have similar effects on the body, constituting therapeutic duplication. The Respondent also contests paragraph 7(c) of the OSC. ALJ-38, at 21. That paragraph alleges that the Respondent issued prescriptions for controlled substances to himself and family members N.A. and U.A. without any documentation or bases for the prescriptions in the patients' medical records. ALJ-1, at 5.

With regards to the allegation in paragraph 7(b) of the OSC, the Respondent argues that ''the Government has failed to meet its burden of proof that the prescription constituted therapeutic duplication.'' ALJ-38, at 21. The Respondent points to a notation in the Respondent's patient file for N.A., dated March 5, 2014, which indicates ''Luntesta doesn't help changed to Ambien 10 mg #30.'' GE-11, at 7; ALJ-38, at 21. Additionally, the Respondent argues that Dr. Perrin testified that he did not know whether patient N.A. was taking the medication in an overlapping fashion. Tr. 189; ALJ-38, at 21. Furthermore, the Respondent argues that he knew patient N.A. would not take the two medications at the same time because patient N.A. is his son, who lived with the Respondent. ALJ-38, at 21; Finding of Fact (''FF'') 41. N.A. came to the Respondent and told him that the medication he was currently taking was not working and asked the Respondent if he could prescribe something else. FF 41.

With regards to the allegation contained in paragraph 7(c) of the OSC, the Respondent argues that ''[t]he Government has failed to prove by a preponderance of the evidence that Respondent prescribed oxycodone to himself as alleged in Paragraph 7c'' of the OSC. ALJ-38, at 21. However, as previously discussed, 7(c) alleges that the Respondent issued prescriptions for controlled substances to himself and his family members, N.A. and U.A., without any documentation or bases of those prescriptions in the patients' medical records. ALJ-1, at 5. It does not mention oxycodone at all. Furthermore, the Respondent admitted at the hearing to the factual allegations contained in 7(c). Tr. 267-68; FF 42.[22]

In order to establish the standard of care for the State of Connecticut, the Government presented the expert opinion of Dr. Perrin. Dr. Perrin testified that the Respondent's practice of issuing overlapping prescriptions of controlled substances to himself and to his family members fell below the standard of care in the State of Connecticut. FF 56; Stip. of Fact 24. The concern with issuing overlapping prescriptions is that if the medications are taken simultaneously there is a potential for harm to the patient. FF 56. Furthermore, there is ''a cumulative effect of too much potentially sedating medication that also has addictive potential.'' Tr. 165; FF 56.

Additionally, according to Dr. Perrin, the Respondent's practice of issuing a prescription or dispensing controlled substances to himself or his family members, without adequate documentation in the medical record, is below the standard of care in the State of Connecticut. FF 60; Stip. of Fact 25-27. Dr. Perrin reasoned that with any prescription of a controlled substance, it is ''important to provide adequate documentation as to the precise reason for why [the] particular substance is indicated.'' Tr. 166; FF 60. Moreover, there needs to be ''an appropriate diagnosis that underlies the prescribing of said substance, and [there] has to be documentation that's beyond cursory to substantiate the choice of prescribing said substance.'' Tr. 166; FF 61. Where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance, there is no legitimate medical purpose for that prescription. FF 61.

Significantly, Dr. Perrin also opined that where a doctor's prescriptions are outside the standard of care, the doctor is also prescribing outside the usual course of professional practice. Tr. 183. Accordingly, Dr. Perrin's credible and persuasive testimony, coupled with the Respondent's admissions, are sufficient to establish that the Respondent's actions of issuing overlapping prescriptions for controlled substances and issuing prescriptions for controlled substances without adequate documentation in the patients' medical records fell below the standard of care in the State of Connecticut and that these prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice.

Dr. Perrin identified two sets of overlapping prescriptions issued by the Respondent to his son, N.A. First, Dr. Perrin identified Government Exhibit 13 as a prescription for Lunesta (with five refills) issued by the Respondent to his son, N.A., on December 6, 2012. Tr. 156-57. Lunesta is a sedative hypnotic agent that is used to treat insomnia. Tr. 156-57. Dr. Perrin identified Government Exhibit 14 as a prescription for Ambien (with five refills) issued by the Respondent to N.A. on March 23, 2013. Tr. 156-57. Like Lunesta, Ambien is a sedative hypnotic used to treat insomnia. Tr. 156. In Dr. Perrin's opinion, the refills indicated on Government Exhibit 13 overlap with the date on the prescription on Government Exhibit 14, and the combination of these two prescriptions constitutes therapeutic duplication. Tr. 157. Second, Dr. Perrin identified Government Exhibit 18 as a prescription for Lunesta (with five refills) issued by the Respondent to N.A. on February 24, 2014. FF 51. Dr. Perrin also identified Government Exhibit 19 as a prescription for Ambien (with 5 refills) issued by the Respondent to N.A. on March 5, 2014. FF 52. In Dr. Perrin's opinion, Government Exhibits 18 and 19 are overlapping prescriptions.[23] FF 53.

