A. Type of response	B. Number of responses	C. Time per response	D. Total hours (column B × column C)
Pre-Application Sampling and Testing 43 CFR 3601.30	10	30 minutes	5
Request for Sale Within a Community Pit or Common Use Area 43 CFR 3602.11	165	30 minutes	83
Request for Sale Not Within a Community Pit or Common Use Area 43 CFR 3602.11	100	30 minutes	50
Mining and Reclamation Plans (Simple) 43 CFR 3601.40	240	2 hours	480
Mining and Reclamation Plans (Complex) 43 CFR 3601.40	25	30 hours	750
Contract for the Sale of Mineral Materials 43 CFR subpart 3602 Form 3600–9	265	30 minutes	133
Performance Bond 43 CFR 3602.14	265	30 minutes	133
Report of Mineral Materials Mined or Removed 43 CFR 3602.29	1,400	1 hour 30 minutes.	2,100
Records Maintenance 43 CFR 3602.28	1,400	1 hour 30 minutes.	2,100
Totals	3,870		5,834

Authorities

The authorities for this action are the Mineral Materials Act (30 U.S.C. 601–602) and the Paperwork Reduction Act (44 U.S.C. 3501—3521).

Mark Purdy,

Bureau of Land Management, Management Analyst.

[FR Doc. 2017–13153 Filed 6–22–17; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–DEWA–22315; PS.SDEWA0040.00.1]

Boundary Adjustment at Delaware Water Gap National Recreation Area

AGENCY: National Park Service, Interior.

ACTION: Notification of boundary adjustment.

SUMMARY: The boundary of Delaware Water Gap National Recreation Area is adjusted to include three parcels of land totaling 1,055.89 acres of land, more or less. Fee simple interest in two parcels and a right-of-way over the third parcel will be donated by the Conservation Fund to the United States along with fee simple interest in 35.39 acres of other land already within the boundary. These properties are all located in Pike County, Pennsylvania.

DATES: The effective date of this boundary adjustment is June 23, 2017.

ADDRESSES: The map depicting this boundary adjustment is available for inspection at the following locations: National Park Service, Land Resources Program Center, Northeast Region, 200 Chestnut Street, Philadelphia, Pennsylvania 19106, and National Park Service, Department of the Interior, 1849 C Street NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Superintendent John J. Donahue, Delaware Water Gap National Recreation Area, 1978 River Road (Off US209), Bushkill, PA 18324, telephone (570) 426–2418.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 16 U.S.C. 460o–2(b), the boundary of Delaware Water Gap National Recreation Area is adjusted to include three parcels totaling 1,055.89 acres of land in Pike County, Pennsylvania: 1,054.26 acres (Tax Map Nos. 175.00–02–06, 176.00–02–01 and 183.00–01–19) in Lehman and Delaware Townships; and 0.47 acre (portion of Tax Map No. 113.00–01–05.004) and 1.16 acres (right-of-way over a portion of Tax Map No. 113.00–01–05.003) in Milford Township. The two parcels in Milford Township, together with 35.39 acres of fee interest already within the boundary (remaining portion of Tax Map No. 113.00–01–05.004, also known as Tract 12795 in the National Recreation Area), are part of a single property that cannot be subdivided. This boundary adjustment is depicted on Map No. 620/137,770 dated April, 2017.

Specifically, 16 U.S.C. 460o–2(b) states that the Secretary of the Interior may make adjustments in the boundary of the national recreation area by publication of the amended description thereof in the **Federal Register**: Provided, that the area encompassed by such revised boundary shall not exceed the acreage included within the detailed boundary first described in the **Federal Register** on June 7, 1977 (42 FR 29071–29103). This boundary adjustment does not exceed the acreage of the detailed boundary so described. The Conservation Fund is in contract to acquire the property in Lehman and Delaware Townships and owns the fee parcel and right-of-way in Milford Township (along with Tract 12795). The Conservation Fund will convey all of these properties, including Tract 12795, to the United States without cost to help mitigate the effects of the upgrade and expansion of the Susquehanna-Roseland electric transmission line across approximately 4.3 miles of the National Recreation Area.

Dated: May 3, 2017.

Joshua R. Laird,

Acting Regional Director, Northeast Region.

[FR Doc. 2017–13154 Filed 6–22–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–26]

Peter F. Kelly, D.P.M.; Decision and Order

On July 10, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Peter F. Kelly, D.P.M. (Respondent), of Roanoke, Virginia. ALJ Ex. 1, at 1. The Show Cause Order proposed the revocation of Respondent's Certificate of Registration No. BK0639279, the denial of any application to renew or modify his registration, and the denial of any other application for a DEA registration, on the ground that he has committed acts which render his registration ''inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4), 823(f)).

As to the jurisdictional basis for the proceeding, the Show Cause Order alleged that Respondent is registered ''as a practitioner in [s]chedules II–V,'' under the above registration number, at the address of 4106 Electric Road, Roanoke, Virginia. *Id.* The Show Cause Order alleged that Respondent's registration does not expire until December 31, 2017. *Id.*

As to the substantive grounds for the proceeding, the Show Cause Order alleged that in June 2000, Respondent was indicted in the Circuit Court for Roanoke County, Virginia, on four felony counts of unlawful possession of

controlled substances which included sufentanil, oxycodone, pethidine, and hydromorphone, as well as one misdemeanor count of marijuana possession. *Id.* The Order alleged that Respondent entered an Alford plea to the charges and was sentenced to probation and a fine. *Id.* The Order further alleged that as a result of the criminal case, on December 12, 2002, Respondent entered into a Memorandum of Agreement with DEA, and that on February 3, 2005, he entered into a Consent Order with the Virginia Board of Medicine for ''recordkeeping and other controlled substance violations,'' which resulted in his being fined and his license being ''placed on probation for twelve months.'' *Id.* at 1–2.

Next, the Show Cause Order alleged that ''[f]rom approximately December 2007 until approximately September 2012, [Respondent's] employee, Vickie Mullen, used [his] DEA registration number to call-in and/or fax-in 72 prescriptions in her own name and 1[,]596 prescriptions in the names of others for controlled substances totaling 127,686 dosage units of hydrocodone (then a [s]chedule III controlled substance) and 5,370 dosage units of Ambien ([z]olpidem tartrate, a [s]chedule IV controlled substance).'' *Id.* at 2. The Order alleged that ''[t]hese prescriptions were not authorized by you and were not for a legitimate medical purpose, but rather were diverted by Ms. Mullen into illegitimate channels, including for her own personal use and the personal use of her son and numerous other individuals.'' *Id.* The Order then alleged that Respondent is ''responsible for the misuse of [his] registration by [his] employees.'' *Id.* (citations omitted). The Order further alleged that Respondent had ''continued to employ Ms. Mullen in [his] medical practice, even after learning of her diversion, in violation of 21 CFR 1301.92.'' *Id.*

The Show Cause Order further alleged that ''[o]n July 10, 2013, DEA executed an Administrative Inspection Warrant . . . at [Respondent's] registered location'' and that the Agency found that Respondent was in violation of several record-keeping requirements. *Id.* More specifically, the Order alleged that Respondent ''failed to take'' both initial and biennial inventories of the controlled substances at his registered location. *Id.* (citing 21 U.S.C. 827(a) & (b); 21 CFR 1304.11(a) & (c)). The Order also alleged that Respondent violated DEA regulations requiring that the inventories list ''the number of commercial containers'' and the ''number of units or volume of each finished form in each container.'' *Id.* (citing 21 U.S.C. 827(a) & (b); 21 CFR 1304.11(e)(3) & (e)(1)(iii)(D)). The Order then alleged that these ''violations are the same as, or similar to, [the] recordkeeping violations previously found by the [S]tate as detailed in [the] February 3, 2005 Consent Order.'' *Id.*

The Show Cause Order also alleged that Respondent left controlled substances, which included hydrocodone, alprazolam, and diazepam, ''out overnight in [his] office, rather than 'stored in a securely locked, substantially constructed cabinet' as required by 21 CFR 1301.75(b).'' *Id.* at 2–3. The Order alleged that Respondent engaged in this practice so that his office manager, ''who is not a DEA registrant, could dispense these drugs to patients prior to [his] arrival in the office.'' *Id.* at 3. The Order then alleged that Respondent ''aided and abetted the unlawful distribution of controlled substances,'' because the office manager did not possess a DEA registration and dispensed controlled substances ''in [his] absence . . . in violation of 21 U.S.C. 822(a)(2) and 21 CFR 1301.11(a).'' *Id.* (citing 21 U.S.C. 841(a) and 18 U.S.C. 2).

Following service of the Show Cause Order, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was placed on the docket of the Office of Administrative Law Judges and was initially assigned to Chief Administrative Law Judge John J. Mulrooney, II. However, on September 22, 2015, the matter was reassigned to Administrative Law Judge (ALJ) Charles Wm. Dorman, who conducted further pre-hearing procedures and an evidentiary hearing on January 12–13, 2016, in Roanoke, Virginia.

On April 11, 2016, the ALJ issued his Recommended Decision. With respect to Factor One, the ALJ found that the Board's 2005 Consent Order ''is the only disciplinary action in the record'' and that the Board terminated his probation one month early. R.D. 29. The ALJ noted, however, that while possessing a state license is a necessary condition for holding a DEA registration, it is not dispositive. As for Factor Three, the ALJ found that while in 2000, Respondent was convicted of possession of marijuana and other controlled substances, these were simple possession offenses which did not involve the manufacture, distribution or dispensing of controlled substances and thus did not fall within Factor Three. *Id.* at 29–30. The ALJ thus concluded that ''there is no evidence to consider concerning Factor Three.'' *Id.* at 30.

The ALJ then addressed the various allegations of misconduct under Factors Two, Four and Five. The ALJ rejected the allegation that Respondent is responsible for the misuse of his registration by Ms. Mullen, holding that the Government was required to show that Respondent had entrusted his registration to Mullen and had failed to produce any evidence that Respondent had given his registration number to Mullen or that he had given her access to his registration whether expressly, impliedly, or negligently. *Id.* at 32–34. The ALJ further found that there was no ''credible or substantial evidence showing that . . . Respondent knew about Mullen's illegal activities prior to August 20, 2012.'' *Id.* at 34. The ALJ specifically rejected the Government's contention that '''it is simply not believable that [Respondent] did not know of [Mullen's] diversion,'' finding that ''the evidence shows that no one, other than Mullen and her cohorts, was aware of Mullen's activities.'' *Id.* at 35.

The ALJ also rejected the Government's contention that Respondent was put on notice that his registration was being misused when, in 2008, he was contacted by a pharmacist regarding two prescriptions that were called-in under his name, and that Respondent should have monitored Mullen and his PMP report. *Id.* at 35. The ALJ cited four reasons for rejecting the Government's argument, including: (1) That a ''fax did not contain any information that suggested that one of Respondent's employees was involved'' and that the ''prescription was not written for one of the Respondent's patients,'' (2) that the Respondent was never informed that Mullen was responsible for the prescriptions, (3) that even the detective who ran the investigation did not check the PMP, and 4) that ''the Government presented no evidence that . . . Respondent breached some duty by not monitoring his PMP.'' *Id.*

The ALJ further rejected the Government's contention that Respondent violated 21 CFR 1301.92, by continuing to employ Mullen even after he learned of her diversion. R.D. 37–38. According to the ALJ, the regulation relied on by the Government ''does not require the immediate termination of an employee; it only requires that the employer immediately assess the employee's conduct to determine what employment actions to take against the employee.'' R.D. 37. The ALJ found that Respondent complied with the regulations because he told Mullen that she would be retained ''only until her replacement showed minimal proficiency,'' he ''began advertising [her] position the same week that he discovered her diversion,'' and

''promptly hired and began to train Mullen's replacement.'' *Id.* The ALJ also noted that ''Respondent moved his fax machine to a room with a deadbolt on the door, called local pharmacies to alert them to Mullen's actions, took away Mullen's keys to the office, and monitored his DEA number on the PMP system.'' *Id.*

The ALJ further noted that Mullen was ''Respondent's only insurance secretary,'' that ''her position was essential to the continued operation of . . . Respondent's practice,'' and while ''Respondent's office manager was competent to perform the duties of the insurance secretary, she could not do so and also perform her various duties.'' *Id.* at 38. According to the ALJ, ''[f]or small businesses that depend on each employee performing essential business functions, it is reasonable to expect that terminating an employee can be a process rather than an instantaneous action.'' *Id.* The ALJ thus concluded that Respondent acted ''[c]onsistent with the requirements of 21 CFR 1301.92'' by taking ''immediate action towards terminating Mullen's employment because of her misconduct'' and rejected the allegation. *Id.*

With respect to the recordkeeping allegations, the ALJ rejected Respondent's contention that he was not subject to the recordkeeping requirements of 21 U.S.C. 827(a), because he did not ''regularly engage[] in the dispensing or administering of controlled substances and charge[d] his patients, either separately or together with charges for other professional services, for substances so dispense or administered.'' *Id.* at 39 (quoting 21 U.S.C. 827(c)(1)(B)).

