certifying or diagnosing a patient as needing medical marijuana, but acknowledged a lack of investigative information that Respondent ''ever handed any marijuana to anybody for cash.'' (Tr. 77–78.) The weight of the evidence demonstrates that Respondent's activities, as it relates to marijuana, were primarily limited to medical marijuana recommendations. (*See, e.g.,* Gov't Ex. 2, at 3–4.)

Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent ''distributed marijuana[,] * * * aided and abetted the distribution of marijuana[,]'' or engaged in other related conduct. *Cf. Marion ''Molly'' Fry, M.D.,* 67 Fed. Reg. 78,015 (DEA 2002) (the respondent's registration not revoked '''merely because' she recommended marijuana to a patient 'based on a sincere medical judgment' '' but primarily because she distributed marijuana and aided and abetted in distribution of marijuana).

A remaining issue in this case is whether Respondent has accepted responsibility for his past misconduct, and demonstrated that he will not engage in future misconduct. The Government argues that there ''is nothing in the record that evinces Respondent's acceptance of responsibility * * *.'' (Gov't Br., at 18.) The Government also notes that Respondent lacked candor throughout his testimony, simply claiming that he was unaware of certain regulations or attempting to justify his prescribing practices by ''fabricat[ing] a story * * *.'' (*Id.* at 18–19.) Respondent does not specifically address acceptance of responsibility in his post-hearing brief, but he instead claims that the Government did not meet its burden of proof because he did not intentionally violate any state or federal regulations, and because ''the government's case rests entirely upon a web of lies spun by two undercover agents * * *.'' (Resp't Br., at 14–15.)

As discussed above, Respondent's testimony as a whole fails to adequately accept responsibility for his past misconduct, particularly with regard to his prescribing practices to the UCs. Under Agency precedent, in the absence of a credible explanation by the practitioner, as few as two incidents of diversion are sufficient to revoke a registration. *Alan H. Olefsky, M.D.,* 57 FR 928, 929 (DEA 1992). Respondent's lack of credibility during numerous material portions of his testimony weighs heavily against a finding that Respondent has accepted responsibility, let alone demonstrated that he will not engage in future misconduct. *See Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (DEA properly considers physician's candor, forthrightness in assisting investigation, and admitting of fault as important factors in determining whether registration is consistent with public interest).

I find by a preponderance of the evidence that Respondent has not accepted responsibility for his past misconduct, nor has he credibly demonstrated that he has learned from his past mistakes and would properly handle controlled substances in the future. An ''agency rationally may conclude that past performance is the best predictor of future performance.'' *Alra Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995). I find that Factor Five weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest.

VI. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's DEA COR AE5382724, based on Factors Two, Four and Five of 21 U.S.C. 823(f). Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA,* 412 F.3d 165, 174 (DC Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72, 311 (DEA 1980).

The record reveals that Respondent has not sustained his burden in this regard. In fact, as discussed above, Respondent's testimony in numerous instances was not credible and reflected an overall lack of admission of past misconduct. Respondent's testimony was also effectively devoid of any credible demonstration that he has learned from his past mistakes and will not engage in future misconduct. In light of the foregoing, Respondent's evidence as a whole fails to sustain his burden to accept responsibility for his past misconduct and demonstrate that he will not engage in future misconduct.

I recommend revocation of Respondent's DEA COR AE5382724 as a practitioner, and denial of any pending applications for renewal or modification, on the grounds that Respondent's continued registration would be fully inconsistent with the public interest as that term is used in 21 U.S.C.§ 824(a)(4) and 823(f).

Dated: April 5, 2012

s/Timothy D. Wing
Administrative Law Judge

[FR Doc. 2012–18747 Filed 7–31–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–57]

Margy Temponeras, M.D.; Decision and Order

On December 15, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having considered the entire record, I have decided to adopt the ALJ's recommended rulings, factual findings, and his legal conclusions, except as discussed below.[1] I further hold that the record establishes that Respondent engaged in acts which are sufficiently egregious to warrant the revocation of her registration and that she has not rebutted this conclusion.[2]

[1] All citations to the ALJ's recommend decision are to the slip opinion.

[2] In discussing the public interest factors of 21 U.S.C. 823(f), the ALJ ''conclude[d] that the reference in 21 U.S.C. 823(f)(5) to 'other conduct which may threaten public health and safety' would as a matter of statutory interpretation logically encompasses the factors listed in Section 824(a).'' ALJ at 19 n.24 (citing *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993)).

To be sure, the Agency decision in *Chen* stated that ''[t]he administrative law judge has concluded here that the reference in 21 U.S.C. 823(f)(5) to 'other conduct which may threaten the public health and safety' would as a matter of statutory interpretation logically encompass the bases listed in 21 U.S.C. 824(a).'' 58 FR at 65402. However, whether this constitutes a holding or merely dictum, *Chen* is totally devoid of any indication that the traditional tools of statutory construction (*i.e,* text, structure, statutory purpose, and legislative history) were employed in reaching this conclusion. Indeed, while factor five focuses on ''other conduct,'' several of the grounds for revocation are based on a registrant's status and do not require inquiry into the nature of the underlying conduct. *See* 21 U.S.C. 824(a)(3) (authorizing revocation where registrant ''has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized'' to engage in controlled substance activities or such sanction has been recommended by competent state authority); *id.* § 824(a)(5) (authorizing revocation where registrant has been excluded or is subject to exclusion from participating in federal healthcare programs under mandatory exclusion provisions). In addition, construing factor five in this manner renders superfluous factor one, which authorizes the Agency to consider the recommendation of the state licensing board or disciplinary authority, as well as the provision of section 823(f) stating that the ''[t]he Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''