In Dr. Perrin's opinion, the notation in the Respondent's patient file for why he changed N.A.'s prescription to Ambien is not sufficient to justify the therapeutic duplication. FF 55. However, it was also Dr. Perrin's opinion that prescribing overlapping prescriptions could be legitimate if there was an explanation as to why one substance was being withdrawn in favor of another; for example, due to an adverse reaction, intolerance, or truly ineffective after a fair trial. Tr. 170-71. As the Respondent argues, he knew that his son was not taking both medications at the same time, noting that his son lived with him. He also testified that he noted in his son's patient file that Lunesta was not working based on what his son had told him, so he changed his son's prescription to Ambien. GE-11, at 7; ALJ-38, at 21. I find that the note in N.A.'s patient file clearly indicates why the Respondent changed his son's prescription from Lunesta to Ambien. Further, based on the evidence before me, it is apparent that the Respondent was intimately involved in his son's welfare. *See Belinda R. Mori, N.P.,* 78 FR 36582, 36587 (2013).

Accordingly, the Government's allegations that the Respondent repeatedly issued controlled substance prescriptions to himself and his family

[22] When inquiring about paragraph 7(c), Government counsel states, ''My question on this was whether you admit that this occurred. It's a factual question.'' Tr. 268. To which the Respondent replied, ''Yeah, it's a factual question. This occurred, yes, it occurred.'' Tr. 268.

[23] Paragraph 7(b) of the OSC alleges that the Respondent issued overlapping prescriptions to his son in 2014. The Government's evidence would support a finding that the Respondent issued only one overlapping prescription to his son in 2014, the one issued on March 5, 2014. *See* GE–19. The Respondent was never placed on notice that the Government would be introducing prescriptions from 2012 and 2013, GE–13–14, to support this allegation. *See* ALJ-37, at 6, para. 25. Accordingly, when making my Recommended Decision in this case, I place no weight on the evidence of an overlapping prescription that occurred in 2013.

members for other than legitimate medical purposes and outside the course of professional practice, as alleged in paragraphs 7(a) and 7(c)-7(f) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration. However, as discussed above, I find that the Government has not established, by a preponderance of the evidence, the allegation contained in paragraph 7(b) of the OSC. Therefore, the allegation contained in paragraph 7(b) of the OSC is **NOT SUSTAINED**.[24]

III. Improper Prescribing to Patients

The Government alleged that the Respondent repeatedly issued controlled substance prescriptions to patients for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 CFR 1306.04(a). ALJ-1, at 6-10. Specifically, the Government alleged that the Respondent issued multiple overlapping prescriptions for controlled substances to his patients, issued prescriptions to his patients without any, or sufficient, documentation or bases for the prescriptions in the patients' records, and dispensed controlled substances to patients from his office supply without any, or sufficient, documentation of dispensing those controlled substances, or the bases for them in the patients' medical records. ALJ-1, at 6-10.

The Respondent stipulated to all of the factual allegations regarding improper prescribing to patients. Stip. of Fact 28-57. Specifically, the Respondent admitted that on at least 20 occasions between 2012 and 2014, he issued multiple overlapping prescriptions for controlled substances to at least four separate patients. Stip. of Fact 29-32. The Respondent admitted that on at least 35 occasions between 2010 and 2014, he issued prescriptions to at least eight separate patients without any documentation or bases for the prescriptions in their medical records. Stip. of Fact 33-40. The Respondent admitted that on at least nine occasions between 2012 and 2014, he dispensed controlled substances to at least three of his patients from his office supply without any documentation or bases for dispensing those controlled substances in their medical records. Stip. of Fact 41-43. The Respondent admitted that on at least 26 occasions between 2011 and 2014, he issued prescriptions to at least seven patients without sufficient documentation or bases for the prescriptions in their medical records. Stip. of Fact 44-50. Finally, the Respondent admitted that on at least 45 occasions between 2010 and 2014, he dispensed controlled substances to at least seven patients from his office supply without sufficient documentation or bases for them in their medical records. Stip. of Fact 51-57.

The Government again offered the testimony of Dr. Perrin to establish the standard of care in the State of Connecticut regarding the allegations of the Respondent's improper proscribing to patients. Dr. Perrin testified that the Respondent's practice of issuing multiple overlapping prescriptions for controlled substances fell below the standard of care in the State of Connecticut. FF 56. Dr. Perrin further explained that the concern with issuing overlapping prescriptions is the potential for diversion with additional controlled substances floating around. Tr. 207; FF 57. Additionally, Dr. Perrin noted that where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance, there is no legitimate medical purpose for the prescription. Tr. 202; FF 61. Therefore, the Respondent's practice of issuing controlled substance prescriptions or dispensing controlled substances from his office supply to patients without adequate documentation or bases for the prescription or dispensing in the patient's medical record fell below the standard of care in the State of Connecticut, and was also outside the usual course of professional practice. Tr. 183; FF 61.