Based on the findings of the 2005 Virginia Board of Medicine Consent Order, the ALJ then found that the Government had proved that Respondent failed to conduct an initial inventory. *Id.* at 40 (citing 21 U.S.C. 827(a)(1)). He also found that the Government had proved that Respondent failed to conduct and ''maintain[ ] a proper biennial inventory'' because his records did not contain an actual count of the controlled substances taken either at the beginning or close of business but rather ''a running balance of controlled substances after dispensing.'' *Id.* at 41 (citing 21 CFR 1304.11(c)). The ALJ further found that the inventories were not compliant because they did not contain ''the number of commercial containers of each controlled substance'' and the ''the number of units or volume of each commercial container of controlled substances.'' *Id.* at 42 (citations omitted).

Next, the ALJ rejected the Government's contention that Respondent violated 21 CFR 1301.75, which requires that controlled substances be stored ''in a securely locked, substantially constructed cabinet,'' when he left the controlled substances out overnight for his office manager to administer to patients who were undergoing procedures the following morning. *Id.* at 44. The ALJ specifically noted that the DEA regulation does not define the term ''cabinet,'' but that the New College edition of the American Heritage Dictionary of the English Language (1976) includes as one of the word's definitions, ''a small or private room set aside for some specific activity.'' *Id.* The ALJ noted that the room in which the medications were kept was locked, that only the Respondent and his office manager had a key, that the room had a steel reinforced door and steel doorframe with a deadbolt, that Respondent's office was protected by a security system, and that there was no evidence that the room ''was used for any purpose other than to store controlled substances prior to 2014.'' *Id.* The ALJ thus concluded that the Government failed to prove the violation. *Id.*

However, the ALJ found that the Government proved the allegation that Respondent had aided and abetted the unlawful distribution of controlled substances by having his office manager, who was not registered, administer controlled substances to patients who were to have procedures on days when he was late arriving at his office. *Id.* at 44–45. The ALJ specifically rejected Respondent's argument that his office manager was exempt from registration under 21 CFR 1301.22(a), because she was an ''agent or employee . . . acting in the usual course of . . . her . . . employment.'' *Id.* at 45. Based on Respondent's testimony that the office manager administered controlled substances to patients ''only on 'limited occasions,' '' the ALJ explained that he was ''find[ing] as a matter of fact that [her] administration of controlled substances was described repeatedly as 'occasional,' which is the opposite of 'usual[,]' '' and ''[t]herefore, [section] 1301.22(a) does not apply.'' *Id.* As to this violation, the ALJ also found that Respondent did not acknowledge his misconduct. *Id.* at 46.

Finally, the ALJ found that Respondent's 2000 state court convictions for unlawful possession of various controlled substances could be considered under Factor Five. The ALJ noted, however, that ''these convictions occurred over 15 years ago, and [that] Respondent has not been convicted of any controlled substance offenses since 2000.'' *Id.* at 47. The ALJ further rejected Respondent's contention that DEA was estopped from relying on the convictions because it subsequently entered into an MOA with Respondent. *Id.* The ALJ also rejected Respondent's contention that his possession of the drugs did not actually violate federal law because his home was a warehouse which was exempt from registration under the Controlled Substances Act (CSA), reasoning that issue could not be re-litigated in this proceeding. *Id.*

Based on his findings of the recordkeeping violations, the aiding and abetting of the office manager's unlawful distribution of controlled substances, and the 2000 convictions, the ALJ concluded that the Government had established ''a *prima facie* case that . . . Respondent has acted in a manner that is inconsistent with the public interest and that marginally supports the sanction [revocation] that the Government requests.'' *Id.* at 48. Turning to whether Respondent had rebutted the Government's *prima facie* case, the ALJ found that while ''Respondent acknowledged his three violations, [he] did not show remorse for his actions'' and that he had not accepted responsibility. *Id.*

While the ALJ found that Respondent had not ''rebut[ted] the Government's *prima facie* showing that a sanction is appropriate,'' he also concluded that the egregiousness of Respondent's misconduct was mitigated by various circumstances. *Id.* at 50; *see also id.* at 52. However, even taking ''these matters into considerations,'' the ALJ still found that ''Respondent's violations, in combination, are serious and raise concerns of whether his registration is consistent with the public interest.'' *Id.* at 53. Continuing, the ALJ explained that ''[i]n light of . . . Respondent's failure to accept responsibility, the record supports the conclusion that [his] registration should be suspended and [he] should obtain training concerning recordkeeping, as well as storage and administration of controlled substances.'' *Id.*

The ALJ thus recommended that Respondent's registration be suspended for a period of one year, to begin three months from the effective date of the Decision and Order in this matter, and that the suspension be stayed if during this period, Respondent completed courses in ''controlled substance recordkeeping,'' ''control substance storage,'' and ''the administration of controlled substances.'' *Id.* The ALJ also recommended that if his proposed suspension was stayed, that his

registration be restricted to authorize only the prescribing of controlled substances for a period of one year to begin on the stay's effective date. *Id.* And he further recommended that if the suspension is stayed, Respondent ''undergo an annual audit to ensure compliance with controlled substance regulations . . . by an independent auditor hired by . . . Respondent, for three years from the effective date of the stay[,]'' with ''[t]he first audit [to] be conducted no later than one year after the effective date of the stay,'' with the results to be forwarded to the local DEA office ''within [10] business days after the audit.'' *Id.* at 53–4.

Respondent filed Exceptions to the Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action.

Having considered the record in its entirety, including Respondent's Exceptions, I agree with the ALJ that the Government has failed to prove that Respondent is liable either for entrusting his registration to Ms. Mullen (his insurance clerk) or because he knew or should have known of her criminal misconduct prior to August 20, 2012. I also agree with the ALJ that the Government has failed to prove that Respondent violated 21 CFR 1301.75, on those occasions when he left controlled substances outside of the controlled substances safe but the drugs were left locked in the drug room.

I further agree with the ALJ that Respondent failed to conduct an initial inventory and that he also failed to take a proper biennial inventory because he did not actually count the drugs that were on hand. In addition, I agree with the ALJ that Respondent aided and abetted a violation of 21 U.S.C. 841 when he directed his office manager to administer controlled substances to patients prior to procedures when he was not present in the office. Finally, I agree with the ALJ that Respondent was convicted in 2000 in state court of four felony offenses and one misdemeanor offense of unlawful possession of controlled substances.

I disagree, however, with the ALJ's rejection of the Government's contention that Respondent should have immediately terminated Mullen after he determined that she had been calling and faxing in fraudulent prescriptions and refill requests for hydrocodone and zolpidem. While I agree with the ALJ that Respondent did not acknowledge any of his misconduct, I disagree with his recommended sanction of a stayed suspension. Instead, I conclude that relevant factors support the imposition of an outright suspension of Respondent's registration for a period of one year, as well as the requirement that Respondent take a course in controlled substance recordkeeping if, following termination of the suspension, he intends to resume either administering or engaging in the direct dispensing of controlled substances. I make the following factual findings.

Findings of Fact

Respondent's License and Registration Status

Respondent is a board certified Doctor of Podiatric Medicine who is licensed by the Virginia Board of Medicine. GX 2. At all times relevant to the events at issue, Respondent maintained offices in Roanoke, Bedford, Radford, and Rocky Mount, Virginia. RX 13, at 2.

Respondent is also the holder of DEA Certificate of Registration BK0639279, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the registered address of 4106 Electric Road, P.O. Box 20566, Roanoke, VA 24018. ALJ Ex. 8, at 15. Respondent's registration does not expire until December 31, 2017. *Id.*

The Prior Criminal and Administrative Proceedings

On September 13, 2000, Respondent pled guilty in the Circuit Court of Roanoke County Virginia to four felony counts of possession of the controlled substances sufentanil, oxycodone (with acetaminophen), pethidine (meperidine), and hydromorphone,[1] as well as a single misdemeanor count of possession of marijuana. GX 1, at 1. The Circuit Court, while finding the evidence sufficient to convict Respondent, withheld adjudication pursuant to the written plea agreement. *Id.* at 2. Thereafter, on October 30, 2000, the Circuit Court sentenced him to probation for a period of one year, the terms of which required him to perform 100 hours of community service, to forfeit his driver's license for 30 months, to undergo drug abuse testing and counseling, and to pay costs. *Id.* at 4; *see also* RX 83, at 1. Respondent successfully completed probation and on October 31, 2001, the charges were dismissed. GX 1, at 6; RX 83, at 1.

Shortly after Respondent was sentenced, representatives of the DEA notified him that his registration was subject to revocation based on the above proceeding; the letter also offered Respondent the opportunity to voluntarily surrender his registration. RX 83, at 1. Sometime thereafter, Respondent's attorney wrote a letter to the DEA representatives informing them that he had successfully completed his probation and that all of his drug tests were negative and that his propensity for drug abuse risk was found to be negligible. *Id.* On December 12, 2002, DEA agreed to renew his registration subject to a Memorandum of Agreement (MOA) which remained in effect for a period of one year. *Id.* at 2.

On October 15, 2004, the Virginia Board of Medicine notified Respondent that it would hold ''an informal conference'' to inquire into various allegations that he ''violated certain laws and regulations governing the practice of podiatry in Virginia.'' GX 2, at 1. The Board raised 19 different allegations including, *inter alia,* that he violated Virginia law by: (1) Unlawfully possessing controlled substances based on his Alford plea; (2) that prior to February 15, 2001, he ''failed to perform an initial inventory, establish a biennial inventory date, and failed to take an inventory of all [s]chedule II to V controlled substances at least every two (2) years''; and (3) that the inventory he ''performed on February 15, 2001 lacked the time it was performed and the name of the individual who performed it.'' [2] *Id.* at 1–3.

On February 3, 2005, Respondent and the Board entered into a Consent Order, which found that Respondent had violated various provisions of Virginia law. The findings included ''that he . . . did not establish an initial inventory or maintain current and accurate records of his inventory, receipt and distribution of controlled substances,'' and that he

[1] Each of the felony counts involved a schedule II controlled substance. *See* 21 CFR 1308.12(b)(1)(vii) (hydromorphone); *id.* § 1308.12(b)(1)(xiii) (oxycodone); *id.* § 1308.12(c)(18)(pethidine); *id.* § 1308.12(c)(27) (sufentanil). Respondent maintained that the drugs (other than the marijuana) were both ''expired and existing medications'' which he moved from his office to his house because, based on his drug counts, some of the drugs were missing and while he suspected one of his employees, he ''didn't really have any evidence to confront her and report this.'' Tr. 383–84. However, Respondent asserted that the pethidine ''was left over from [his] ex-wife's . . . rhinoplasty procedure, and she doesn't really take any narcotics, so she had some of these left over.'' *Id.* at 387. Respondent asserted that he entered the Alford plea because had he gone to trial, ''it would have made the front page [of the] paper for the whole week'' and ''would have cost me all my patients and reputation.'' *Id.* at 388. Respondent subsequently maintained that during the hearing on his plea, the Commonwealth's Attorney ''was unable to point to any specific violation of law.'' *Id.* at 389–90. However, the Circuit Court's orders identified the specific provisions of the Virginia Code violated by Respondent. *See* GX 1, at 1 (Trial Order citing Va. Code §§ 18.2–250 and 18.2- 250.1); *id.* at 3 (Sentencing Order citing same provisions).

[2] Some of the other allegations included that he administered expired controlled substances to his patients, and that he dispensed schedule III and IV controlled substances to patients for their ''at home use'' ''without a license from the Board of Pharmacy.'' GX 2, at 1–2.

''did not provide for adequate storage for controlled substances maintained in his office.'' GX 3, at 1–2. The Consent Order further found that ''since the Board brought these matters to his attention in July 2002, [Respondent] has revised and updated his controlled substance recordkeeping, storage and dispensing practice, and believes that he is fully compliant with all regulatory requirements regarding controlled substances.'' *Id.* at 4.

Based on its findings, the Board imposed a monetary penalty of $2,000 and placed Respondent on probation for a period of one year. *Id.* at 5. The Board further required that Respondent certify ''that he has read and agrees to fully comply with Chapters 33 and 34 of the Code of Virginia,'' that he ''successfully complete [a] continuing education course[] in recordkeeping,'' and that ''[w]ithin 60 days from the entry of [the] Order,'' he ''submit to an inspection and audit by an Investigator of the Department of Health Professions (DHP) to ensure that he is in compliance with record keeping, storage and dispensing requirements.'' *Id.* at 5–6. The Order also provided that ''[w]ithin 9 months from the inspection and audit . . . Respondent's practice may be subject to an unannounced inspection by a'' DHP Investigator. *Id.*

On January 11, 2006, a Committee of the Board met to review Respondent's compliance with the Consent Order and found that he ''had fully complied with all terms [of] the Order.'' GX 4, at 1. The Board thus terminated Respondent's probation and restored his license to unrestricted status. *Id.*

The Diversion Occurring at Respondent's Practice

Sometime in 2004, Respondent hired Ms. Vicki Mullen to work at his Roanoke office, where her duties included preparing and filing insurance claim forms. Tr. 73, 81. According to Respondent's office manager, Mullen was authorized to use Respondent's signature stamp on the forms. *Id.* at 81. She also had access to the fax machine.[3] *Id.* at 408.