Continued

The ALJ's Footnote 9

Among the allegations raised by the Government were: (1) That Respondent had failed to include required information on various prescriptions (such as a patient's address) in violation of 21 CFR 1306.05(a); (2) that she failed to take initial and biennial inventories of the controlled substances she obtained and dispensed, in violation of 21 CFR 1304.11(b) & (c); and (3) that she failed to properly complete various order forms for schedule II controlled substances (DEA Form 222), in violation of 21 CFR 1305.13(e). ALJ Ex. 1, at 3 (Order to Show Cause). According to the record, the prescriptions were seized pursuant to a search warrant executed at a local pharmacy. Tr. 53–55. As for the inventories and DEA 222s, these were apparently seized during the execution of a search warrant at Respondent's registered location.

At the hearing, Respondent's counsel requested that the Government turn over the prescriptions, *see* Tr. 124–25; some fifty DEA Form 222s, *see id.* at 80–81, 353–54; and the daily inventories done by the employees of Respondent's dispensary. *Id.* at 423. The Government objected to each of these requests on the ground that there is no right to discovery in these proceedings. *See id.* at 80, 128, 423. The ALJ denied each of these requests, explaining in his opinion that the requests were ''untimely and unsupported by applicable legal authority.'' ALJ at 6 n.9 (citing *Roy E. Berkowitz,* 74 FR 36,578, 36,760 (2009) (holding that there is no ''general right to discovery under either the APA or DEA regulations'') (citing *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75,959. 75,961 (2000))).

While I adopt the ALJ's rulings, I do so only because the requests were untimely. In his Supplemental Pre-Hearing Ruling, which was issued on August 5, 2011, the ALJ made clear that ''[a]ny requests for subpoenas by either party are to be filed no later than 4:00 p.m. EDT on August 26, 2011.'' ALJ Ex. 8, at 7. Respondent did not comply with the ALJ's order and instead waited until the hearing to request the documents. Respondent, however, had notice of the Government's intent to litigate these issues from the outset of the proceeding; thus, she cannot claim that she was unaware until the hearing that she would need the various documents to respond to the allegations.[3] Because Respondent failed to timely request the documents, the ALJ properly denied those requests.[4]

The ALJ's Legal Conclusions Regarding Respondent's Operation of a Dispensary

The gravamen of the Government's case was Respondent's operation of a dispensary, which in the Government's view was illegal because Respondent dispensed thousands of controlled substance prescriptions which were issued by her father, who was not registered at the location of Respondent's practice, and Respondent does not hold a pharmacy registration under the Controlled Substances Act. *See* ALJ Ex. 1, at 1. The evidence showed that beginning in either November or December 2008, Respondent began dispensing controlled substances at her practice location and that during the period in which it operated, the dispensary filled 3,397 prescriptions for controlled substances issued by her father, most of which were for oxycodone, a schedule II narcotic, and Xanax, a schedule IV benzodiazepine. Tr. 210–11. In addition, the evidence showed that the prescriptions were filled and delivered to the patients by employees who were not licensed as pharmacists.

The ALJ concluded that Respondent violated Ohio law because she was not licensed as a Terminal Distributor of Dangerous Drugs and did not fall within the exemption provided under state law for ''a business practice with a sole shareholder who is a licensed health professional.'' *See* ALJ at 21 (citing Ohio Rev. Code Ann. § 4729.51(B)(1)(j)).[5] The ALJ based his reasoning in part on the evidence showing ''that Respondent established, solely owned, and operated two limited liability companies, Unique Pain Management ([her] medical practice) and Unique Relief ([her] dispensary), both of which are located at 418 Center Street, Wheelersburg, Ohio,'' and that the two entities were ''physically separate'' from each other, although Respondent could observe the dispensary through a system of security cameras and a monitor she maintained in her office. *Id.* The ALJ also noted that the dispensary also filled ''a significant

Finally, it should be noted that since shortly after the CSA's enactment and years before section 823(f) was amended to include the public interest factors, DEA ''has consistently held that where a registration can be revoked under section 824, it can, a fortiori, be denied under section 823 since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next.'' *Serling Drug Co.* v. *Detroit Prescription Wholesaler, Inc.,* 40 FR 11918, 11919 (1975). *See also John R. Amato,* 40 FR 22852 (1975) (Denying application where practitioner's state license had been revoked, holding that section 823(f) ''must logically give the Administrator the authority to deny a registration if the practitioner is not authorized by the State to dispense controlled substances. * * * To hold otherwise would mean that all applications would have to be granted only to be revoked the next day under 21 U.S.C. 824(a)(3). This [A]gency has consistently held that where a registration can be revoked under section 824, it can, a fortiori, be denied under section 823.'').

Indeed, no court has ever questioned the Agency's longstanding and consistent interpretation that it has authority to deny an application on any of the grounds set forth in section 824(a). *Cf. National Muffler Dealers Assn., Inc.,* v. *United States,* 440 U.S. 472,477 (2011) (''A regulation may have particular force if it is a substantially contemporaneous construction of the statute by those presumed to have been aware of congressional intent.''); *EEOC v. Associated Dry Goods Corp.,* 449 U.S. 590, 600 n.17 (1981) (''a contemporaneous construction deserves special deference when it has remained consistent over a long period of time'').