Dr. Perrin's testimony, coupled with the Respondent's admissions, is sufficient to establish that the Respondent issued controlled substances for other than a legitimate medical purpose and outside the course of professional practice. Accordingly, the Government's allegations contained in paragraph 9 of the OSC are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

IV. Failure to Maintain Security of Controlled Substance.

The Government alleged that the Respondent failed to maintain adequate security of his controlled substances. Specifically, the Government alleged that the Respondent's ''controlled substances were stored in an unlocked cabinet in an unlocked room . . . in the front-desk reception area . . . ,'' in violation of 21 CFR 1301.75(b) and Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-326-1(d). ALJ-1, at 11. Clearly, a registrant must maintain the physical security of his controlled substances to prevent unlawful diversion. *Jerry Neil Rand, M.D.,* 61 FR 28895, 28897 (1996). Further, registrants are required to store controlled substances in ''a securely locked, substantially constructed cabinet.'' 21 CFR 1301.75(b). When a registrant leaves controlled substances unattended, the controlled substances must be placed in a proper storage cabinet. *Jeffery J. Becker, D.D.S.,* 77 FR 72387, 72405 (2012) (citing to *D-Tek Enter.,* 56 FR 28926 (1991), and the Merriam-Webster Dictionary).

The Government bears the burden of proof concerning this allegation. 5 U.S.C. 556(d); 21 CFR 1301.44(e); *Jack A. Danton, M.D.,* 76 FR 60900, 60920 (2011). To prove this allegation, the Government presented the testimonies of [R.M.], [N.C.], [P.L.], and [M.J.]. In addition, the Respondent also testified on this issue. Initially, no witness testified that the Respondent stored his controlled substances in the ''front-desk reception area'' of his office. Second, it is also clear that prior to February 21, 2014, the Respondent stored his controlled substances in a louvered closet that did not have a lock on it. FF 33, 34, 35, 36, 38. Third, the closet where the Respondent's controlled substances were stored was located in a room (''examination room''), which contained a patient examination table and expensive unused medical equipment. FF 32, 33, 34, 35.

The question of whether the examination room where the controlled substances were stored, in an unlocked closet, was locked, is not readily clear. Neither [R.M.] nor [N.C.] could recall if the examination room was locked on March 4, 2016. Tr. 21-22, 42. [P.L.] testified that the door to the examination room was not locked when she was at the Respondent's office in January 2014, but she did not know if the door was locked when she was there in February 2014. Tr. 58, 61. [M.J.]'s testimony concerning whether the door to the examination room was locked during her visits to the Respondent's office in January 2014 and again in February 2014, is not particularly precise. Concerning the January visit she testified that the Respondent ''told us that [the controlled substances] were stored in an unlocked examination room in an unlocked closet, which we also later visually observed.'' Tr. 85. It is not clear just what was ''observed.'' When

[24] There was lengthy discussion during the hearing concerning the issue of whether it is below the standard of care in the State of Connecticut for a physician to self-prescribe. That issue is not squarely before me, however, because the OSC does not contain that allegation.

asked if the examination room was locked in February 2014, [M.J.] testified, ''Not to my recollection.'' Tr. 95. She noted, however, that she was not the first one in the room; rather, she was right behind another investigator who ''opened it right up.'' *Id.* Further confusing the matter, she could not recall, however, if the Respondent had led them into the examination room. *Id.* Thus, the Government presented four witnesses who had a total of eight opportunities [25] to observe whether the door to the examination room was locked prior to their entrance into the room. Only [P.L.] testified that the room was unlocked on her first visit to the Respondent's office on January 31, 2014, but she provided no explanation of how or why she recalled that fact.

The Respondent testified that he kept the examination room locked because he had kept expensive medical equipment in the room since about 2009. Tr. 229-30, 301-03. The Respondent also testified: that the outside door to his clinic was kept locked except during normal business hours, Tr. 228-29; that his office had a ''key pad'' security alarm and an alarm would sound if someone entered the clinic without disabling the alarm system, Tr. 228; and that he had security cameras installed in his clinic. Tr. 228.

Comparing the testimony of the Government's witness with that of the Respondent, and considering the Respondent's stated reason for keeping the door to the examination room locked, I find that the preponderance of the evidence does not support the conclusion that Respondent stored his controlled substances in an unlocked room. Rather, the evidence supports the conclusion that the door to the examination room was kept locked.

Here the Government charged that the Respondent's security measures violated 21 CFR 1301.75(b), which requires that Schedule II–V controlled substances ''be stored in a securely locked, substantially constructed cabinet.'' While the regulations do not define the term ''cabinet,'' the New College Edition of the *American Heritage Dictionary of the English Language* (1976) includes the following definition of ''cabinet'': ''a small or private room set aside for some specific activity.'' Further the *Danton* decision suggests that that the term ''cabinet'' has a broader meaning than the Government seeks to impose.