Beginning on or about December 31, 2007, Mullen began calling in prescriptions to pharmacies for various drugs including 90 to 120 dosage units of hydrocodone 10 mg (then a schedule III and now a schedule II controlled substance) and 30 dosage units of zolpidem (the generic version of Ambien, a schedule IV controlled substance). GX 12, at 1. According to the credited testimony, at one Walmart pharmacy, Mullen would call the pharmacy's doctor's line and leave a message for a prescription representing that she was calling on behalf of Respondent. The Walmart pharmacy would fill the prescriptions even though Mullen did not provide Respondent's DEA registration number.[4] Tr. 42. Instead, notwithstanding that DEA regulations require that an oral prescription contain all of the information mandated under 21 CFR 1306.05, including the prescriber's DEA registration number,[5] the pharmacist would retrieve Respondent's registration number from the computer and put it on the call-in prescription form which the pharmacy would complete.[6] *Id.* at 48. Mullen did not give her name as the person calling in the prescriptions; rather, she used such names as Virginia Norvel, Liz Norville, and Liz Chilton. *See* GX 6, at 2; GX 7, at 5, 7, 12, 14; Tr. 106.

On some occasions, the pharmacies would fax a refill request to Respondent's office. On these occasions, Mullen would use Respondent's signature stamp to manifest that he had approved the refill request and fax the authorization back to the pharmacy which typically authorized three refills. *See* GX 7, at 9; GX 8, at 5, 7, 13, 15, 17, 19; GX 9, at 7, 13, 23, 29, 34, 38; GX 10, at 9, 15, 19.

However, notwithstanding Respondent's claim that Mullen did not have access to his DEA number,[7] the record contains numerous refill request forms that suggest otherwise. These forms include a ''Prescriber Comments'' box with lines for printing the ''Prescriber's Name,'' the ''Prescriber's DEA #,'' as well as lines for the ''Prescriber's Signature''—which was where Mullen would use Respondent's signature stamp—and the ''Date.'' *See* GX 8, at 5. Notably, a number of these forms included Respondent's DEA number which was hand-written in the ''Prescriber Comments'' box. *See* GX 8, at 5, 7, 13, 15, 17, 19; GX 9, at 7, 13, 23, 29, 34, 38; GX 10, at 9, 15, 19.

Over the course of the scheme, Mullen called in or faxed in prescriptions and refill requests for 82 prescriptions for herself which Respondent had not authorized.[8] Tr. 106–07. On some occasions, she called in prescriptions listing her son and a daughter-in-law as the patients. *Id.* at 105. Moreover, Mullen's son provided her with the names and dates of birth of his co-workers, who agreed to pick up the prescriptions. *Id.* at 105–06. Mullen also called in and or stamped refill requests for 13 prescriptions for 90 dosage units of hydrocodone 10 mg, with Respondent's office manager listed as the patient. RX 36. In her testimony, Respondent's office manager denied that she had received any of these prescriptions. Tr. 84.

Between December 31, 2007 and August 20, 2012, Mullen called in, or stamped and faxed, prescriptions and refill requests for 1,596 prescriptions and refills for hydrocodone and zolpidem. GX 12. In total, the prescriptions resulted in the dispensing of 127,686 dosage units of hydrocodone and 5,370 dosage units of zolpidem under Respondent's registration.[9] GX 11, at 2.

While Mullen was able to continue her illegal activity for nearly five years, she came to the attention of the Virginia State Police as early as November 18, 2008. GX 6, at 2. According to the evidence, on November 17, 2008,

[3] According to the testimony of Respondent's office manager, Respondent saw patients once a week at his Roanoke office; he also did surgeries once a week at the Roanoke office, however, he did not do surgeries every week. Tr. 56.

[4] According to the credited testimony of both Respondent and his office manager, his DEA registration was not posted and was kept in a file with his license in his office. Tr. 71, 319, 405. Also, his signature stamp did not contain his registration number. *Id.* at 80 & 405. Nor did Respondent's prescription blanks contain his DEA number. *Id.* at 71; *see also* RX 16. Respondent did not, however, keep his office door locked. Tr. 274.

[5] The only exception is the prescriber's signature. 21 CFR 1306.21(a).

[6] On cross-examination, a Diversion Investigator provided testimony suggesting that pharmacies ''normally'' fill oral prescriptions or called-in prescriptions that are missing ''the doctor's DEA number because it is already on file.'' Tr. 148. Moreover, the record contains numerous prescriptions that were reduced to writing by the pharmacist, but which were missing Respondent's DEA number. *See* GX 7. While in some instances, the DEA number was written on the prescription, the Government put forward no evidence that the pharmacist had obtained Respondent's DEA number off the voice mail message left by Mullen rather than through the pharmacy's database.

[7] *See* Tr. 174–75 (Colloquy between Respondent's counsel and DI regarding refill request form (GX 7, at 9): ''Q[.] And as faxed back from, allegedly from the doctor's office, it does not have a DEA number on it, does it?'' A[.] No.'').

[8] While the testimony was to the effect that Mullen called in or faxed in 72 prescriptions for herself, the PMP report lists 82 prescriptions/refills. RX 24.

[9] According to Detective Findley of the Virginia State Police Drug Diversion Unit, Mullen stated that only ''one pharmacy called [the] office to verify the prescriptions,'' and because Mullen ''was there by herself and . . . took the phone call [she] obviously told the pharmacist that it was fine, to go ahead and fill'' the prescription. Tr. 225. Detective Finley further testified that zolpidem is a sleep medication which is not usually prescribed by podiatrists and that the issuance of two to three monthly prescriptions by a podiatrist should have been suspicious to a pharmacist and that it would be unusual for a podiatrist to continue prescribing this drug. *Id.* at 226–27. With respect to the hydrocodone prescriptions, Detective Finley agreed with Respondent's counsel that ''it would be unusual for a podiatrist to maintain somebody on narcotic pain medication at the levels'' of these prescriptions. *Id.* at 227.

Mullen called in two prescriptions for Tramadol, which although it was not then a federally-controlled substance, it was a controlled substance under Virginia law, to a Walmart Pharmacy in Christiansburg, Virginia. *Id.* Upon reviewing the prescriptions, the pharmacist noted that they were issued by the same doctor (Respondent), for the same exact prescription to two patients (C.T. and S.F.), who, while they had different last names, had the same address. *Id.* According to the pharmacist, the prescriptions were purportedly called in by Liz Norville. *Id.*

Finding the two prescriptions to be suspicious, the pharmacist called Respondent's office and was told that ''no one named Liz Norville . . . worked at that office [and] that they had no patients by the name of'' C.T. and S.F. *Id.* Later that day, Respondent called the pharmacist and confirmed that C.T. and S.F. were not his patients and that ''no one had called those in from his office.'' *Id.* Respondent also faxed to the pharmacist a written statement, stating that ''[n]either did my office nor I call in prescriptions for [C.T. or S.F.] at any time. They are not my patients.'' GX 5, at 1. The next day, the pharmacist reported the prescriptions to Detective Larry Findley, who was assigned to the Drug Diversion Unit of the Virginia State Police.[10] Tr. 189; RX 93–A.

The same day, Detective Findley went to the pharmacy, interviewed the pharmacist and obtained a written statement from her, as well as the statement Respondent had provided to the pharmacist. GX 6, at 2; Tr. 189–90. Using video footage, the Detective, with the assistance of one of the store's asset protection officers, was able to identify the individual who picked up one of the prescriptions as M.F.,[11] who has the same last name as S.F. RX 93–A. The Detective called M.F., who ''admitted to picking up the forged prescriptions.'' *Id.* She also told the Detective that Vicki Mullen had called in the prescriptions. *Id., see also* Tr. 191.

Thereafter, on November 20, 2008, the Detective interviewed Mullen, who admitted that she had called in the forged prescriptions. RX 93–A. While on February 6, 2009, Mullen was indicted in state court on the charge that she ''did obtain or attempt to obtain [Tramadol], by fraud, deceit, misrepresentation, embezzlement, or subterfuge, or by the concealment of a material fact,'' which was punishable as a Class 6 felony under Virginia law, at no point did the Detective tell Respondent that Mullen had been arrested.[12] Tr. 214.

The Detective further admitted that he did not obtain a Prescription Monitoring Program (PMP) report using Respondent's DEA registration number to determine what controlled substance prescriptions were being dispensed under his registration. *Id.* at 210. He also did not obtain a PMP report showing the prescriptions obtained by Ms. Mullen. *Id.* at 212. While the Detective testified that he did not remember the exact date on which the state police's drug diversion agents were given access to the PMP, he acknowledged that during the period in which he was investigating the tramadol prescriptions, he probably had the ability to obtain a PMP report of Respondent's controlled substance prescriptions. *Id.* at 211–12. While the Detective's testimony also suggests that he obtained a report from the Walmart Pharmacy of the prescriptions dispensed to the individuals who were filling the forged prescriptions, he did not ask the pharmacy to provide a report of Ms. Mullen's prescriptions. *Id.* at 212–13. Moreover, the Detective did not notify any other pharmacies to be on the lookout for potentially forged prescriptions from Respondent's office. *Id.* at 214.

Notably, by November 17, 2008, Mullen's criminal conduct had already resulted in the dispensing of 200 prescriptions and refills, each being for 90 dosage units of hydrocodone, by three Walmart Pharmacies. *See* GX 12, at 1–7. And by this date, Mullen herself was able to fill a prescription or a refill for 90 dosage units of hydrocodone 10 mg on nine different occasions. *See* GX 13, at 1. Indeed, Mullen's criminal conduct continued unabated even after she was indicted, and even after May 27, 2009, when she pled guilty to two counts of prescription fraud and was offered probation for one year and a deferred adjudication of the charges. *See* GX 14, at 3–4, 7–9; GX 12, at 9–49. At no point was Respondent notified that Mullen had pled guilty to the charges, and he was not otherwise notified of Mullen's conviction by ''the parole [sic] system.'' Tr. 428; *see also id.* at 357.[13]

Mullen continued to work for Respondent until late September 2012, nearly five weeks after August 20, 2012, when his office manager found a faxed refill request from a Walmart Pharmacy (#1301) for 90 dosage units of Lortab 10 mg for a patient named J.L. GX 15, at 2; *see also* RX 18; Tr. 342–43. According to the office manager, she pulled a chart for a patient with the same name and determined that there was no such original prescription in the chart; she also determined that while the actual and purported patient had the same names and address, they had different birthdates. Tr. 60. The office manager showed the refill request to Respondent, who determined that he did not write the prescription. *Id.; see also id.* at 342.

Respondent then called the pharmacy. GX 15, at 2; Tr. 343. The pharmacist reviewed J.L.'s prescription history and told Respondent that J.L. had been obtaining Lortab prescriptions/refills on a monthly basis since May 17, 2011, ''when the original prescription was called in by'' a person who gave Vicki as her first name but a different last name than Mullen. GX 15, at 2; Tr. 348; *see also* RX 27 (telephone prescription of May 17, 2011 with no DEA number); RX 28, at 1–4 (request for refills dated 6/30/11 (four total refills), 11/22/11 (one refill), 12/20/11 (four total refills), 4/10/12 (four total refills). The pharmacist verified that the refill requests were faxed to and from Respondent's office. GX 15, at 2; *see also* RX 28, at 1–4.

Respondent told the pharmacist ''that somebody was fraudulently using [his] DEA number.'' Tr. 350. He also told the

[10] On cross-examination, Respondent asserted that he ''didn't think [the November 2008 incident] had anything to do with me. There was nothing to link my employee with that at all.'' Tr. 404. He then testified that he thought the incident was ''associated more with'' a podiatrist who practiced in the Christiansburg, Virginia area and who had bought another practice in an area where there was ''a large drug ring down there.'' *Id.* at 404–05. Respondent explained that ''I addressed the issue as it was presented to me'' and ''I had [the office manager] search our computer database and our current patient files.'' *Id.* at 407. He further testified that because the purported patients were not his patients he made no changes to his office practices and had ''[n]o reason to'' discuss the incident with Mullen. *Id.* at 408.

After Respondent acknowledged that Mullen had access to the fax machine and his signature stamp, the Government asked him what measures he had in place to supervise employees when he was in his other offices. *Id.* at 408–09. Respondent asserted that ''aside from recording all calls, and having copies faxed to my email, I can't think of any measure that wouldn't be extreme, and quite burdensome.'' *Id.* He then acknowledged that he took no such measures. *Id.* at 410.

[11] The asset protection officer had worked at the same Walmart in Salem, Virginia as had M.F. RX 93–A.

[12] Mullen was not arrested until February 20, 2009, after she was indicted. Tr. 217.