[3] Moreover, having reviewed the record, it contains substantial evidence (as the ALJ found) to support each of these allegations.

[4] That there is no general right to discovery in these proceedings would not have barred a timely request for these documents. Respondent did not seek broad-based discovery of whatever the Government had obtained in the course of its investigation, but rather, specific documents which were clearly relevant and material to these three allegations because they are the very basis for the three allegations. Thus, if the requests had been timely, this case would have been governed by the principle that ''[d]iscovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny him due process.'' *McClellan* v. *Andrus,* 606 F.2d 1278, 1286 (DC Cir. 1979) (noting that report was subject to discovery in administrative proceeding because it was potentially ''uniquely relevant to appellant's case'' and ordering agency to turn over report to administrative tribunal for *in camera* review to determine relevancy and to allow Government to assert any claim of privilege). *See also Echostar Communications Corp.* v. *FCC,* 292 F.3d 749, 756 (DC Cir. 2002) (noting that ''McClelland was seeking a specific document 'uniquely relevant to [his] case' ''). *See also* 5 U.S.C. 555(d) (''Agency subpoenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought.''). *See also* 21 U.S.C. 875 & 876.

As the Agency has previous noted, under *Goldberg* v. *Kelly,* 397 U.S. 254, 270 (1970), '' 'where governmental action seriously injures an individual, and the reasonableness of the action depend on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue.' '' *Beau Boshers, M.D.,* 76 FR 19401, 19403 (2011) (quoting 397 U.S. at 270). Moreover, the Supreme Court has further explained that '' 'the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation.' '' *Id.* (quoting *Bowman Transp., Inc.,* v. *Arkansas-Best Freight System, Inc.,* 419 U.S. 281, 288 n.4 (1974)). Where the Government alleges that one has failed to properly maintain or complete required records, it cannot seize those records and then refuse to turn them over in response to a timely request for them.

[5] The ALJ also noted that an Ohio Board of Pharmacy guidance document, which interprets this provision, states that ''if the business practice has a single prescriber * * * who is the sole shareholder, member, or owner of the practice, then this business practice is not required to be licensed as a Terminal Distributor of Dangerous Drugs with the Ohio Board of Pharmacy. Previously, this exemption was only for a prescriber who practices as a Sole Proprietor.'' ALJ at 21 (quoting Ohio State Board of Pharmacy, *Licensing Issues For Prescribers—Updated* (July 2008)).

portion'' of the prescriptions issued by Respondent's father. *Id.* at 22.

Continuing, the ALJ reasoned that:

> [t]o the extent Ohio law permits a sole practitioner to dispense or personally furnish controlled substances directly to a patient without a Terminal Distributor license, Respondent's dispensing practices were well outside of those parameters. Respondent established a distinctly separate legal entity to fill prescriptions that was physically separate from Respondent's medical office. Furthermore, Respondent's dispensary was not limited to filling prescriptions issued only by Respondent, but also routinely filled prescriptions issued by Respondent's father, notwithstanding the fact that Respondent did not have a Terminal Distributor license as required by state law.

Id. (citing Ohio Rev. Code Ann. §§ 4729.51(B)(1)(j) & 4729.551).

However, I need not decide whether under Ohio law, Respondent's creation of ''a distinctly separately legal entity to fill prescriptions,'' *id.,* required her to hold a Terminal Distributor license, because the Government did not raise this issue in either the Order to Show Cause or its pre-hearing statements. Nor are the few fragments of testimony regarding this license (which primarily involved the Board of Pharmacy Compliance Agent's statements regarding the reason for his February 2011 visit to the dispensary) sufficient to conclude that the parties litigated the issue by implied consent. Indeed, any such conclusion is belied by the fact that when Respondent's counsel attempted to question the Board's Compliance Agent about whether a Board employee had told Respondent's staff that she did not need to have a Terminal Distributor's License, the Government objected that the questions were outside the scope of direct examination as well as irrelevant and the ALJ sustained the objections.[6] Tr. 345–47.

Under these circumstances, it is clear that the issue was not ''fairly and fully litigated at [the] hearing'' and therefore cannot be the basis for a sanction. *Yellow Freight System, Inc.,* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992). As the Sixth Circuit further explained:

> [A]n agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.

Id. (citing *MBI Motor Co., Inc.* v. *Lotus/East, Inc.,* 506 F.2d 709, 711 (6th Cir. 1974)).

Moreover, ''where the Government's case 'focus[es] on another issue and [the] evidence of [an] uncharged violation [is] ''at most incidental,' '' the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as a basis for imposing a sanction.'' *CBS Wholesale Distributors,* 74 FR 36746, 36750 (2009) (quoting *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 136 (2d Cir.1990) (quoting *NLRB* v. *Majestic Weaving Co.,* 355 F.2d 854, 861–62 (2d Cir. 1966))). Thus, because the issue was not properly raised and the evidence was at most incidental, I reject the ALJ's legal conclusion (and his discussion of Ohio law) that Respondent violated Ohio law because she failed to obtain an Ohio Terminal Distributor's license.