In *Danton,* DEA investigators found oxycodone in a closet in Danton's office. 76 FR at 60907-08, 60920. The closet was in the dispensing area of the clinic. *Id.* at 60920. The closet also contained security monitoring equipment. *Id.* The investigators, however, did not know if the closet was locked or even if it could be locked. *Id.* The DEA alleged that Danton had violated 21 CFR 1301.75 because the oxycodone was in a closet that ''was not a securely locked, substantially constructed cabinet suitable for the storage of control substances.'' *Id.* Because the Government failed to demonstrate how the closet failed to meet the requirements of the regulation, the Administrator found that the Government failed to prove that Danton had violated 21 CFR 1301.75(b). *Id.*

In this case the Government's focus in charging the Respondent with failing to maintain adequate security of his controlled substances was whether those substances were in a locked cabinet. *See* ALJ-1, at 11; Tr. 22-23, 39, 43, 67, 95, 134. That is understandable due to the language in 21 CFR 1301.75(b) that controlled substances are to ''be stored in a securely locked, substantially constructed cabinet.'' There are no further regulations, however, that define those terms. *See* Tr. 67-68. Further when questioned on DEA guidance related to a substantial cabinet, [M.J.] testified, ''It needs to be substantially secure. The intent of the storage is to have it be secure so as to prevent from theft or diversion.'' Tr. 123. Further, 21 CFR 1301.71(b) states that the Administrator can consider *any* of 15 different security related factors in deciding whether a registrant was in ''substantial compliance'' with 21 CFR 1301.75(b). Thus the answer to the question of whether the Respondent failed to maintain adequate security of his controlled substances is not solely dependent on the answer to the question of whether the container in which the controlled substances were located was itself locked. If that were the case, the 15 factors and the language of ''substantial compliance'' contained in 21 CFR 1301.71(b) would be meaningless.

In this case the Respondent kept his controlled substances in a locked room where he stored high value medical equipment. Second, the Respondent's office was protected by a security system and by cameras. Third, there were only a total of three individuals who worked in the Respondent's office. Fourth, there is no evidence that the Respondent's office was located in a high crime area or that there was an absence of local police protection. Finally, there is no evidence that the examination room was being used for any purpose other than to store high valued medical equipment and the Respondent's controlled substances.

Given the nature of the evidence contained in the administrative record, it is not necessary to find that the ''examination room'' met the requirements of 21 CFR 1301.75(b). Rather, in light of the absence of evidence as to why the ''examination room'' failed to satisfy the requirements of 21 CFR 1301.75(b), and considering the five points detailed in the paragraph above, as well as the guidance contained in *Danton*,[26] I find that the Government failed to prove that the Respondent violated 21 CFR 1301.75(b) when he stored his medication in the locked ''examination room.'' Further, considering [M.J.]'s testimony that the ''intent of the storage is to have it be secure so as to prevent from theft or diversion,'' Tr. 123, the record established that the Respondent clearly met that intent.

In light of the discussion above, and giving due consideration to the factors contained in 21 CFR 1301.71(b), the Government's allegation that the Respondent violated 21 CFR 1301.75(b) is **NOT SUSTAINED**. Furthermore, the Government's allegations that the Respondent violated the cited provisions of Connecticut Regulations, Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-32601(d), with respect to his storage of his controlled substances are not sustained.[27]

Factor Five: Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the DEA 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 19386, 19386 n.3 (2011). Under Factor Five, the Government has alleged two bases upon which it seeks to revoke the Respondent's COR. First, citing *Dreszer,* the Government alleges that a statement that the Respondent made to DEA and Connecticut investigators that '' 'benzos' [were] not worthy of DEA investigation, particularly given how other doctors in [his] community were distributing Schedule II controlled substances,'' is conduct that may threaten the public

[25] [M.J.] and [P.L.] each had three opportunities to observe the door. They went to the Respondent's office twice on January 31, 2014, and once on February 21, 2014. FF 38-39. [R.M.] and [N.C.] were both at the Respondent's office on March 4, 2016. FF 15, 21.

[26] I also considered the Administrator's analysis in *Howard N. Robinson, M.D.,* 79 FR 19356, 19372 (2014).

[27] The Government made no argument in its post-hearing brief concerning paragraph 10 of the OSC.

health and safety. ALJ-1, at 11, para. 11(a). Next the Government alleges that the Respondent attempted to mislead DEA and Connecticut investigators by denying that he had issued prescriptions to family members and by denying that he had any medical records concerning his treatment of family members. *Id.* at para. 11(b). The Government further alleged that several days after the Respondent denied having such records, he produced a file concerning his treatment of family members and that the delay in producing the records ''strongly suggest[s] that the file was created after the fact in response to the DEA's investigation.'' *Id.* The Government alleges that such conduct is evidence of a lack of candor, which is ''an important factor when assessing whether a physician's registration is consistent with the public interest.'' *Id.* at 11-12 (citing *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005)). In its Post-Hearing Brief the Government argues that the Respondent was also less than candid during his testimony on cross-examination, when he ''was forced to admit that he had previously testified differently.'' ALJ-37, at 22-23.

I. The ''Benzos'' Statement

Paragraph 11(a) of the OSC alleges that the Respondent's purported statement that '''benzos' [were] not worthy of DEA investigation, particularly given how other doctors in [his] community were distributing Schedule II controlled substances,'' ALJ-1, at 11, is conduct that should be considered under Factor Five. The only authority the Government cites for its position is the *Dreszer* decision. In its Post-Hearing Brief, the Government does not even address this issue. ALJ-37.