[13] During cross-examination by Respondent, the Detective was asked whether he recalled that during Mullen's plea hearing in federal court, the Court asked him if he was ''convinced that [Respondent] had no idea this was going on until it was brought to [Respondent's] attention by his ex-wife, if I understand that,'' and that he [the Detective] had answered, ''Yes, sir.'' Tr. 228. While the Detective acknowledged his previous testimony, *id.,* the transcript of Mullen's federal court plea hearing was not made part of the record, and nothing in the record of this proceeding establishes that Respondent's ex-wife brought ''this'' to Respondent's attention, let alone when she may have done so.

pharmacist ''to block [his] DEA number.'' *Id.* Respondent acknowledged, however, that a couple of prescriptions were filled after this conversation. *Id.* A spreadsheet compiled by the Government shows that on August 29 and September 2, 2012, two refills, each being for 120 dosage units of hydrocodone, were filled by this same pharmacy. GX 12, at 49. The spreadsheet also shows that 10 other refills for 90 or 120 dosage units of hydrocodone were dispensed between August 22 and September 15, 2012.[14] *Id.* However, the prescription numbers support a finding that Mullen had either called in or faxed back the fraudulent authorization for each of these refills prior to August 20, 2012. Tr. 166; GX 12, at 47–49.

Respondent further determined that only Mullen was working in his Roanoke office that afternoon as he and his office manager had worked at his Radford office. GX 15, at 2. Respondent confronted Mullen over the phone who ''confessed to falsifying [his] signature, submitting the refill authorizations, and picking them up.'' *Id.;* Tr. 354. Respondent asked Mullen ''how many other people she used for the[] false prescriptions''; Mullen answered ''about five.'' GX 15, at 2; Tr. 355.[15]

Respondent called DEA and spoke with a Diversion Investigator, who told him to call Detective Findley. Tr. 347. Respondent called Detective Findley; the two met at Respondent's Radford office that afternoon. *Id.* at 347, 355. According to Respondent, Findley told him that ''Vicki Mullen's history extended beyond the falsified prescriptions mentioned above, to include other stores, and other CIII medications.'' GX 15, at 2. Findley told Respondent that Mullen had committed similar acts in 2008. *Id.*

Several days later, Respondent accessed the Virginia Court System's Web site and found the records of the 2009 criminal case in which Mullen pled guilty to obtaining drugs by fraud. RX 23, at 1–6. He also ran a PMP report on Mullen. RX 24. The Report showed that from January 21, 2008 through August 24, 2012, Mullen had obtained 56 prescriptions/refills for 90 dosage units of hydrocodone 10 mg and 26 prescriptions/refills for 30 dosage units of zolpidem 10 mg which were dispensed under Respondent's registration. *Id.*

On August 24, 2012, Respondent had Mullen prepare a written statement regarding her misconduct. *See* GX 16. In the statement, Mullen listed the stores she had used, including three Walmarts and three CVSs. *Id.* at 1. She also stated that Respondent and his office manager ''had no part or knowledge of my activities.'' *Id.*

While Respondent told Mullen that she would be fired, and placed an ad for her replacement, he retained her as an employee through September 28, 2012. *See* RX 49; Tr. 360. He testified that if he had another employee who could have done his insurance billing, Mullen ''would have been out the door immediately.'' Tr. 362. He maintained that he ''could not operate'' his practice without his insurance clerk, that 99 percent of his cash flow came from insurance reimbursements, and that if he had fired Mullen immediately, ''we would have had a backlog, and things would have started trailing off in three weeks.'' *Id.* at 361. He also asserted that he had tried both ''electronic billing'' and ''any number of substitutes,'' but these measures had not ''worked.'' *Id.* at 362. And he maintained that to prevent a re-occurrence of Mullen's criminal activity, he had moved the fax machine into the medication room, which had a steel door and frame with a deadbolt lock for which Mullen did not have a key, and took away her office keys. *Id.* at 359, 421.

Respondent further asserted that ''I needed to isolate [Mullen] from any of these communications, to keep the office safe from her.'' *Id.* at 362. Yet Respondent offered no testimony that Mullen was denied access to the office phone. And when asked by his counsel if Mullen would abide by ''[t]he limitations [he] placed on her with what she was doing,'' Respondent answered: ''She didn't indicate anything. She didn't have much choice in the matter.'' *Id.* at 363.

Respondent also asserted that at the time he decided to retain Mullen while she trained her replacement he acted in ''proportion of things that I knew. So it wasn't . . . what we're looking at in retrospective now with this huge situation. It was only with a handful of information that I had, less than a dozen.'' *Id.* at 426. Yet, as found above, on August 24, 2012, Respondent ran a PMP report on Mullen's prescriptions. The report showed that between January 21, 2008 and August 24, 2012, Mullen herself had obtained 56 prescriptions for 90 hydrocodone 10 mg and 26 prescriptions for 30 tablets of zolpidem 10 mg. RX 24. So too, Respondent testified that Mullen had given him copies of two refill request forms, which she had stamped with his signature and faxed back, which authorized the dispensing of four refills of hydrocodone to J.B. (120 du) and R.H. (90 du). RX 26; *see also* GX 12, at 26, 48.

Consistent with Mullen's August 24, 2012 statement, both Respondent and his office manager denied having any knowledge of Mullen's criminal activity, including the 2009 state proceeding, until late August 2012. Tr.75–76, 88 (office manager's testimony); *id.* at 355, 357, 381–82. (Respondent's testimony). Respondent also disputed statements made by Mullen in an unsworn ''declaration'' to the effect that he had knowledge of the 2008 diversion incident and that both he and the office manager knew ''before 2012 that [she] was diverting drugs from his office.'' GX 20, at 1 (Mullen declaration); Tr. 381–82 (Respondent's testimony).[16] While the opening sentence of Mullen's declaration states that she was ''duly sworn,'' nothing else in the declaration establishes that she appeared before a person authorized to administer oaths. *See* GX 20, at 4 (signature page). Nor does the declaration contain an attestation clause.[17] *See id.; see also* 28 U.S.C. 1746.

[14] Four of the refills were dispensed by a different Walmart Pharmacy (#3243), three were dispensed at still another Walmart Pharmacy (#2312), one was filled at two different CVS pharmacies (#s 06285 and 03949), and another prescription was dispensed at a Walgreens Pharmacy (#7604). GX 12, at 49.

Respondent testified that he had called various pharmacies to report these incidents, but did not ''exactly know when [he] did that,'' before claiming that he might have done this on August 20, 2012, before he left for his Radford office. Tr. 359. Respondent then explained that he notified one of the Walmarts that his ''DEA number [wa]s being . . . falsified and abused'' and that ''should go to all of the Walmarts'' because ''they're going to be on a network.'' *Id.* at 360. He also stated that he had called ''a handful of these'' pharmacies, including CVS and Walgreens, and that he knew it worked because he subsequently received phone calls from pharmacists questioning prescriptions. *Id.* As for why the two prescriptions were filled at Walmart #1301 even after he had informed this pharmacy that the refill authorization for J.L. was fraudulent, Respondent testified that he ''figured the same thing would happen with this Walmart 1301 also. So, I had no reason not to believe it would work.'' *Id.*

[15] According to Respondent, sometime between August 20 and 24, 2012, Mullen gave Respondent three refill authorization forms which had been faxed to his office from Walmart Pharmacies #s 2312 and 3243. *See* RX 26. One of the requests, which was dated March 13, 2012, was for Mullen herself and authorized the dispensing of four refills of 30 Ambien 10 mg. *Id.* at 1. The other requests, which were dated November 22, 2010 and August 14, 2012, authorized the dispensing of four refills of 90 Lortab 10 mg to R.H. and four refills of 120 Lortab 10 mg to J.B. *Id.* at 2–3.

[16] Both the office manager and Respondent also disputed Mullen's statement in the 2015 declaration that Respondent ''stood over me and at one point he leaned over me, grabbed my shoulder and shook me.'' GX 20, at 3; Tr. 86 & 369.

[17] On November 6, 2014, Mullen, along with her son, were indicted on multiple counts of violating 21 U.S.C. 841(a)(1) (unlawful distribution of hydrocodone and zolpidem), 846 (conspiracy to distribute hydrocodone and zolpidem), and 843(a)(3) (obtaining controlled substances by fraud), and a single count of violating 21 U.S.C. 843(a)(2)

Respondent further testified that he never authorized Mullen to call in prescriptions for pain medications and/or controlled substances using his name and DEA number. Tr. 319. Indeed, he asserted that Ms. Mullen ''doesn't know my DEA number.'' *Id.* When asked whether he ever authorized Mullen to fax in refill prescriptions, Respondent ''doubted that because whenever I gave out prescriptions for any kind of pain medicine . . . I would give that to the patient directly. And then if [the patient] needed a refill, I would refill it with the patient when I saw [him/her], so that was directly handed to the patient.'' *Id.* at 320.

Asked whether he accepted responsibility for the ''diversion that occurred out of [his] office and under [his] identity,'' Respondent answered that Mullen ''was not entrusted with [his] DEA number'' and that ''there was nothing I could do to supplement that.'' *Id.* at 429. He further testified that when ''I found out about this, I acted immediately,'' and ''as far as . . . acting in the public interest, I think I did that.'' *Id.* Continuing, Respondent testified that ''[a]s far as if you're asking me if I accept responsibility for all of her diversion for the five years and so forth, I don't know how I could do that.'' *Id.* at 429–30.

The DEA Administrative Inspection and Investigation

On July 10, 2013, DEA Diversion Investigators executed an Administrative Inspection Warrant (AIW), presumably at Respondent's Roanoke office as it was his registered location.[18] RX 88, at 1; Tr. 135. In testimony which was both confused and confusing, the DI stated that Respondent had various recordkeeping violations, which, in his view, included that the ''initial inventory wasn't listed.'' Tr. 135–36. The DI then asserted that while Respondent ''had a dispensing log and it did have the number of pills that was dispensed each time and a running count . . . DEA requires a beginning inventory, which would actually . . . be the drug strength, the number of commercial containers or the size of the commercial containers.'' *Id.* at 136. However, on questioning by the ALJ as to whether the beginning inventory would be ''from the date that he opened his practice or . . . from the date that he received these particular drugs,'' the DI explained that ''[i]t would be from the last biennial inventory. So he did have a biennial inventory. So that we can use that as a beginning inventory.'' [19] *Id.* at 137. After acknowledging that a biennial inventory is done ''[e]very two years,'' the DI acknowledged that ''we would use that biennial inventory or the initial inventory'' as the ''starting point.'' *Id.* at 137–38.

However, upon questioning by Government counsel, the DI testified that there was no beginning inventory, that this is the same as the initial inventory which must be created when a person first becomes registered and obtains drugs, and that there was also no biennial inventory. *Id.* at 138. Then asked if there were ''any other regulation violations in terms of the inventories that were required to be kept,'' the DI answered: ''No. Basically he didn't list the number of commercial containers or how many dosage units were in each commercial container.'' *Id.* The DI also testified that he found it troubling that Respondent's violations ''were similar'' to those found in the 2005 Consent Order, ''especially about the biennial inventory and initial inventory.'' *Id.* at 140. The DI further asserted that Respondent's recordkeeping violations ''should have been rectified . . . back in 2005,'' and that the records ''should have been done correctly . . . actually, ever since [Respondent] entered into the MOA with DEA.'' *Id.* at 141.

The DI acknowledged, however, that Respondent had receipt records that went back beyond the period of the audit he conducted, which covered a period of two years. *Id.* at 161, 163. The DI also conceded that Respondent could account for nearly every pill he had obtained, the exception being that he was off three pills of hydrocodone 10/650 mg. *Id.* at 162–63.

Regarding the recordkeeping allegation, Respondent testified that DHP's inspector who audited his records did not raise any issue with respect to his recordkeeping and ''said they were good.'' *Id.* at 397. Respondent testified that based on his conversation with the inspector, he continued to maintain the records in ''just the same way'' until the DI advised him as to the ''deficiencies he found.'' *Id.* at 398. Respondent then testified that as a result of his conversation with the DEA, he changed his recordkeeping practices ''right away.'' *Id.*

The DI also testified that in the summer of 2015, he interviewed Respondent's office manager. *Id.* at 133. In the interview, the office manager denied any knowledge that prescriptions were being called-in in her name. *Id.* She also told the DI that Respondent was not ''aware of that.'' *Id.*

The office manager also told the DI that ''sometimes the controlled substances, which would be [h]ydrocodone, Xanax, and [d]iazepam . . . would be left out for . . . her to administer to the patient.'' *Id.* at 134. The DI testified that the office manager is not a registrant and that she is not permitted to administer controlled substances when Respondent is not present because she is ''not registered'' and ''doesn't have the training to handle controlled substances.'' *Id.* The DI also testified that leaving the controlled substances out overnight is not permitted, and that under the Code of Federal Regulations, controlled substances ''have to be secured in a substantial cabinet,'' such as ''a steel cabinet'' or ''a safe.'' *Id.* Finally, the DI asserted that Respondent did not maintain effective controls against diversion because he was not monitoring his employee closely enough, *id.* at 142, and that Respondent ''has an obligation to know about any diversion that happens with his employees or any criminal information.'' *Id.* at 144. However, when asked by Government counsel if there were ''[a]ny other controls that [Respondent] should have been using,'' the DI answered: ''I don't believe so.'' *Id.*

The DI conceded that Respondent no longer has controlled substances in his office. *Id.* at 165–66. He also acknowledged that he had looked at Respondent's prescriptions since 2013, and that none of these prescriptions raised any concern. *Id.* at 166.