However, the ALJ also concluded that Respondent violated federal law because she ''dispensed or directed and authorized the dispensing of controlled substances from an unregistered location on numerous occasions between November 2008 and May 2011.'' ALJ at 24 (citing 21 U.S.C. 822(a)(2) & (e); *id.* § 841; 21 CFR 1306.06). The ALJ offered no further explanation for this conclusion. While I hold that the ALJ erred in concluding that she violated section 822(e), which requires ''[a] separate registration * * * at each principal place of business or professional practice where the applicant * * * dispenses controlled substances,'' 21 U.S.C. 822(e), the record clearly supports a finding that Respondent's dispensing activities violated the CSA.

The evidence of record shows that Respondent's dispensary was located at the same address as her medical practice. This was also the address at which Respondent was registered with the Agency.[7] *See* GX 1. Thus, Respondent did not violate the requirement that she obtain a separate registration for each principal place of professional practice where she dispensed controlled substances.

Rather, Respondent violated the CSA because she exceeded the authority granted by her registration when she dispensed controlled substance prescriptions issued by her father without holding a pharmacy registration. Under 21 U.S.C. 822(b), ''[p]ersons registered by the [Agency] under this subchapter to * * * dispense controlled substances * * * are authorized to possess * * * or dispense such substances * * * *to the extent authorized by their registration and in conformity with the other provisions of this subchapter.''* (emphasis added).

Under Federal law and DEA regulations, a registered physician is authorized to prescribe, administer or ''dispense directly'' to her patients in the course of professional practice. *See* 21 CFR 1306.11(b) (''An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription. * * *''); *id.* § 1306.21(b) (''An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription * * *.''). *See also* 21 U.S.C. 829 (''Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug under the Federal Food, Drug, and Cosmetic Act * * * may be dispensed without'' a prescription); *id.* § 829(b) (schedule III & IV).

In addition, DEA regulations provide that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, or registered institutional practitioner.'' 21 CFR 1306.06. Accordingly, Respondent, who did not hold a pharmacy registration, exceeded the authority of her registration because she authorized her employees to fill prescriptions issued by her father.[8] *See* 21 U.S.C. 822(b); *id.* § 841(a) (rendering unlawful the knowing or intentional dispensing of a controlled substance ''[e]xcept as authorized by this subchapter''). And in filling her father's prescriptions, she also violated 21 CFR 1306.06.

So too, Respondent violated Ohio law because she allowed unlicensed

[6] Subsequently, Respondent succeeded in eliciting testimony from one of her employees regarding a phone conversation he had with an employee of the pharmacy board regarding whether she was required to have a Terminal Distributor's license. Tr. 567. However, given that the Government had already argued that this line of questioning was irrelevant, which it was in light of the Government's failure to disclose its intent to litigate the issue in either the Show Cause Order or its pre-hearing statement, I conclude that this testimony is not enough to establish implied consent and that the issue is not properly before the Agency.

[7] There is no evidence that the dispensary had a separate suite number as might be the case in a large medical office building.

[8] The evidence also showed that Respondent's father did not hold a registration at the address of Respondent's dispensary.

personnel to fill the prescriptions and failed to personally furnish the controlled substances to her patients.[9] *See* ALJ at 23–24. As the ALJ found, Respondent used unlicensed personnel to fill the prescriptions which her dispensary delivered to her patients. While Ohio law exempts ''a prescriber,'' which includes a physician who is authorized to practice medicine and prescribe drugs, *see* Ohio Rev. Code Ann. § 4729.01(I), from the prohibition against the unauthorized practice of pharmacy under Ohio Rev. Code Ann. § 4729.28, the exemption requires that the physician ''personally furnish [ ] the [prescriber's] patients with drugs, within the prescriber's scope of professional practice.'' *Id.* § 4729.29(A)(1).[10] Moreover, ''[w]hen a prescriber personally furnishes drugs to a patient pursuant to [the exemption], the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws.'' *Id.* § 4729.29(B).

Respondent did present evidence that she had a security camera system and monitor in her office which allowed her to observe the operation of her dispensary. *See* Resp. Br. 3 (citing Tr. 400). However, given that she was actively seeing patients, her counsel's suggestion that she observed the actually delivery of the drugs to the patients, and thus was in compliance with Ohio's requirement that she ''personally furnish'' the drugs, is, as a factual matter, ludicrous. I thus hold that she violated Ohio law because she did not personally furnish the controlled substances to her patients.[11]

In her brief, Respondent further claims that she ''was ill-advised by counsel'' as to whether she needed a pharmacy registration ''and was specifically told she was doing everything correctly with respect to operating the dispensary.'' Resp. Br. 7. Respondent then maintains that ''[i]f a mistake was made it was not the Respondent's.'' *Id.* While the ALJ recounted the testimony of one Respondent's employees regarding the purported legal advice she received, *see* ALJ at 17 (citing Tr. 545, 559–60), he did not address Respondent's contention.