Based upon my review of the testimony, I concluded that the Respondent made a statement to [M.J.] and [P.L.] that closely matches the language cited in the paragraph 11(a) of the OSC. But my review of the *Dreszer* decision does not convince me that such a statement would be a basis for revocation under Factor Five. As the Respondent appropriately argues, ''nothing in *Dreszer* stands for the proposition that Respondent's simple statements . . . rise to the level of creating even a possible threat to public health or safety.'' ALJ-38, at 23. While I need not decide if language by itself, wherein the individual simply states an opinion, would ever give rise to actionable ***conduct***, the Government has come nowhere near meeting its burden of proof concerning the language quoted above. Accordingly, the allegations contained in paragraph 11(a) of the OSC are **NOT SUSTAINED**.

II. Attempt to Mislead

In paragraph 11(b) of the OSC, the Government alleged that the Respondent engaged in acts wherein he attempted to mislead the DEA during its investigation concerning him. First, the Government alleges that the Respondent told the investigators that he did not issue prescriptions to members of his family. Second, the Government alleges that the Respondent told the investigators that he did not have any records concerning the medical treatment he provided to family members, and then ''several days'' later the Respondent produced a file of those records. The Government further alleges that the manner in which the Respondent produced the records ''strongly suggests that the file was created after the fact . . . .'' ALJ-1 at 11.

A. Statements Concerning Prescribing to Family Members

The evidence of whether the Respondent told the investigators that he did not prescribe to family members is a bit convoluted. [P.L.] testified that the Respondent initially told the investigators that he did not prescribe to family members because he did not want to take responsibility of something going wrong. Tr. 55-56. [P.L.] then showed him some prescriptions he had written for family members and the Respondent verified he had written the prescriptions. Tr. 56. On cross-examination, however, [P.L.] testified that she did not recall the exact language the Respondent had used, and that it was possible that he had answered ''mostly not,'' when he was asked if he wrote prescriptions to family members. Tr. 70. [M.J.], who sat through [P.L.]'s testimony, testified that the Respondent initially denied writing prescriptions to family, but she, too, indicated that his answer was ''mostly not.'' Tr. 86-87. The Respondent testified that he acknowledged writing prescriptions to family members, but his position was ''mostly no.'' Tr. 255.

Keeping in mind that the Government has the burden of proof concerning each of its allegations, I find that the testimony does not support the conclusion that Respondent denied that he had written prescriptions to members of his family. Both of the Government witness on this issue, as well as the Respondent, used the terms ''mostly not.'' Further, even if the Respondent initially denied writing to family members, he quickly corrected the record. Under these facts, I find no ''attempt to mislead.'' [28] Accordingly, the Government's allegation, contained in Paragraph 11(b) of the OSC, that the Respondent told the investigators that he did not issue prescriptions to members of his family in an attempt to mislead them is **NOT SUSTAINED**.

B. Fabrication of Family Medical Records

With respect to the family medical records, which the Respondent produced, the Government alleged that after the Respondent denied having the records he produced them a few days later. The Government further suggests that the Respondent used the time to create the file ''after the fact in response to the DEA's investigation . . . .'' ALJ-1, at 11. The Government has not alleged, nor has it argued, that the Respondent lied to the investigators when he told them he did not have family medical records. Rather, the Government's allegation in paragraph 11(b) of the OSC and in its argument in its Post Hearing Brief is that the Respondent falsified the medical records ''to thwart DEA's investigation.'' ALJ-37, at 22. In support of this allegation the Government cited the same two cases in both the OSC and its post-hearing brief: *Jerry Neil Rand, M.D.,* 61 Fed. Reg. 28895 (1996), and *Nelson A. Smith, D.D.S,* 58 Fed. Reg. 65403 (1993).

The testimony supporting the allegation that the Respondent told [M.J.] and [P.L.] that he did not have family medical records is not contradicted. [P.L.] testified that the Respondent was asked if the investigators could see the medical records concerning his treatment of family members and ''[h]e did not have any.'' Tr. 56. [M.J.] also testified that the Respondent denied having any patient charts for his family members. Tr. 87. The Respondent did not provide direct testimony on this issue, but he did testify that he did not intentionally mislead the investigators. Tr. 256.

The evidence is also clear that the Respondent did not produce the file containing the patient charts for himself and members of his family ''several days'' after he told the investigators that he did not have such files. [M.J.] and [P.L.] met with the Respondent on January 31, 2014. FF 15. It was on that date that the Respondent told [M.J.] and [P.L.] he did not have treatment files for family members. FF 16. [M.J.] and [P.L.] found out about the patient charts from

[28] I also note that the Respondent has some difficulty hearing, which certainly could have contributed to miscommunication. Tr. 254; *see also* Tr. 210.

a doctor who worked with the Respondent. Tr. 88. The Respondent also mentioned the patient files before they were produced. Tr. 88. Then, about 18 months after the January 31, 2014 meeting with the Respondent, [M.J.] ''submitted an administrative subpoena . . . in July of 2015 for the family records . . . and [the Respondent] returned them to [her] . . . within a week or so.'' Tr. 88. Thus the OSC does not paint an accurate picture of what actually happened.[29]

While the facts underlying the allegation contained in paragraph 11(b) of the OSC are relatively clear from the record, *the allegation is one of specific intent*—that the Respondent *attempted to mislead* by first denying that he had family medical files and then producing them a few days later after he had created them. As with any allegation, the Government bears the burden of proof regarding its claim that the Responded *attempted to mislead* DEA investigators during their investigation. *See* ALJ-1, at 11. Concerning this allegation, however the Government's case rests primarily upon conjecture. Further, ''under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.' '' *Alvin Darby, M.D.,* 75 Fed. Reg. 26993, 26999 n.31 (2010) (citing *NLRB v. Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)). In my view, suspicion is all the Government has presented on the issue of whether the Respondent created the family medical files after he was asked about them on January 31, 2014.