As to the allegation that he did not provide adequate security for the controlled substances that he left out of the safe the night before he would perform procedures, Respondent

(use of a DEA registration number issued to another). GX 20, at 132–40. Mullen pled guilty to all six counts, and on July 17, 2015, she was sentenced to 18 months incarceration. *Id.* at 156–158.

[18] The Government did not submit the AIW for the record and the DI did not testify to the exact date on which the AIW was executed. Tr. 135. I thus derive the date of the inspection from the closing inventory document, which was submitted by Respondent. RX 88. Even though the Show Cause Order alleged that various other records did not comply with the CSA and DEA regulations, the Government did not submit these either.

[19] The CSA does not use the term ''beginning inventory.'' *See* 21 U.S.C. 827(a)(1). Rather, it uses the term ''initial inventory'' to describe the requirement that ''every registrant . . . shall . . . as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances . . . make a complete and accurate record of all stocks thereof on hand[.]'' *Id.* While the CSA also requires a registrant who engages in the dispensing of controlled substances to take an inventory ''every second year thereafter,'' the statute calls this inventory a ''biennial inventory.'' *See id.* The term ''beginning inventory'' simply refers to an inventory that is used as the starting point for an audit of a registrant's handling of controlled substances.

testified that his office was in ''a freestanding building,'' that it was the only office in the building, that he had a security system that had motion and door detectors that was monitored, that the door and door frame to the drug room were made of steel, and that the door had a deadbolt lock. *Id.* at 305–10. He further testified that Ms. Mullen did not have a key to the room. *Id.* at 308.

As for his practice of allowing his office manager to administer controlled substances to patients prior to procedures, Respondent testified that this ''was not a routine practice'' and occurred only ''on occasion.'' *Id.* at 336. Respondent added that this would occur if he was ''inevitably going to be late, right when the patient starts . . . complaining about that,'' prompting a call from his office manager ''asking[] if she [could] administer. . . the medicines.'' *Id.* at 337. Respondent explained that his office manager ''had already checked the [patient's] vitals,'' and that he ''would either say yes or no about that.'' *Id.* He also testified that he did procedures only one day a week, and that it ''would only be the first case in the morning, if that happened at all.'' *Id.*

While Respondent testified that he would leave drugs outside of the safe (in the storage room) either the night before the procedure or if he had ''come in earlier in the morning,'' he further explained that he would leave out only the aliquot for ''just that one patient,'' and that it was kept ''behind the locked door'' of the drug room. *Id.* at 338–39. According to Respondent, opening the safe required both a key and a combination, but only he knew the combination. *Id.* at 340. Respondent stated that he had ended the practice of allowing his office manager to administer medication in September 2013, after a patient questioned the practice. *Id.* at 341.

Asked by the ALJ whether he thought ''it was improper to have [his office manager] administer'' controlled substances to patients when he was ''not in the office,'' Respondent maintained that he ''thought it was a common practice.'' *Id.* at 431. He then maintained that ''my interpretation of the state code and publications by the Board of Medicine, it seemed like it was all right.'' *Id.* However, Respondent provided no such materials to corroborate that this practice complied with state law.

Asked by the ALJ when he first started using the PMP, Respondent testified: ''August 24, 2012.'' *Id.*at 435. When then asked by the ALJ why he didn't ''use it prior to that time,'' Respondent asserted that he had tried several times but ''couldn't get a log-in.'' *Id.; see also id.* at 366–67. Respondent then testified that he later found out ''that the site had been hacked . . . in 2009'' but did not remember when he had tried to access the PMP. *Id.* at 367 & 435. Nor did he testify as to why he had previously sought to access the PMP. However, Respondent testified that he now monitors the state PMP every month to determine if someone is misusing his registration. *Id.* at 382.

Discussion

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). So too, ''[t]he Attorney General may deny an application for [a practitioner's] registration . . . if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* § 823(f). In the case of a practitioner, *see id.* § 802(21), Congress has directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant'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.

Id. § 823(f).

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether'' to suspend or revoke an existing registration or deny an application. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[20]

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving [by substantial evidence] that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, I conclude that the Government's evidence with respect to Factors Two, Four, and Five [21] supports the conclusion that Respondent has committed acts which render his ''registration inconsistent

[20] 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/applicant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[21] With respect to Factor One, the Virginia Board has not made a recommendation to the Agency in this matter. Moreover, even under the broader view taken in numerous agency cases of what constitutes relevant evidence under this factor, the Virginia Board's 2005 restoration of Respondent's medical license to unrestricted status is of *de minimis* probative value in assessing whether his continued registration is consistent with the public interest given that the most serious allegations in this matter post-date the Board's action. Thus, the most that can be said for the Board's restoration of his medical license to unrestricted status is that Respondent currently possesses authority to dispense controlled substances under Virginia law and therefore meets the CSA's prerequisite for maintaining a practitioner's registration. *See Frederic Marsh Blanton,* 43 FR 27616 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'') However, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''); *see also Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to Factor Three, I agree with the ALJ that there is no evidence that Respondent has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution or dispensing of controlled substances,'' 21 U.S.C. 823(f)(3), and that the simple possession offenses of which he has been convicted are properly considered under Factor Five. The Agency has recognized, 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 under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). Thus, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

with the public interest.'' 21 U.S.C. 823(f), 824(a)(4). While I agree with the ALJ's conclusion that a sanction is appropriate, I find that the record supports a stronger sanction than that recommended by the ALJ.

Factors Two, Four and Five—Respondent's Experience in Dispensing Controlled Substances, Compliance with Applicable Laws Related to Controlled Substances, and Such Other Conduct Which May Threaten Public Health and Safety

Respondent's Liability for Mullen's Misuse of His Registration

In the Show Cause Order, the Government alleged that Respondent is ''responsible for the misuse of [his] registration by'' Ms. Mullen. ALJ Ex. 1, at 2. Moreover, in its post-hearing brief, the Government asserts that Respondent ''knew or should have known about the diversion that Ms. Mullen was committing under his name'' based on the fraudulent tramadol prescriptions that were brought to his attention by a pharmacist in November 2008. Gov. Post-Hrng. Br. 15–16. The Government notes Respondent's testimony that he ''didn't think [these acts of diversion] had anything to do with him,'' even though the prescriptions were called in under his name, and argues that ''he admitted [that] he made no changes in his office practices, did not discuss the situation with his employees and did not begin to use Virginia's PMP to monitor the drugs being prescribed under his'' registration. *Id.* at 16–17. The Government then argues that the Agency has consistently applied the principle ''that a registrant bears responsibility for the misuse of their [sic] registration . . . by an employee.'' *Id.* at 17. Also pointing to the ''testimony'' it presented in the form of Ms. Mullen's unattested declaration, the Government argues that Respondent entrusted his registration to Ms. Mullen because her ''duties also included occasionally calling-in patient prescriptions to pharmacies.'' *Id.* at 20.

The ALJ rejected the allegation, reasoning that the Government did not prove that Respondent ''provide[d] Mullen with access to his registration number expressly, impliedly, or negligently,'' R.D. 34, or that Respondent either had knowledge or was willfully blind to Mullen's actions prior to August 20, 2012. *Id.* at 35. While I agree with the ALJ that the Government's proof was inadequate to support the imposition of liability for entrusting his registration to Mullen, I disagree with substantial aspects of the ALJ's reasoning.

First, the ALJ's opinion suggests that he gave weight to Respondent's testimony that he did not believe that the 2008 incident had anything to do with him. *See* R.D. 35. Specifically, in rejecting the Government's contention that ''Respondent should have monitored Mullen and his PMP report, the ALJ reasoned, in part, that ''the 2008 fax [22] did not contain any information that suggested that one of Respondent's employees was involved'' and that ''the refill prescription was not written for one of the Respondent's patients.'' *Id.*

As for Respondent's contention that he did not believe the incident involved him, the incident obviously involved him because his name was being used as the purported issuer of the prescriptions. Moreover, neither Respondent nor the ALJ explained why one would reasonably expect an employee who was engaged in criminal activity by calling in fraudulent prescriptions to give her actual name. Indeed, with respect to the person who was calling in the prescriptions, there were only two possibilities: either the prescriptions were being called in by someone who did not work for him or by someone who did.[23] The record does not, however, establish whether the pharmacist told Respondent that ''Liz Norville'' (Mullen) had provided Respondent's phone number in the voice mail message that she left for the prescription.

I agree with the ALJ that the Government did not prove that Respondent either had actual knowledge of, or was willfully blind to, Mullen's criminal behavior until August 20, 2012.[24] R.D. 35–36. However, DEA has previously held that ''[c]onsistent with a registrant's obligation to 'provide effective controls and procedures to guard against theft and diversion of controlled substances,' every registrant has a duty to conduct a reasonable investigation upon receiving credible information to suspect that a theft or diversion had occurred.'' *Rose Mary Jacinta Lewis,* 72 FR 4035, 4042 (2007) (quoting 21 CFR 1301.71(a)). Thus, the Government is not required to show that a registrant either had actual knowledge of, or was willfully blind to, an employee's or agent's criminal behavior.[25]

The Agency has further explained that ''the precise scope of'' the duty to investigate ''necessarily depends upon the facts and circumstances.'' *Id.* Moreover, a registrant's duty to investigate potential theft or diversion by his employees (or agents) applies to all such acts, regardless of whether the employee has been entrusted with authority to use his registration. *Cf. John V. Scalera,* 78 FR 12092 (2013). In *Scalera,* the former Administrator denied a physician's application for registration, based, in part, on his testimony that he ''had no idea'' and did not ''know anything about'' how unlawful prescriptions that were issued under his name as the prescriber were either called-in or faxed to the pharmacies. *Id.* at 12095–96; *see also id.* at 12099. The Administrator further noted the physician's testimony that ''there was not enough evidence to convince him that any of his employees had actually called in the prescriptions with his surrendered number.'' *Id.* at 12097; *see also id.* at 12099. Notably, the former Administrator denied the physician's application notwithstanding that there was no showing that the physician had entrusted his registration to any employee,[26] holding that ''[h]aving failed to explain why the . . . prescriptions were called in, [r]espondent has offered no credible assurance that similar acts will not occur in the future''). *Id.* at 12100.

Nonetheless, the Agency has not previously held that the potential misuse by an employee or agent of a

[22] While there was a 2008 fax, this document was generated by Respondent in response to the call from the pharmacist questioning the prescriptions, which were phoned-in.

[23] I acknowledge the possibility that someone outside of a physician's practice could call-in (or fax-in) a fraudulent prescription to a pharmacy. Thus, obtaining the phone number provided by the caller (or the number used to fax the prescription) would tend to eliminate one of the two possible sources of the prescription's origin. There is, however, no evidence that the pharmacist told Respondent that ''Liz Norville,'' the name Mullen used on this occasion, had provided his office phone number when she called in the prescriptions, or whether the pharmacy had obtained Respondent's phone number from its dispensing software.

[24] As noted previously, in support of its contention that Respondent authorized Mullen to use his registration and was also aware that she was diverting controlled substances, the Government produced an unattested declaration by Ms. Mullen. Notwithstanding that some of the statements made by Mullen in this document are corroborated by other evidence, the Government's failure to ensure that Ms. Mullen attested to the truth of her statements under penalty of perjury renders this document inherently unreliable.

[25] The Government did not explicitly cite this duty or *Jacinta Lewis* in the Show Cause Order, its Pre-Hearing Statements, or its Post-Hearing brief. Because I reject the Government's contentions as to the steps Respondent should have taken but did not following the 2008 incident, I need not decide whether the Government failed to provide adequate notice of its intent to rely on this duty in this matter.

[26] In *Scalera,* the physician had previously surrendered his registration. 78 FR at 12094. While the physician testified that office employees had access to his registration number, there was no showing by the Government that the physician had authorized the employees to call in prescriptions.

practitioner's state prescribing authority to divert a non-federally controlled drug triggers the duty to investigate whether his DEA registration has also been misused. I now hold that where a registrant is provided with credible information that his state prescribing authority is being used to divert a state-controlled (but not federally-controlled) drug, such information triggers the duty to investigate whether his DEA registration is also being used to divert federally controlled substances. However, as this is a new and additional duty beyond that which was announced in *Jacinta Lewis,* which applies only to a practitioner's receipt of information that his DEA registration is being misused, I conclude that it cannot be retroactively imposed on Respondent.

Moreover, even if the duty had been announced prior to the 2008 incident, I would find unpersuasive the Government's contention that Respondent should be held liable because ''he made no changes in his office practices, did not discuss the situation with his employees and did not begin to use Virginia's PMP to monitor the drugs being prescribed under his DEA number.'' Gov. Post-Hrng. Br., at 16–17. *See also id.* at 21 (arguing that ''[e]ven assuming . . . that [Respondent] did not know of Ms. Mullen's diversion, his failure to discover it over a five-year period and his failure to properly monitor Ms. Mullen or to even check his own PMP report demonstrates a gross and reckless disregard for his responsibilities as a registrant and for the public health and safety'').