I do and I reject the contention. Even crediting the testimony of Respondent's employee that he had a discussion with an attorney regarding the dispensary's compliance with DEA regulations and was told that ''we were doing it perfectly,'' Tr. 545, the employee's testimony was exceedingly vague as to what issues were discussed and does not establish that Respondent discussed whether she needed to obtain a DEA pharmacy registration because she was filling the prescriptions issued by her father. Thus, even were the Agency to recognize a defense of good faith reliance on legal advice, the defense fails here because Respondent has not established that there was a ''full disclosure of all pertinent facts'' to the attorney and that her reliance was ''in good faith.'' *United States* v. *Lindo,* 18 F.3d 353, 356 (6th Cir.1994); *see also United States* v. *Painter,* 314 F.2d 939, 943 (4th Cir. 1963). Indeed, the contention is belied by the employee's testimony that he really ''didn't trust some of the opinions [he] was getting from'' the attorney and that upon looking at the DEA rules, he determined that Respondent's father had to be registered at her clinic if narcotics were stored there.[12] Tr. 559–60. Moreover, because Respondent invoked her Fifth Amendment privilege and declined to answer any questions (other than to state her name and that she had a registration as an individual practitioner), she cannot establish that she relied in good faith on the attorney's advice.

The Inventory Violations

The ALJ found that Respondent violated DEA regulations requiring that she take initial and biennial inventories. ALJ at 27–29. While I agree that the evidence establishes various violations, I find much of the ALJ's discussion of the evidence and his reasoning confusing.

The ALJ found that Respondent did not have an initial inventory as required by DEA regulations. *See* ALJ at 27 (citing 21 CFR 1304.11(b) & (c)). While I adopt this finding, I do so based solely on the evidence that when the Board of Pharmacy Compliance Agent conducted his February 9, 2011 inspection, Respondent's dispensary manager stated that ''one had not been done.'' Tr. 314. Under Federal law, ''every registrant * * * shall * * * as soon * * * as such registrant first engages in the * * * dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand.'' 21 U.S.C. 827(a). Moreover, under DEA regulations, ''[i]n the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.'' 21 CFR 1304.11(b). While under DEA regulations, a registrant is required to keep, and make available for inspection, an inventory for only two years, *see* 21 U.S.C. 827(b), a period which, given the evidence that Respondent opened the dispensary in November or December 2008, would have lapsed at the time of the February 2011 inspection, the statement of the dispensary manager is sufficient to find that this violation occurred.

Moreover, by the date of the February 2011 Pharmacy Board inspection, Respondent was required to have performed a biennial inventory. *See id.* § 827(a); 21 CFR 1304.11(c). However, while Respondent had an ''on-hand inventory'' that ''was within the computer itself,'' Tr. 314, this did not comply with DEA regulations which require that an inventory ''be maintained in written, typewritten, or printed form.'' 21 CFR 1304.11(a). And while there is evidence showing that during the May 2011 search, documents that were labeled as ''biannual inventories'' were seized, the fact remains that Respondent was required to have on hand a proper biennial inventory at the time of the February 2011 inspection.[13]

[9] In contrast to the issue of whether Respondent was required to hold an Ohio Terminal Distributor's license, the Government provided notice of its intent to litigate the issue of Respondent's use of unlicensed individuals to fill controlled substance prescriptions. ALJ Ex. 5, at 5.

[10] This citation, as well as the citation to section 4729.29(B), are to the provisions which were in effect during the period at issue here.

[11] As for the other violations, I agree with the ALJ's conclusions that Respondent failed to properly complete DEA Form 222s for the schedule II controlled substances she purchased, and that the records were not kept separate from other records as required by DEA regulations. *See* ALJ at 25–26 (citations omitted). I also agree with the ALJ's conclusion that Respondent failed to include required information on some prescriptions. *See* ALJ at 30 (citing GX 7).

[12] Having concluded that the Government did not provide adequate notice of its intent to litigate the issue of whether Respondent was required to hold a Terminal Distributor's license, it is unnecessary to decide the issue of whether Respondent properly relied on the statement of an Ohio Pharmacy Board employee that Respondent did not need to hold this license. Tr. 548.

[13] Had Respondent produced at the February 2011 inspection an inventory which complied with 21 CFR 1304.11(a) & (c), I would not place any weight on the fact that the inventory was labeled as a ''biannual'' rather than ''biennial.''

The ALJ further noted that it was ''[o]f significance, [that] no invoices, DEA Form 222s, or dispensing logs were used to conduct the biennial inventory.'' ALJ at 28 (citing Tr. 480–82). However, while the CSA requires that a registrant retain its invoices, form 222s, as well as a dispensing log, for at least two years, *see* 21 U.S.C. 827(b), taking an inventory does not require doing anything more than counting the drugs on hand and making a record which includes the information required under 21 CFR 1304.11(e).

The ALJ further concluded that ''no compliant * * *tory was * * *the May 17, 2011 search.'' ALJ at 28. However, the DI who seized the inventories during the May 17, 2011 search did not offer any

Conclusion

Having adopted the ALJ's conclusion (as modified herein) that Respondent violated the CSA by dispensing thousands of controlled substance prescriptions issued by her father and thus acted outside of the authority granted by her registration, I conclude that this conduct is egregious and warrants the conclusion that she has committed acts which render her continued registration inconsistent with the public interest and is sufficient by itself to support the revocation of her registration. *See* 21 U.S.C. 824(a)(4). The additional violations established on this record—her failure to have inventories, failure to complete form 222s, failure to include required information on prescriptions, her commingling of schedule II records with other records, as well as her state law violations of failing to personally furnish the drugs to her patients—buttress this conclusion. Because I further adopt the ALJ's findings that Respondent has presented no evidence that she accepts responsibility for her misconduct, I will order that her registration be revoked and that any pending application be denied.[14]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4) and 28 CFR 0.100(b), I order that DEA Certificate of Registration BT5598214, issued to Margy Temponeras, M.D., be, and it hereby is, revoked. I further order that any pending application of Margy Temponeras, M.D., to renew or modify her registration, be, and it hereby is, denied. This Order is effective August 31, 2012.