I, therefore, reject the Government's allegation that the Respondent fabricated Government Exhibit 11 in an attempt to mislead the DEA during its investigation. First, unlike the two cases the Government relies upon, *Rand* and *Smith,* the Government presented no direct evidence that the Respondent either altered patient files or falsified those files. Second, the Respondent did not quickly produce the files after he first denied having them; rather he produced them 18 months later, and in response to a subpoena. Third, a review of Government Exhibit 11, and comparing it to prescriptions written to family members, reveals nothing suggestive of fabrication, and the Government has not identified or presented evidence of any specific examples of fabrication. Finally, the Respondent is a well-educated medical doctor, who immigrated to the United States and passed the Foreign Medical Graduates exam only three months after he arrived here. He appears to be an intelligent and well-spoken individual. Certainly if the Respondent created Government Exhibit 11 to mislead the DEA he could have done a far better job in fabricating medical records for himself and for family members. In fact, it is the poor quality of those medical records that the Government relied upon as the bases of other allegations the DEA successfully brought against the Respondent in the OSC. *See* ALJ-1, at 5-6, para. 7(c)-(f). Accordingly, the Government's allegation, in Paragraph 11(b) of the OSC, that the Respondent told the investigators that he did not have any records with respect to his family members and then several days later produced those records *in an attempt to mislead* the DEA is **NOT SUSTAINED**.

III. Lack of Candor

In its Post-Hearing Brief, the Government argues that the Respondent demonstrated a lack of candor during his testimony at the hearing on March 13, 2017. ALJ-37, at 22-23. In addition, the Government proposed 12 facts that it contends support its argument that the Respondent's testimony demonstrated a lack of candor. ALJ-37, at 11-12.

The DEA has consistently held that ''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether . . . registration is consistent with the public interest.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8236 (2010) (citing *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005)). For example, the DEA held that a respondent's lack of candor weighed against his registration under Factor Five when he lied to DEA investigators ''when first confronted'' about his wrongful conduct. *John V. Scalera, M.D.,* 78 Fed. Reg. 12092, 12100 (2013). The DEA ''places great weight on a registrant's candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt, D.O.,* 75 Fed. Reg. 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 Fed. Reg. 74334, 74338 (2007)). Thus, the DEA may consider a respondent's lack of candor to be a threat to public health and safety. *Annicol Marrocco, M.D.,* 80 Fed. Reg. 28695, 28705 (2015).

The Government contends that the Respondent was less than candid when testifying about: the number of Suboxone patients the Respondent currently treats; whether he had ever provided a prescription in exchange for service; whether he had told investigators that benzodiazepines were not commonly diverted or abused; whether he would prescribe controlled substances to someone who said they were giving the controlled substances to someone else; and whether he had ever taken drugs home to give to a family member. ALJ-37, at 11-12. Many of these issues were raised in context of testimony the Respondent apparently gave in prior hearings or depositions. The Government, however, did not offer the transcripts of those prior testimonies. Furthermore, even the transcripts of prior testimony, which may differ from testimony the Respondent presented in his testimony before me, would neither prove nor disprove that the Respondent lacked candor when he testified on March 13, 2017.[30]

Many of the items of testimony are not as clear cut as the Government suggests. For example, there is no evidence in the record concerning the number of Suboxone patients the Respondent treats. When asked multiple times, the Respondent consistently testified that he treats between 90–100 patients. Tr. 216, 275-78. While Government counsel made the statement, ''I don't believe that's actually the case. I believe you're treating less than that,'' Tr. 278, the Government presented no evidence as to the number of Suboxone patients the Respondent is treating. This issue raised by the Government does not demonstrate any lack of candor, and the number is totally irrelevant to these proceedings. In fact when Government counsel was given the opportunity to proffer the relevance of this information, all he said was, ''I was just going to credibility of the witness . . . .'' Tr. 279.

With respect to the issue of whether the Respondent ever bartered his medical services, my understanding of the testimony was that he had done that in the past, but he would not do it again because it is considered unethical. Tr. 250. Furthermore, whether he did or did

[29] The Government has provided no explanation of why it alleged that the Respondent produced the family records ''several days'' after having told investigators that he did not have any, when in fact they were produced about 18 months later after the documents were subpoenaed. A fair reading of the OSC suggests that something sinister was afoot by denying the existence of the documents but them producing them only several days later. The OSC suggests a linkage between the denial and quick turn-around time. The record does not support that conjecture.