The Government offered no explanation as to what changes Respondent should have made to his office practices (other than to check his PMP report) or other steps he should have taken ''to properly monitor Ms. Mullen.'' As for its claim that Respondent did not discuss the situation with his employees, while there is evidence that he did not discuss the matter with Mullen, perhaps Mullen would have confessed and perhaps not. Thus, it is unclear what this would have accomplished. Finally, as for the contention that Respondent should have checked his own PMP report, under Virginia law in effect at the time of the 2008 incident, Respondent was not authorized to obtain a PMP report showing his own prescribings. *See* Va. Stat. § 54.1–2523.B & C (2008). Indeed, Virginia law did not authorize the disclosure by the PMP Director of this information until 2013.[27] *See* 2013 Va. Laws Ch. 739(H.B. 1704) (Amending Va. Code § 54.1–2523.C by authorizing the Director to disclose, ''in his discretion,'' ''.8 Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the program, to that prescriber.'').

Nonetheless, where a practitioner receives credible information that fraudulent prescriptions under his name are being presented for state but not federally-controlled drugs, and the state PMP permits a practitioner to obtain information as to his controlled substance prescribings, that practitioner has a duty to obtain that information and to determine whether unlawful prescriptions for federally controlled substances are also being dispensed under his registration. Moreover, even if state law does not authorize a practitioner to obtain a PMP report of the dispensings which have been attributed to him, a practitioner is obligated to obtain that information from a pharmacy that reports a fraudulent prescription to him. If information obtained from either the PMP or a pharmacy shows that one's registration is being misused, a registrant must report that information to DEA (as well as local law enforcement authorities) even if the practitioner concludes that no employee or agent is involved in the misuse of his registration.[28] A practitioner is not excused from this duty because others, who also have responsibilities to investigate, such as law enforcement officers and pharmacists, failed to carry out those responsibilities.

In conclusion, I agree with the ALJ's legal conclusion that on this record, the Government has not sustained the allegation that Respondent is liable for Mullen's criminal misconduct. However, regardless of whether a registrant has entrusted his registration to an employee, upon receiving credible information that his registration may be the subject of misuse, a registrant has a duty to conduct a reasonable investigation to determine whether his employees are involved in the misuse of his registration. A failure to do so constitutes ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5).

To establish a violation of this duty, the Government is not required to prove that the registrant had actual knowledge or was willfully blind to the fact that an employee was engaged in diversion. Rather, the Government is required to show only that the registrant received credible information creating a suspicion that his registration was being misused, that reasonable measures were available to the registrant to determine if his/her employee or agent was misusing his registration, and that the registrant failed to take such measures.

Respondent's Continued Employment of Mullen After He Became Aware of Her Criminal Conduct

As found above, even after Mullen admitted to Respondent that she had submitted the fraudulent refill authorization for hydrocodone and he was told by Detective Findley that Mullen had a history of submitting fraudulent prescriptions which included the 2008 tramadol prescriptions, Respondent continued to employ Mullen. Indeed, within days of receiving this information, Respondent found the state court records showing that Mullen had pled guilty to obtaining prescription drugs by fraud. He also obtained a PMP report showing that from January 21, 2008 through August 24, 2012, Mullen had filled 56 prescriptions/refills for 90 dosage units of hydrocodone 10 mg and 26 prescriptions/refills for zolpidem 10 mg. Respondent nonetheless continued to employ Mullen for another five weeks, asserting that he needed to retain her because she was his insurance clerk and needed her to maintain his cash flow while a new insurance clerk was hired and trained.

The ALJ rejected the Government's contention that Respondent violated 21 CFR 1301.92 because he continued to employ Mullen ''even after learning of her diversion.'' Show Cause Order (ALJ

[27] The Government argues that Respondent's ''failure to discover [Mullen's diversion] over a five-year period and his failure to properly monitor'' her ''demonstrates a gross and reckless disregard for his responsibility as a registrant.'' Notably, the Government does not explain by what method Respondent should have discovered Mullen's diversion when the state police detective acknowledged that he did not tell Respondent about Mullen's 2008 arrest and the subsequent convictions until the August 2012 incidents, and only a single pharmacy questioned the dosing of a prescription (but not its legitimacy) after the 2008 incident.

Given the scope of the diversion, there is much about this case (such as the failure of the detective to tell Respondent of Mullen's arrest and convictions, not to mention that the terms of her probation did not prohibit her from working in a doctor's office; the fact that prescriptions which were missing Respondent's DEA number were routinely filled notwithstanding that they were facially invalid; as well as that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside of the scope of what is usually prescribed by podiatrists), which is deeply disturbing. While the Government believes Respondent's and his office manager's testimony as to his lack of knowledge is implausible, the burden was on the Government to prove otherwise under the theory it advanced in this case.

[28] Depending upon the extent of the misuse, the practitioner may need to request the cancellation of his registration number and the issuance of a new registration number.

Ex. 1), at 2; R.D. 37–38. According to the ALJ, this regulation ''does not require the immediate termination of an employee; it only requires that the employer immediately assess the employee's conduct to determine what employment action to take against the employee.'' R.D. 37.

In the ALJ's view, ''Respondent immediately assessed both the seriousness of Mullen's violations and her position of responsibility, as required under'' the regulation. *Id.* The ALJ also gave weight to Respondent's testimony that while Mullen remained in his employment, he moved the fax machine into the secure medication room, took away her office keys, called local pharmacies to alert them to Mullen's actions, and monitored his DEA number on the PMP system.[29] R.D. 37. The ALJ further gave weight to the testimony that Respondent needed to retain Mullen for this period because 99 percent of his cash flow came from insurance payments and ''no replacement could immediately fill Mullen's position so as to continue the Respondent's normal business operations,'' even though Respondent acknowledged that his ''office manager was competent to perform these duties.'' *Id.* at 38.

Continuing, the ALJ explained that ''[f]or small businesses that depend on each employee performing essential business functions, it is reasonable to expect that terminating an employee can be a process rather than an instantaneous action.'' *Id.* The ALJ then rejected the allegation, concluding that Respondent had acted ''[c]onsistent with the requirements of 21 CFR 1301.92'' by taking ''immediate action towards terminating Mullen's employment because of her misconduct.'' *Id.*

Section 1301.92 is contained in a section of part 1301 which follows the heading: ''EMPLOYEE SCREENING–NON-PRACTITIONERS,'' thus raising the question, which was not addressed by either party or the ALJ as to whether it even applies to Respondent who is a practitioner. I need not decide this question because under the public interest standard applicable to practitioners, the Agency's authority includes not only those acts that constitute violations of its regulations, it also includes ''[s]uch other conduct which may threaten the public health and safety.'' [30] 21 U.S.C. 823(f)(5).

Moreover, whether I were to apply section 1301.92 or evaluate Respondent's conduct under Factor Five, I would come to the same result. Here, the evidence shows that by August 24, 2012, Respondent knew that Mullen had been convicted in state court of two counts of prescription fraud. And once he obtained the PMP report which showed the controlled substances prescriptions she obtained under his DEA registration, Respondent knew that Mullen had committed at least another 82 felony offenses of prescription fraud.

To the extent the ALJ's recommendation suggests that Respondent properly ''assessed . . . the seriousness of Mullen's violations,'' R.D. 37, I disagree. Indeed, proof that Mullen had committed a single act of prescription fraud should have resulted in her immediate termination. Of further note, when confronted on cross-examination as to why he retained Mullen even after he obtained the PMP report, Respondent attempted to minimize the scope of Mullen's misconduct when he testified that ''I acted upon the, you know, the proportion of things that I knew. So it wasn't—it wasn't what we're looking at in retrospective now with this huge situation. It was only with a handful of information that I had, less than a dozen.'' Tr. 426.

However, by August 24, 2012, Mullen's criminal conduct in obtaining prescriptions for herself alone made this an indisputably ''huge situation'' given that she had obtained more than 5,000 dosage units of hydrocodone 10 mg, the strongest dosage form of this highly abused controlled substance, not to mention another 780 dosage units of zolpidem. Notably, the ALJ, in his discussion as to why he rejected the Government's contention that Respondent should have immediately fired Mullen, did not address this testimony.

I also disagree with the ALJ that the measures undertaken by Respondent justify his failure to immediately terminate Mullen. As for his moving the fax machine into the secure medications room, this did not address Mullen's ability to phone in prescriptions. So too, while Respondent took away Mullen's keys to the office, obviously she was allowed into the office in order to train her replacement and Respondent offered no testimony that anyone was watching Mullen on those days when he was at his other offices.

As for the ALJ's finding that Respondent ''monitored his DEA number on the PMP system,'' R.D.37, while Respondent claimed he did this ''every month,'' Tr. 382, he offered conflicting testimony as to when he started doing so. Specifically, after testifying that he checked the PMP every month to see if anyone was misusing his number, when then asked by his counsel if he had found any misuse since August 2012, Respondent answered: ''No. I will say I've been doing every month for approximately a year, nine months, something like that that. No, no deviations there.'' [31] *Id.* at 382–83. Yet when later asked by the ALJ ''when did you start using the PMP on a regular basis?'' Respondent answered: ''August 24 of 2012.'' *Id.* at 435. Not only is this conflict in his testimony unresolved, Respondent did not testify as to any other instance during the remaining period of Mullen's employment in which he accessed the PMP to determine what prescriptions were being dispensed under his registration.

To be sure, there is evidence that Respondent called local pharmacies to alert them to Mullen's actions. Yet the evidence also shows while Respondent claimed to have called ''a handful of these'' pharmacies on August 20, 2012 (the day the refill authorization form was found on the fax), at least 12 refills for 90 or 120 dosage units of hydrocodone were nonetheless dispensed by several of these pharmacies after that date, including by those he called. Moreover, Respondent saw patients at four different locations

[29] The ALJ also found that ''Respondent's office manager monitored Mullen from August 20, 2012, until she left the Respondent's employment.'' R.D. 37 (citing Tr. 79). The cited testimony involved only the question by Respondent's counsel: ''Do you recall whether you were more vigilant watching Ms. Mullen during that month that she was still there?'' followed by the office manager's answer: ''I would say yes.'' Tr. 79. The office manager did not, however, offer any further testimony explaining in what manner she was more vigilant in watching Mullen during this period.

[30] Notwithstanding that the Government did not cite Factor Five with reference to this allegation, Respondent clearly knew that his conduct in retaining Mullen in his employment after discovering that she was diverting drugs was at issue in the proceeding and put on a full defense against the allegation. Of consequence, the public interest factors do not impose substantive legal duties which can be violated, but simply shape the scope of relevant evidence in the proceeding, and Respondent clearly knew throughout the proceeding that the Government was alleging that his retention of Mullen was conduct which renders his registration inconsistent with the public interest. ALJ Ex. 1, at 1–2 (citing 21 U.S.C. 824(a)(4) and 823(f)).

Of further note, 21 CFR 1301.76(a), which is titled ''[o]ther security controls for practitioners,'' provides, in part, that ''[t]he registrant shall not employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances.''

[31] Even if Respondent meant that he had been checking the PMP for one year and nine months (since the date of the hearing), this still would not support a finding that he had commenced doing so every month since August 2012 and did so while Mullen remained employed with him.

in southwestern Virginia, and while there is no evidence as to the number of pharmacies in this area of Virginia, presumably there are more than ''a handful.''

I further reject Respondent's contention that he was justified in continuing to employ Mullen because he needed to maintain his cash flow while a new insurance clerk was hired and trained. The evidence showed that Respondent's office manager could have performed these duties, and while she testified that she could not do so and perform her other duties, no evidence was offered that Respondent could not have hired someone to fill the office manager's duties or that he could not have hired a billing service. Moreover, Respondent offered no evidence that he did not have access to other sources of funds (such as his savings, credit cards, or a line of credit) to support his practice while a new insurance clerk was hired and trained. As for the ALJ's suggestion that Respondent acted reasonably because he ran a small business and Mullen performed an essential business function, a DEA registrant is obligated at all times to act in the public interest.

It is true that ''there was no evidence that Mullen used her position in . . . Respondent's office to generate any fraudulent prescriptions after August 20, 2012.'' R.D. 38. Respondent was nonetheless willing to risk causing additional harm to the public health and safety. His conduct in continuing to employ a serial diverter clearly constitutes ''conduct which *may threaten* the public health and safety.'' 21 U.S.C. 823(f)(5) (emphasis added).

The Recordkeeping Allegations

Pursuant to 21 U.S.C. 827(a)(1), ''every registrant shall . . . as soon . . . as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances . . . and every second year thereafter, make a complete and accurate record of all stocks thereof on hand.'' *See also* 21 CFR 1304.11(c) (''After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years.''). Moreover, ''[e]ach inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. . . . The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.'' *Id.* § 1304.11(a).

The evidence shows that in 2005, Respondent entered into a Consent Order which found that he ''did not establish an initial inventory.'' GX 3, at 1–2. Moreover, during the July 2013 inspection, Diversion Investigators found that Respondent did not have a biennial inventory which was based on an actual count of the drugs on hand as required by DEA regulations. *See* 21 CFR 1304.11(a) & (c). Rather, he maintained a perpetual inventory, which was not based on an actual count of the drugs on hand at the required biennial interval, but rather, as the ALJ found, was ''a mathematical calculation of how many [controlled substances] the Respondent *should* have had after dispensing the listed amounts.'' R.D. 41. Thus, I agree with the ALJ that Respondent violated 21 U.S.C. 827(a) by failing to establish an initial inventory (as found in the 2005 Consent Order) and by failing to ''make a complete and accurate'' biennial inventory. R.D. 40–41.