Dated: July 24, 2012.

Michele M. Leonhart,

Administrator.

D. Linden Barber, Esq. & Frank Mann, Esq., for the Government.

Bradley Davis Barbin, Esq., for the Respondent.

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

I. Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., to determine whether the Drug Enforcement Administration (DEA, Agency or Government) should revoke a physician's DEA Certificate of Registration (COR) as a practitioner pursuant to 21 U.S.C. 824(a)(4) and deny, pursuant to 21 U.S.C. 823(f), any pending applications for renewal or modification thereof and any application for a new COR. Without this registration, Margy Temponeras, M.D. (Respondent), of Wheelersburg, Ohio, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of her practice.

On May 16, 2011, the Administrator, DEA, issued an Order to Show Cause and Immediate Suspension of Registration (OSC/IS), which was personally served upon Respondent on May 17, 2011.[1] The OSC/IS immediately suspended Respondent's DEA COR as a practitioner, and also provided notice to Respondent of an opportunity to show cause as to why the DEA should not revoke Respondent's COR, pursuant to 21 U.S.C. 824(a)(4), and deny, pursuant to 21 U.S.C. 823(f), any pending applications for renewal or modification thereof and any applications for a new COR, alleging that Respondent's continued registration is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f).

The OSC/IS alleged that Respondent is registered as a practitioner authorized to handle controlled substances in Schedules II through V under DEA COR BT5598214.

The OSC/IS further alleged in relevant part:[2]

That between approximately January 1, 2007 and November 3, 2009, Respondent made approximately 3,397 unauthorized distributions of controlled substances. These distributions from Respondent's registered location were purportedly based on prescriptions issued by Dr. John Temponeras, who is registered with DEA as a practitioner in Portsmouth, Ohio. Respondent is not registered with DEA as a pharmacy. All in violation of 21 U.S.C. 841 and 21 CFR 1306.06;

That Respondent failed to take an initial inventory and biennial inventories of the controlled substances in the dispensary that Respondent operated in violation of 21 CFR 1304.11(b) and (c);

That Respondent failed to make and keep complete and accurate records of the receipt of controlled substances by, among other things, failing to complete DEA Form 222 with the amount and date received of controlled substances in violation of 21 CFR 1305.13(e); and

That Respondent frequently issued prescriptions for controlled substances that did not contain all of the information required by 21 CFR 1306.05(a).[3]

Following prehearing procedures, a hearing was held in Cincinnati, Ohio between September 13, 2011, and September 14, 2011, with the Government and Respondent each represented by counsel. Both parties called witnesses to testify and both introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

II. Issue

Whether the record establishes that Respondent's DEA COR BT5598214 as a practitioner should be revoked and any pending applications for renewal or modification of that registration should be denied on the grounds that Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

III. Evidence and Incorporated Findings of Fact[4]

I find, by a preponderance of the evidence, the following facts:

---

testimony that the inventories were not compliant other than because they were not done within two years of the opening of the dispensary. Tr. 84. The ALJ further noted the testimony of one of Respondent's employees ''that the process to conduct a biennial inventory consisted of [her] husband using a computer printout while she physically counted the controlled substances, adding that she did not 'document anything' from the inventory.'' ALJ at 28 (quoting 481–82).

It should be noted that even if the counts matched the printout, at a minimum, the inventories would have been required to document whether they were done on the opening of business or on the closing of business. *See* 21 CFR 1304.11(a). However, because the inventories were not submitted into evidence, there is no basis for concluding that they did not contain the required information.

[14] The ALJ noted that Respondent did not present ''any evidence demonstrating that she will not engage in future misconduct.'' ALJ at 31. This is not entirely accurate as the record suggests that following the February 2011 visit of the Pharmacy Board's Compliance Agent, her employees did take inventories. However, Respondent did not put on any other evidence as to remedial measures and her failure to testify warrants, as the ALJ held, the adverse inference that she does not accept responsibility for her misconduct. *See id.* (citing cases).

[1] ALJ Exs. 1, 3.

[2] The Government represented prior to hearing that it intended to proceed against Respondent only with regard to allegations contained in numbered paragraphs two, eight, nine, and ten of the OSC/IS.

[3] The section requires in relevant part that ''[a]ll prescriptions for controlled substances shall * * * bear the full name and address of the patient * * * [and] directions for use * * *.''

[4] In addition to the evidence discussed in this Section, additional evidence and findings of fact are discussed in later Sections of this Recommended Decision.

A. The Government's Evidence

The Government's evidence included testimony from five witnesses: Respondent; DEA Diversion Investigator (DI) Christopher Kresnak (DI Kresnak); DI Paula Albert (DI Albert); Ohio State Board of Pharmacy Compliance Agent Joseph Kinneer (Agent Kinneer); and DI Stephanie Burkhart (DI Burkhart). In addition to testimonial evidence, the Government also introduced various documentary exhibits, to include: Respondent's COR record; [5] three DEA Form 222 purchaser records;[6] copies of prescriptions issued by Respondent between August and November 2006; [7] and a document reflecting standard procedures for Unique Pain Management.[8]

Respondent was called to testify but refused to answer any questions related to the relevant allegations in the OSC/IS by asserting her Fifth Amendment privilege. (Tr. 35–36; 41–42.)