[30] For example, it is possible that the Respondent was lacking in candor during his prior testimony, rather than during the March 13, 2017 hearing. He also could have just been confused. Further, there is no evidence in this Administrative Record that the Respondent's March 15, 2016 deposition, Tr. 280, was taken in any sort of DEA proceeding or court proceedings that involved the DEA.

not barter in the past is not relevant to the issues before me. There is no lack of candor concerning this irrelevant issue.

The Government has made much of the Respondent's exact wording when he discussed benzodiazepines with [M.J.] and [P.L.]. Nevertheless, the Respondent admitted during the hearing that he had made a comparison between benzodiazepine and oxycodone, stating that oxycodone was more addictive. Tr. 253. He also testified that at the time he met with [M.J.] and [P.L.] he was of the impression that ''benzodiazepines were not being abused and diverted.'' Tr. 238. During the Government's cross-examination of the Respondent on this subject, I did not find any lack of candor regarding this issue.

The Government incorrectly characterizes the Respondent's testimony about whether the Respondent would prescribe controlled substances to a patient who told the Respondent that he was giving some of the controlled substances to another individual. My review of the record leads me to the conclusion that the Respondent testified that he would not do that now, not what he may have done in the past. The record is not clear what question may have been asked at an earlier deposition concerning this peripheral issue. Tr. 285-88. I find no lack of candor.

Finally, the Government suggests that the Respondent lacked candor when he testified concerning whether he had ever taken ''drugs'' home to give to family members. In context, I find no relevance to any answers to this line questioning, particularly concerning the issues before me. First, the Respondent was not on notice of this issue and the question did not deal with controlled substances; rather, the Respondent was asked about ''drugs''. Second, I do not find a lack of candor because the Respondent essentially testified that he did not remember if he had taken drugs home to give to a family member, and then acknowledged that an earlier deposition indicated that he ''*may* have taken drugs home.'' Tr. 290-91 (emphasis added).

Earlier in this decision I assessed the Respondent's credibility at length. Upon further review, specifically considering the Government's allegation that the Respondent lacked candor during his testimony, I reemphasize my earlier finding. When accessing the Respondent's credibility, I find that the clear and confident manner in which the Respondent testified on direct examination outweighs the manner in which he testified on cross examination. Further, when comparing his testimony to that of other witnesses, I find that it was generally consistent with that of the Government's witnesses. Thus, I find that the Respondent's testimony to be generally credible. Accordingly, the Government's allegation, raised in its Post Hearing Brief, that the Respondent's testimony at the hearing demonstrated a lack of candor is **NOT SUSTAINED**.

DISCUSSION

Factors One and Three neither weigh for or against revocation in this case. As discussed, the Government did not present sufficient evidence of any other conduct the Respondent may have engaged in that may threaten the public health and safety. Accordingly, Factor Five does not weigh in favor of revocation. However, Factors Two and Four strongly weigh in favor of revoking the Respondent's COR because of his improper recordkeeping, and improper prescribing to himself, his family members, and his patients. Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that the Respondent's registration would be inconsistent with the public interest.

After the Government presents a *prima facie* case for revocation, the Respondent has the burden of production to present ''sufficient mitigating evidence'' to show why he can be entrusted with a DEA registration. *See Medicine Shoppe—Jonesborough,* 73 Fed. Reg. 364, 387 (2008) (quoting *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20734–35 (2009).

The Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. *See Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15228 (2003). To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 Fed. Reg. 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *See Wesley G. Harline, M.D.,* 65 Fed. Reg. 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct, *Jeffrey Patrick Gunderson, M.D.,* 61 Fed. Reg. 26208, 26211 (1996), and may be required to acknowledge the scope of his misconduct, *Arvinder Singh, M.D.,* 81 Fed. Reg. 8247, 8250–51 (2016).

Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 Fed. Reg. 38363, 38364 (2013).

Here, the Government accurately argued in its Post-Hearing Brief that ''[t]he record contains no evidence that Respondent has actually accepted responsibility for the misconduct at issue in these proceedings and this is fatal to his cause.'' ALJ-37, at 23. While the Respondent admitted to many of the facts that support the allegations against him, he failed to fully accept responsibility for the most egregious aspects of his actions. Specifically, the Respondent failed to acknowledge that his prescribing and dispensing practices fell below the standard of care in the State of Connecticut. FF 62. Furthermore, the Respondent refused to admit that the prescriptions that he issued or dispensed to himself, his family, and his patients were issued or dispensed for other than legitimate medical purposes and outside the course of professional practice, despite being provided the opportunity to do so.[31] Tr. 264-66. I find, however, that by