In his Exceptions, Respondent raises two contentions to the ALJ's findings. First, he argues that because he was engaged in administering medication to his patients, he was ''not required to perform the initial and biennial inventories that are required of other registrants.'' Exceptions, at 1 (citations omitted). Respondent points to 21 U.S.C. 827(c)(1)(B), which states, in relevant part, that the recordkeeping provisions of section 827 ''shall not apply . . . to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered.'' Exceptions, at 1–2. Respondent argues that ''DEA had the burden of proof as to this allegation,'' and because the Government failed ''to offer evidence that [he] falls into the statutory exception,'' the allegation must be rejected. *Id.* at 2. Respondent further maintains that ''[t]his is not a case where [he] seeks to invoke a statutory exception; rather, DEA seeks to invoke it.'' *Id.*

Respondent is mistaken. Section 827(a) states that ''*[e]xcept as provided in subsection (c)* of this section . . . *every registrant shall* . . . as soon . . . as such registrant first engages in the . . . distribution[] or dispensing of controlled substance, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand.'' (emphasis added). Thus, section 827(a) makes plain that the provisions of subsection C are simply exceptions to the provisions of subsection A and B, which are generally applicable to all registrants.

Fatal to Respondent's contention is 21 U.S.C. 885(a)(1). It provides that:

> It shall not be necessary for the United States to negative any exemption or *exception* set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, *hearing, or other proceeding under this subchapter,* and the burden of going forward with the evidence with respect to any such exemption *or exception shall be upon the person claiming its benefit.*

21 U.S.C. 885(a)(1) (emphasis added). By its plain terms, this provision applies not only to criminal proceedings but also to suspension and revocation proceedings.

Because section 827(c) is clearly an exception to the generally applicable recordkeeping requirements and Respondent is ''the person claiming its benefit,'' he had the burden of producing evidence to show why he was entitled to the exception. *Id.* As Respondent produced no evidence showing that he did not ''charge[ ] his patients, either separately or together with charges for other professional services, for substances so dispensed or administered,'' *id.* § 827(c)(1)(B), he is not entitled to claim the exception. I therefore reject Respondent's exception and hold that Respondent violated section 827(a) by failing to maintain proper inventories.[32]

The Failure To Maintain Adequate Physical Security Allegation

As found above, on occasion, the night before he was to perform a procedure, Respondent would set out in a cup—outside of the controlled substance safe—the controlled substances that his office manager was to provide to his first patient. However, the evidence shows that the drugs were nonetheless kept locked in his medication room which was secured with a steel door (and door frame) that had a deadbolt lock. The evidence also shows that this office was a freestanding building and that Respondent had a security monitoring system.

The ALJ rejected the Government's contention that Respondent violated 21 CFR 1301.75, which provides that ''[c]ontrolled substances listed in [s]chedules II, III, IV, and V shall be

[32] As Respondent did not maintain a proper initial and biennial inventory at all, these are the violations he committed. Having made these findings, I agree with Respondent that the ALJ's additional findings that his inventory did not contain the number of containers and the number of units or volume in each container, *see* R.D. at 42, ''are subsumed under the 'greater' violation'' of failing to take a biennial inventory. Exceptions, at 3.

stored in a securely locked, substantially constructed cabinet.'' R.D. 43–44. Noting that the Agency's regulations do not define the term ''substantially constructed cabinet,'' the ALJ explained that at least one prominent dictionary provides a definition of the term ''cabinet'' which includes ''[a] small or private room set aside for some specific activity.'' R.D. 44 (quoting American Heritage Dictionary of the English Language 185 (1976)). The ALJ further gave ''consideration to the factors contained in 21 CFR 1301.71(b)'' and found that Respondent's use of the Extra Meds Room ''to store his controlled substances substantially complied with the requirements of 21 CFR 1301.71(b).'' *Id.*

Of note, section 1301.75(b) does not require that most schedule II through V controlled substances be stored in a safe, and indeed, section 1301.75(e) specifies two drugs (carfentanil etorphine hydrochloride and diprenorphine) which ''shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.'' 21 CFR 1301.75(b) & (e). And while the use of the word ''cabinet'' to describe a small room appears archaic,[33] I agree with the ALJ that in light of the small amount of controlled substances that were stored outside of the safe and the level of security provided by the medication room and the office's alarm system, Respondent nonetheless remained in substantial compliance with section 1301.75 when he left the drugs outside of the safe but locked in the medication room.

Aiding and Abetting the Unlawful Distribution of Controlled Substances by an Unregistered Person

The Government alleged and the ALJ found that Respondent aided and abetted the unlawful distribution of controlled substances when he allowed his office manager to administer the controlled substances, which he had set out in the drug room the night before, to those patients who were undergoing procedures and he had yet to arrive at his office. R.D. 44–46. The evidence showed that Respondent's office manager did not hold a registration to dispense controlled substances.[34] *Id.* at 44 (citing Tr. 57). The ALJ further rejected Respondent's contention that his office manager was exempt from registration under 21 CFR 1301.22(a) because in administering the drugs, she was Respondent's ''agent or employee'' and was ''acting in the usual course of . . . her business or employment.'' *Id.* at 45.

In so holding, the ALJ reasoned that because in his post-hearing brief, ''Respondent described [the office manager's] administration of controlled substances as occurring only on 'limited occasions,' '' ''Respondent himself argued . . . that [she] did not administer controlled substances in the usual course of business.'' *Id.* (quoting Resp. Post-Hrng. Br. 38). Continuing, the ALJ explained that he was ''find[ing] as a matter of fact that [the office manager's] administration of controlled substances was described repeatedly as 'occasional,' which is the opposite of 'usual.' Therefore, 21 [CFR] 1301.22(a) does not apply.'' *Id.*

Respondent takes exception to the ALJ's legal conclusion. He argues that his office manager was an agent within the meaning of the CSA, which defines the term as ''an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser.'' Exceptions, at 4 (quoting 21 U.S.C. 802(3)). Respondent further notes that ''[w]hile the phrase 'in the usual course of business' is used many times in the CSA and the associated regulations, it is not defined.'' *Id.* at 5 (citing 21 U.S.C. 822(c); 21 CFR 1300.04). Respondent then maintains that ''[t]he fact that a business practice occasionally, or on limited occasions, does not mean that it is not in the usual course of that business.'' *Id.* Respondent argues that the testimony shows ''that during the course of [his] surgical practice, it was in the usual course of business for [the office manager] to administer medication in lieu of [his] doing it personally when [he] was not going to be in the office when the surgery patient arrived[.]'' *Id.* Respondent thus contends that the office manager ''was acting as [his] agent and employee within the scope of her responsibilities and duties'' and was not required ''to be registered.'' *Id.* Respondent thus contends that he ''did not aid and abet an illegal distribution of a controlled substance under 21 U.S.C. 841(a).'' *Id.*

I need not decide whether the frequency of the office manager's administrations of controlled substances to Respondent's patients was sufficient to establish that she was acting in the usual course of her employment when she did so. Rather, I conclude that because under Virginia law, the office manager could not legally administer controlled substances to Respondent's patients, it does not matter whether she did so only ''on limited occasions'' or routinely, and that because her conduct was unlawful, it cannot qualify under section 822(c) as ''acting in the usual course of [a registrant's] business or employment.''

The Virginia Drug Control Act defines the term ''[a]dminister [to] mean[ ] the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient . . . by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient . . . at the direction and in the presence of the practitioner.'' Va. Code § 54.1–3401. Even assuming that the office manager's conduct in providing the drugs to patients falls within the provision allowing a practitioner's ''authorized agent'' to do so, the Virginia Drug Control Act contained extensive and detailed provisions governing the circumstances in which drugs can be administered by someone other than a licensed prescribing practitioner. *See id.* § 54.1–3408. Relevant here is subsection U, which states:

> Pursuant to a specific order for a patient and under *his direct and immediate supervision,* a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not included intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

Id. § 54.1–3408.U. Even assuming that this provision allows a doctor of podiatry [35] to authorize his employee to administer a controlled substance to his patient, the evidence shows that Respondent would approve the administration when he was ''going to be late,'' prompting his office manager to call and ask ''if she [could] administer . . . the medicines.'' Tr. 337. Respondent was not in the office when this occurred, and while he asserted that

[33] *See Merriam-Webster*.com. Merriam-Webster, n.d. Web. 22 May 2017.

[34] Nor does she hold any DEA registration. Tr. 57.

[35] While this provision specifically refers to ''a doctor of medicine or osteopathic medicine,'' Va. Code § 54.1–3408.U, subsection A refers to ''[a] practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine.'' *Id.* § 54.1–3408.A.

In his Post-Hearing Brief, Respondent implies that this practice was lawful under the Board of Medicine's Rules governing Office-Based Anesthesia. Resp. Post-Hrng. Br. 50. He specifically notes that Board's ''requirements for office based anesthesia'' do not apply to ''[m]inimal sedation/anxiolysis.'' *Id.* (quoting 18 Va. Admin. Code 85–20–320(A)(1). That may be (even though there is no evidence as to whether the cocktail of drugs that were given to the patients resulted in the inducement of ''minimal sedation/anxiolysis'' or ''moderate sedation/conscious sedation,'' which is subject to the requirements for office-based anesthesia), but this argument does not address whether Respondent's practice of having his office manager administer the drugs to the patients in his absence was lawful under Va. Code § 54.1–3408.U.

''he thought it was a common practice'' and was permitted by the Board of Medicine, he produced no materials from the Board such as an opinion letter or Board decision that would support his contention that even though he was not physically present in the office, he was nonetheless engaged in the ''direct and immediate supervision'' of his office manager when he authorized his office manager to administer the drugs to the patients.

Accordingly, I reject Respondent's exception that his office manager was exempt from registration because she was ''acting in the usual course of [her] . . . employment'' and that he is not liable for aiding and abetting the unlawful distribution of controlled substances. As explained above, I further hold that on those occasions when Respondent was not physically present in the office and his office manager administered the controlled substances to various patients, she engaged in an unlawful distribution under 21 U.S.C. 841(a)(1).[36] I further agree with the ALJ that Respondent aided and abetted these violations and that this conduct is actionable under Factor Four. R.D. 46; *see also* 18 U.S.C. 2.

The State Court Convictions

As the ALJ found, in 2000, Respondent pled guilty in state court to four felony counts of the unlawful possession of controlled substances which included sufentanil, oxycodone, pethidine, and hydromorphone, as well as one misdemeanor count of unlawful possession of marijuana. R.D. 47. While the ALJ noted that the Agency had ''declined to revoke'' Respondent's registration based on these convictions and the convictions were over 15 years old, he rejected Respondent's contention that because the Agency entered into the Memorandum of Agreement (MOA) with Respondent it is now estopped from seeking revocation based on these convictions. *Id.*

Respondent takes exception to the ALJ's ruling. Exceptions, at 10–11. He argues that that ''[t]he ALJ cited no basis for his finding that the MOA did not estopped [sic] DEA from relying on [his] 2000 conviction [sic] in its attempt to sanction him today.'' *Id.* at 10. He also argues that he ''has not found an agency decision that relied on conduct predating a MOA as a basis for revoking a registration.'' *Id.* And he argues that ''[t]he MOA was a contract between DEA and [himself],'' that the MOA placed restrictions on his registration ''[i]n lieu of initiating procedures for the revocation of'' his registration, that he ''fulfilled his obligations under the'' MOA, and that ''DEA is bound by its agreement to accept the MOA in lieu of seeking revocation based on [his] 2000 conviction'' under ''[s]imple contract law.'' *Id.* at 11.

I disagree. While the MOA noted that ''[i]n light of [his] past actions, authority exists under 21 U.S.C. [823(f) and 824a)(4)] for DEA to initiate Show Cause action to revoke [his] registration'' and that ''[i]n lieu of initiating procedures for the revocation of [his] [r]egistration,'' the parties had agreed to various terms including the renewal of his registration, none of those terms precluded the Agency from relying on the state court convictions in any subsequent proceeding.[37] RX 83, at 2. Thus, applying ''simple contract law,'' Respondent got exactly what he bargained for—the renewal of his registration subject to various conditions. What he did not bargain for was the ability to preclude the Agency from considering the state court convictions in the event he committed additional misconduct in the future and was subject to a Show Cause Order.[38]

I therefore reject Respondent's exceptions that I am precluded from considering Respondent's state court convictions by the MOA. However, in light of the fact that Respondent's convictions occurred 17 years ago and that there is no evidence that Respondent has been subsequently convicted of either a federal or state offense related to controlled substances (whether falling within the scope of Factor Three or Factor Five), I place only limited weight on the state court convictions.