DI Kresnak testified in substance that he has approximately eight years of experience with DEA as a DI. (Tr.45.) DI Kresnak testified that Respondent is registered with DEA as a practitioner under DEA COR BT5598214 with an expiration date of November 30, 2012, and a current status listed as ''under suspension.'' (Tr. 47; Gov't Ex. 1.) DI Kresnak further testified that Respondent has never held any other type of DEA registration, including a pharmacy registration. (Tr. 48.) Respondent has never been registered with the State of Ohio as a pharmacist and has never held a pharmacy license in Ohio. (*Id.*)

DI Kresnak next testified that Respondent owns and operates two limited liability companies–her medical practice, Unique Pain Management, and her dispensary, Unique Relief. (Tr. 48–49.) Both of Respondent's businesses are located in the same building at 418 Center Street, Wheelersburg, Ohio. (Tr. 49.) DI Kresnak testified that he was present inside both businesses on May 17, 2011, and he described the physical layout of the location to include Respondent's office on the far left hand corner from the entrance, with the ''dispensary* * * on the right-hand side of the building, * * *.'' (Tr. 50–51.) DI Kresnak testified that he interviewed Respondent on that same day, and in response to a question about why the dispensary was operating, Respondent ''said words to the effect that many of the local pharmacies stopped filling for her prescriptions and that she wanted to provide a low-cost convenience for her patients.'' (Tr. 52.)

DI Kresnak also testified that pursuant to a search warrant at Prime Pharmacy Group d/b/a Medi-Mart Pharmacy, in Portsmouth, Ohio, he obtained prescriptions covering the time period 2005 to 2006 for Schedule III through V controlled substances, and identified twelve controlled substance prescriptions issued by Respondent. (Tr. 53, 54–55.) The twelve prescriptions related to more than one patient, but DI Kresnak did not know how many patients exactly, nor could he recall any of the patients' names.[9] (Tr. 118, 188.) DI Kresnak testified that of the twelve prescriptions, only one was compliant with DEA regulations. Eleven were noncompliant because they lacked a patient address. (Tr. 54; 123–24.)

DI Kresnak next explained that DEA Form 222s are used by industry to order Schedule II controlled substances, and are issued to registrants by DEA. (Tr. 55.) DI Kresnak testified that a DEA Form 222 contains, among other information, the name and address of a registrant, ''what the registrant is authorized to order,'' and a serial number. (Tr. 56.) A DEA Form 222 consists of three copies: the ''brown sheet,'' which goes to the distributor; a carbonated second ''green'' copy, which also goes to the distributor; and a ''blue'' copy, which is maintained at the registrant or practitioner's registered address when the registrant or practitioner orders Schedule II controlled substances. (Tr. 56–57.) DI Kresnak further explained that the distributor completes relevant information on the Form 222 at time of shipping, to include the National Drug Code (NDC) and number of controlled substances shipped. (Tr. 58.) The distributor then sends the green carbonated copy to the DEA office where the distributor is located. (Tr. 58.)

DI Kresnak testified that he reviewed approximately fifty DEA Form 222s seized from Respondent's dispensary, and on approximately six to ten forms he observed various discrepancies:

> Many of them weren't filled out properly, missing information. Several of them didn't even indicate whether a shipment had been received. One * * * just doesn't reflect anything. There were several, maybe seven lines filled out on it and there's nothing indicating any product was received.

(Tr. 60.) DI Kresnak compared the green copies of DEA Form 222s sent to DEA by the distributor with those seized from Respondent's dispensary, and testified that he recalled a specific discrepancy:

> I observed one particular 222 * * * where the distributor indicated that they [sic] did not fill the order. The blue copy of the 222, which is found in the dispensary, which is required by the Code to fill out how many is [sic] received, indicated that there were 60 received. There were 60 ordered. The blue copy was indicating 60 received, but the distributor's copy to DEA indicate[d] they did not fill that order.

(Tr. 63.) DI Kresnak further testified that he reviewed data from DEA's Automated Reports and Consolidated Order System (ARCOS),[10] which confirmed that the information reflected on the distributor's DEA Form 222 was accurate. (Tr. 63–64.)

DI Kresnak also testified about three specific DEA Form 222s seized from Respondent's dispensary on May 17, 2011, which he found to be deficient. (Tr. 64–65; Gov't Ex. 6.) DI Kresnak testified that one was deficient ''[i]f these drugs were received * * * [because] a date received is omitted.'' (Tr. 65; Gov't Ex. 6, at 1.) A second form is deficient because the ''number of packages received is omitted and the date received is omitted.'' (Tr. 66; Gov't Ex. 6, at 2.) A third form is deficient because the ''number of packages is omitted on both items and the date received.'' (Tr. 66; Gov't Ex. 3, at 3.) DI Kresnak further testified somewhat tepidly with regard to whether the controlled substances were actually shipped to Respondent, that he ''believed they were'' further explaining that he believed ''we found

[5] Gov't Ex. 1.

[6] Gov't Ex. 6.

[7] Gov't Ex. 7.

[8] Gov't Ex. 8.