[31] Additionally, the Government requests that I draw an adverse inference against the Respondent, with respect to his admission of responsibility, because the Respondent invoked his Fifth Amendment rights when asked by Government counsel if his actions were outside the course of professional practice. ALJ-37, at 26. It is well settled that at a DEA administrative hearing, it is permissible to draw an adverse inference from a respondent's failure ''to testify in response to probative evidence offered against'' him. *Darryl J. Mohr, M.D.,* 77 Fed. Reg. 34998, 35001 (2012) (citing *Baxter* v. *Palmigiano,* 425 U.S. 308, 316 (1976)). The Respondent argues that I should not draw a negative inference here because, unlike cases cited to by the Government, the Respondent did not refuse to testify, but just refused to answer questions that the Respondent argues called for a legal conclusion. ALJ-38, at 26. However, in *Mohr,* the registrant, offered testimony at hearing only in regards to his prescribing to K.R., an undercover patient. *Mohr,* 77 Fed. Reg. at 35000. Dr. Mohr offered no testimony as to why he prescribed to K.R. and also offered no testimony addressing his medical justification for prescribing a controlled substance to B.K., another undercover patient. *Id.* at 35001. Based on Dr. Mohr's failure to address why he prescribed to both patients, the Administrator found it ''appropriate to draw the adverse inference that [Dr. Mohr] knowingly prescribed controlled substances to both B.K. and K.R. without a legitimate medical purpose.'' *Id.* Accordingly, based on the Respondent's unwillingness to acknowledge that his prescribing of controlled substances was outside the course of professional conduct, it is appropriate to draw the adverse inference that the Respondent did not accept responsibility for the allegations set for in paragraphs 7 and 9 of the OSC and which are supported by a preponderance of the evidence. *See MacKay v. DEA,* 664 F.3d 808, 820 (10th Cir. 2011) (holding that it was not ''improper for the Deputy

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entering into Stip. of Fact 4-21 the Respondent accepted responsibility for his recordkeeping violations that occurred in his practice prior to February 2014, as alleged in paragraph 4 of the OSC. FF 24. This limited acceptance of responsibility is outweighed by his numerous prescribing and dispensing transgressions, for which he has not accepted responsibility.[32] *See Hatem M. Ataya, M.D.,* 81 Fed. Reg. 8221, 8244 (2016) (''[T]here are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application.'').

When considering whether the Respondent's continued registration is consistent with the public interest, the ALJ must consider both the egregiousness of the registrant's violations and the DEA's interest in deterring future misconduct by both the registrant as well as other registrants. *David A. Ruben, M.D.,* 78 Fed. Reg. 38363, 38364 (2013); *see also Richard J. Settles, D.O.,* 81 Fed. Reg. 64940, 64945 n.17 (2016) (''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' (quoting *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 462 (2009)). While I do not believe that the Respondent's transgressions rise to the level of intentional or knowing diversion, I do find his multiple and repeated recordkeeping and prescribing violations to be sufficiently egregious to warrant revocation.[33] *See Dewey C. MacKay, M.D.,* 75 Fed. Reg. 49956, 49974 n.35 (2010) (''[U]nder the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'').

RECOMMENDATION

The Government established that the Respondent's continued registration is inconsistent with the public interest because of his improper recordkeeping and improper prescribing, and/or dispensing, of controlled substances to himself, his family, and his patients. While the Respondent admitted to many of the Government's factual allegations, he failed to fully accept responsibility and acknowledge that his egregious actions fell below the standard of care in the State of Connecticut, and/or lacked any legitimate medical purpose. Accordingly, I **RECOMMEND** that the Respondent's DEA COR be **REVOKED** and that any application for renewal of his registration be **DENIED**.

Dated: May 25, 2017

s/Charles Wm. Dorman

U.S. Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 25, 2017, caused a copy of the foregoing to be transmitted via facsimile and placed in interoffice mail addressed to Paul A. Dean, Esq., Office of Chief Counsel, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; facsimile (202) 307–4946, and a copy to be transmitted via facsimile and mailed, postage prepaid, to counsel for the Respondent, Ronald W. Chapman, II, Esq. and Robert J. Andretz, Esq., 1441 West Long Lake Road, Suite 310, Troy, Michigan 48098; facsimile (248) 644–6324.

Rhonda L. Gore

Secretary to Judge Charles Wm. Dorman Office of Administrative Law Judges

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Administrator to draw an adverse inference from [the Respondent's] failure to testify''). I note, however, that even absent the adverse inference, there is sufficient evidence to support the conclusion that the Respondent has not accepted responsibility for his improper prescribing and dispensing of controlled substances.

[32] Although the Respondent also stipulated to many of the facts underlying the allegations contain in paragraphs 7 and 9 of the OSC, those stipulations do not admit to any misconduct. They just admit to facts. The essence of the allegations contained in paragraphs 7 and 9 of the OSC is that the Respondent's actions involving controlled substances were outside the course of professional practice and furthered no legitimate medical purposes.

[33] I acknowledge that the Respondent has taken some remedial steps to reduce the likelihood that his actions would result in future violations of the CSA and/or its implementing regulations. Nevertheless, a registrant does not accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 Fed. Reg. 62316, 62346 (2012). Further, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 Fed. Reg. 79188, 79202–03 (2016).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 22, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 13, 2018, Navinta, LLC., 1499 Lower Ferry Road, Ewing, New Jersey 08618–1414 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Pentobarbital	2270	II
4-Anilino-N-phenethyl-4-piperidine (ANPP).	8333	II
Levorphanol	9220	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.