Summary of the Government's Prima Facie Case

Given Respondent's knowledge that Mullen had fraudulently obtained controlled substance prescriptions/refills 82 times from January 21, 2008 through August 24, 2012, as well as his knowledge that Mullen had been convicted in state court of two counts of prescription fraud, I conclude that he has committed ''other conduct which may threaten the public health and safety'' when he failed to immediately terminate Mullen. 21 U.S.C. 823(f)(5). I further conclude that Respondent's convictions for the unlawful possession of various controlled substances provide limited support for the finding that Respondent has committed ''other conduct which may threaten public health or safety.'' *Id.*

[36] In his Exceptions, Respondent argues that ''[t]here is no DEA precedent for finding [the office manager's] conduct to be an illegal distribution.'' Exceptions, at 5 (citing *Fred Samimi,* 79 FR 18698 (2014), and *Margy Temponeras,* 77 FR 45675 (2012)). Discussing *Samimi,* Respondent states that ''Dr. Samimi was found by the State of California to have aided and abetted the unlicensed practice of medicine by allowing his staff to dispense (not administer) controlled substances when he was not present. In sustaining that finding as relevant to her consideration, the Administrator made no suggestions that Dr. Samimi's actions violated the CSA.'' *Id.* And discussing *Temponeras,* Respondent noted that ''Dr. Temponeras had unregistered employees dispensing (not administering) drugs to patients by filling prescriptions while she was not actually present[,]'' and that while ''the Administrator found that Dr. Temponeras violated the CSA because she was not registered as a dispenser and . . . violated Ohio law by allowing unlicensed individual[s] to fill controlled substance[ ] prescriptions . . . there was no reference to Dr. Temponeras' conduct as constituting illegal distributions.'' *Id.* at 5–6 (int. quotations omitted).

Neither case supports Respondent. As for *Samimi,* the Government never argued that the physician's practice of allowing unlicensed staff to dispense controlled substances without being directly supervised by him constituted a violation of 21 U.S.C. 841, and thus, that case did not address the question of whether an unregistered person can administer controlled substances to a patient outside of the presence of the physician. *See* 79 FR at 18698 (discussing allegations of Show Cause Order); *id.* at 18710 (discussing state board's findings and relevant state law prohibiting practice of allowing unlicensed and unsupervised office staff to dispense drugs).

As for *Temponeras,* the Agency's decision found that the physician, who was not registered as a pharmacy, ''exceeded the authority of her registration because she authorized her employees to fill prescriptions issued by her father.'' 77 FR at 45677. Notably, the decision cited both 21 U.S.C. § 822(b), which provides that a registrant is authorized to engage in controlled substances activities ''to the extent authorized by [his] registration and in conformity with the other provisions of'' the CSA, and § 841(a), which renders unlawful the knowing or intentional distribution of a controlled substance ''[e]xcept as authorized by'' the CSA. Thus, Respondent's assertion that ''[i]n *Temponeras,* there was no reference to Dr. Temponeras' conduct as constituting 'illegal distributions' '' misstates the case. Exceptions, at 6.

[37] Respondent might have an argument under ''simple contract law'' if, after the MOA expired (that being one year from the date that DEA signed the agreement), the Agency then brought a show cause proceeding based on the exact same grounds that led to the MOA and nothing else. But it has not.

[38] Respondent also argues that he ''has not found an Agency decision that relied on conduct predating a MOA as a basis for revoking a registration.'' Exceptions, at 10. However, in *Mark De La Lama,* 76 FR 20011 (2011), the Agency denied an application (submitted by a nurse practitioner who allowed his registration to expire) based, in part, on his prior convictions for controlled substance offenses which gave rise to an MOA when he first became registered and which he subsequently violated. *See* 76 FR at 20018 & n.15; *id.* at 20019 n.18. While the decision did not place substantial weight on the applicant's convictions due to their age, it did not hold that the Agency could not consider the convictions because they predated the MOA. *See id.*

Moreover, Respondent cites no Agency decision which holds that following the entry of an MOA, the Agency is precluded from considering the conduct which gave rise to the MOA in a subsequent proceeding.

As also found above, Respondent failed to comply with the CSA's requirement that he ''make a complete and accurate record of all stocks . . . on hand'' both when he first engaged in the dispensing of controlled substances as well as ''every second year thereafter.'' 21 U.S.C. 827(a)(1); 21 CFR 1304.11(a) & (c). He also violated the CSA by directing his office manager, who does not hold a registration, to administer controlled substances to those patients who were to undergo procedures when Respondent was not at his office. 21 U.S.C. 841(a); 18 U.S.C. 2. Both his failure to maintain proper records and his conduct in directing his office manager to administer controlled substances to patients is relevant in assessing Respondent's experience in dispensing controlled substances (Factor Two) and his compliance with applicable laws related to controlled substances (Factor Four).

I therefore hold that the Government has met its *prima facie* burden of showing that Respondent ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further conclude that grounds exist to suspend or revoke Respondent's registration.

Sanction

Where, as here, the Government has established grounds to revoke a registration or deny an application, a respondent must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [a registrant] has committed acts inconsistent with the public interest, the [registrant] must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (citing *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Cuong Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995). Also, a registrant's candor during both an investigation and the hearing itself is an important factor to be considered in determining both whether he has accepted responsibility as well as the appropriate sanction. *Michael S. Moore,* 76 FR 45867, 45868 (2011); *Robert F. Hunt, D.O.,* 75 FR 49995, 50004 (2010); *see also Jeri Hassman,* 75 FR 8194, 8236 (2010) (quoting *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest[.]'').

While a registrant must accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct in order to establish that his continued registration is consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate disposition of the matter. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Having considered the relevant facts and circumstances, I disagree with the ALJ's recommended sanction of a one year suspension which would not be effective for three months from the date of my Final Order and which would be stayed provided Respondent takes certain courses within that period. Instead, because I find Respondent's failure to immediately terminate Mullen upon determining that she had fraudulently obtained 82 prescriptions for herself is egregious misconduct, which clearly posed a threat to public health and safety, I am compelled to reject the ALJ's recommended sanction and conclude that the imposition of a substantial period of outright suspension is warranted.[39]

Notably, Respondent did not acknowledge his misconduct in retaining Mullen, and instead, justified his decision to retain her until a new insurance clerk was hired and trained because of his need to maintain his cash flow. Moreover, when confronted as to why he had retained Mullen even after he obtained the PMP report which listed 82 different prescriptions which she had fraudulently obtained, Respondent attempted to minimize the scope of her misconduct, testifying that he ''acted upon . . . the proportion of things that I knew. So it wasn't . . . what we're looking at in retrospective now with this huge situation. It was only with a handful of information that I had, less than a dozen.'' Tr. 426.

It is true that there is no evidence that Mullen continued her criminal acts during the five week period before she was finally terminated. Had the Government produced such evidence, I would revoke Respondent's registration. While it is also true that Respondent moved the fax machine into a room to which Mullen did not have access, this does not mitigate Respondent's misconduct because the evidence shows that many of the fraudulent prescriptions (whether for Mullen personally or for her co-conspirators) were phoned in.

Finally, I conclude that the Agency's interests in both specific and general deterrence also support a substantial period of outright suspension for this misconduct. As to specific deterrence, were Respondent to confront the same situation of a diverting employee in the future, he must know that there will be serious consequences for failing to act responsibly. Also, Respondent may confront different scenarios in which he is faced with the choice of placing his private interests over the public interest. As to the Agency's interests in general deterrence, the community of practitioner registrants must know that there will be substantial consequences for failing to promptly terminate employees who are diverting controlled substances.[40]

[39] Because the ALJ rejected this allegation, he did not address the relevant facts and circumstances related to this misconduct.

[40] Respondent argues that I should consider his cooperation with law enforcement upon discovering the 2012 fraudulent refill request. Resp. Post-Hrng. Br. 67. However, as discussed above, I conclude that the other factors discussed above greatly outweigh his cooperation with the Detective's investigation.

Accordingly, based solely on Respondent's misconduct in retaining Mullen, I conclude that the factors relevant to this misconduct support the outright suspension of Respondent's registration for a period of one year. Moreover, I conclude that Respondent's failure to maintain complete and accurate inventories, as well as his misconduct in directing his unregistered office manager to administer controlled substances to patients, provide additional support for my conclusion that an outright suspension for one year is warranted.

While Respondent's failure to establish an initial inventory occurred sometime ago, his failure to maintain a complete and accurate biennial inventory based on an actual physical count of the controlled substances he had on hand is far more recent. While Respondent testified that he kept the records as he did based on the guidance he received from the state inspector in the 2005 time frame, the requirements to take an actual physical count ''either as of the opening of business or as of the close of business on the inventory date'' and to indicate this ''on the inventory'' are clear on the regulation's face. And even if Respondent was given erroneous advice by the state inspector, Respondent is responsible for knowing what is required by DEA's regulations.[41]

Moreover, while in response to the DI's instructions Respondent started taking an actual count, the ALJ found that ''Respondent did not show remorse for his recordkeeping violations.'' R.D. 49.

As for his practice of directing his office manager to administer controlled substances to patients who were undergoing procedures when he was running late and not in the office, the ALJ also found that there were several factors that mitigate the egregiousness of these violations. According to the ALJ, these factors include that this happened only ''occasionally,'' that Respondent had previously determined what medications should be administered to the patient based on his assessment of the patient's needs, that there is no evidence that the drugs were diverted, and that Respondent had ceased this practice after a patient questioned it. R.D. 50–51.

I do not take issue with the ALJ's conclusions that these factors mitigate the egregiousness of these violations. However, here again, the ALJ found that ''Respondent never acknowledged that [the office manager's] administration of controlled substances violated DEA regulations. . . . Respondent never showed remorse for aiding and abetting dispensations by a non-registrant. Rather, the Respondent denied that these actions were wrongful.'' *Id.* at 46. The ALJ thus concluded that ''Respondent has not accepted responsibility for his conduct, even though he discontinued these practices [and] . . . Respondent has not rebutted the Government's *prima facie* showing that the Respondent violated 21 U.S.C. [§ 841(a)].'' *Id.* I agree.

Respondent's violations in failing to take a proper inventory and in directing his unregistered office manager to administer controlled substances, coupled with his failure to acknowledge his misconduct with respect to both violations, provide additional support for my decision to suspend Respondent's registration for a period of one year. As for the state court convictions, because they did not involve distribution to others and occurred 17 years ago, I give them only limited weight in my determination as to the appropriate sanction.

Accordingly, I will order that Respondent's registration be suspended outright for a period of one year. While Respondent testified that he no longer uses controlled substances during his procedures, if, following termination of the suspension, he intends to resume administering and/or engaging in the direct dispensing of controlled substances, Respondent must provide evidence to the local DEA office that he has completed a course in controlled substance recordkeeping prior to doing so. If Respondent does not provide such evidence, his registration shall be restricted to prescribing controlled substances.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) as well as 21 CFR 0.100(b), I order that DEA Certificate of Registration No. BK0639279 issued to Peter F. Kelly, D.P.M., be, and it hereby is, suspended for a period of one year. I further order that upon termination of the suspension, said registration shall be restricted to prescribing controlled substances, until such date that Peter F. Kelly, D.P.M., provides evidence that he has completed a course in controlled substance prescribing. This Order is effective July 24, 2017.

Dated: June 19, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–13158 Filed 6–22–17; 8:45 am]

BILLING CODE 4410–09–P

[41] In his Recommended Decision, the ALJ discussed eight considerations that in his view, ''mitigate the egregious of the shortcomings of Respondent's controlled substance inventory.'' R.D. 50. However, several of these do not mitigate the violation. For example, the ALJ noted that ''Respondent kept a thorough and detailed perpetual inventory,'' that the DI was able to use the perpetual inventory to do an audit, and that ''there is no evidence that the Respondent's recordkeeping errors resulted in any diversion.'' *Id.* These do not mitigate the violation because the CSA and DEA regulations require that a registrant take an actual physical count of the controlled substances on hand, and an accurate actual count, as memorialized in either an initial or biennial inventory, is essential in conducting an accurate audit. Likewise, an accurate audit is essential in determining whether a registrant is maintaining complete and accurate records of both the controlled substances he receives and those he ''deliver[s] or otherwise dispose[s] of.'' 21 U.S.C. 827(a)(3). As for the ALJ's statement that there is no evidence that Respondent's recordkeeping errors resulted in diversion, generally, it is diversion that results in recordkeeping irregularities and not the other way around.

As for the ALJ's observation that Respondent kept receipt records that ''showed the number of containers, the number of dosages in the containers, and the strength of the dosages,'' these records were prepared by Respondent's suppliers, *see, e.g.,* RX 89, at 37–47; and Respondent is required to maintain these records under the CSA and DEA regulations. *See* 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a); *id.* § 1304.22(c). Moreover, because I hold that the violation is based on his failure to have a biennial inventory based on an actual count of the drugs on hand and not on the fact that his inventory did not list the number of containers, the number of units or volume of each container, and the drug strength, the fact that he had records showing this information for the various receipts does not mitigate the violation.

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0021]

Agency Information Collection Activities; Proposed eCollection eComments; Requested; Extension Without Change, of a Previously Approved Collection; FBI National Academy: End-of-Session Student Course Questionnaire; FBI National Academy: General Remarks Questionnaire

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 22, 2017.

FOR FURTHER INFORMATION CONTACT:

If you have additional comments especially on the estimated public burden or associated response time,