[9] None of the twelve prescriptions were produced by the Government at hearing, and DI Kresnak was uncertain if any of the twelve were the same as those contained in Government Exhibit 7. (Tr. 118–20.) Respondent requested production of the records at hearing and the Government objected, arguing in substance the lack of legal authority for such a discovery request. I denied Respondent's discovery request since it was untimely and unsupported by applicable legal authority. There is no ''general right to discovery under either the APA or DEA regulations, but rather only a limited right to receive in advance of hearing the documentary evidence and summaries of the testimony which the Government intends to rely upon.'' *Roy E. Berkowitz, M.D.,* 74 FR 36,758, 36,760 (DEA 2009) (citing *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75,959, 75,961 (DEA 2000). Respondent made various untimely requests for discovery throughout hearing with regard to other documents, such as original Form 222s, which were denied for similar reasons.

[10] ''Registrants are also required to report records of sales or acquisitions of controlled substances in Schedules I and II, of narcotic controlled substances listed in Schedules III, IV and V, and of psychotropic controlled substances listed in Schedules III and IV with the DEA's Automation of Reports and Consolidated Orders System (ARCOS). 21 CFR 1304.33(c); 21 U.S.C. [§] 827(d). These reports must be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted. 21 CFR 1304.33(b).'' *Easy Returns Worldwide, Inc.* v. *United States,* 266 F. Supp. 2d 1014, 1016 (E.D. Mo. 2003).

documentation that these were shipped, yes.'' [11] (Tr. 82.)

DI Kresnak testified that during the first two years that Respondent operated her dispensary, the majority of Respondent's ordering was completed through an electronic DEA controlled substance ordering system (CSOS), rather than using paper Form 222s. (Tr. 195–96.)[12]

DI Kresnak next testified that during the search of Respondent's dispensary, documents related to inventories were found, to include one marked opening inventory, which ''indicated that the date that they opened the dispensary there was a zero inventory.'' (Tr. 83.) ''No biennial inventory was ever found.'' (Tr. 84.) Rather, several documents entitled ''Biannual Inventories'' were found in a folder marked ''DEA inventories.'' (Tr. 144.) DI Kresnak testified that Respondent's dispensary opened ''sometime in November 2008, maybe December 2008.'' (Tr. 99.) Although DI Kresnak could not recall all of the details, he testified that the inventories appeared to be computer generated, listing the drugs on the far left and dollar values in another column. DI Kresnak did not know what the dollar values represented. He also testified that each inventory was marked ''biannual,'' contained a date, and appeared to be signed by Respondent. (Tr. 136–137.) DI Kresnak testified that as a result of his investigation he determined that ''there was one particular oxycodone product that 100% was missing for the month of April, 2011.'' (Tr. 150.) DI Kresnak further explained that he does not ''recall the number of dosages * * * missing * * * without referring to the audit.'' [13] (Tr. 153.) DI Kresnak testified that he has not seen any inventories in electronic format seized from Respondent, but noted that he has not as yet looked for any. (Tr. 173.)

DI Kresnak next testified that Respondent and Respondent's father, Dr. John Temponeras, were the only practitioners who issued prescriptions for controlled substances in Schedules II through V that were filled at Respondent's dispensary. (Tr. 101.) DI Kresnak further testified that Dr. John Temponeras had previously been a DEA registrant with a registered location in Portsmouth, Ohio. DI Kresnak interviewed Dr. John Temponeras regarding his application for a DEA registration at Respondent's Center Street location in Wheelersburg, Ohio, and learned ''he had written prescriptions [for controlled substances] that were filled at the dispensary, and he basically said he was needing a DEA registration at that location because his daughter said he needed one there.'' (Tr. 102.)

DI Albert testified in substance that she has eleven years of experience with DEA as a diversion investigator. DI Albert testified that she was present at Respondent's business location in Wheelersburg, Ohio, on May 17, 2011, assisting in the execution of a federal search warrant and service of the OSC/IS. (Tr. 202.) DI Albert described the location as ''a medical clinic and a—I guess, a dispensary.'' (Tr. 202.) By dispensary, DI Albert testified that she meant ''[t]hey filled prescriptions and dispense[d] medication to patients.'' (*Id.*) The location was described as having the doctor's office on the left of the building, and on the right after passing through a door there was another lobby and ''[i]nside that lobby there was a set of windows with thick glass, and behind those windows were [sic] the dispensary.'' (Tr. 203.)

DI Albert further testified that Darryl Leadingham (Mr. Leadingham) and Sue Leadingham (Mrs. Leadingham) were working in the dispensary on May 17, 2011. DI Albert interviewed Mr. Leadingham regarding his responsibilities in the pharmacy, and learned that ''he was responsible for the computer system, the security system in the whole building, the cameras. * * * [H]e ordered the controlled substances that were dispensed out of the dispensary, and he also worked as far as entering patient information into the computer system, printing labels, dispensing the controlled substances, billing patients' insurance, * * *.'' (Tr. 203–04.) In terms of dispensing, Mr. Leadingham indicated that patients would bring a physical hard copy prescription that either Respondent or Respondent's father had issued with an original signature. The information was entered in the computer system which would generate three labels, the first for the prescription bottle, second for the original hard copy prescriptions, and third on the outside bag containing all of the bottles of medicine distributed. (Tr. 208.)

DI Albert testified that Mrs. Leadingham similarly stated that ''she was there to dispense the medication and put the information, print the labels and bill the insurance or accept cash.'' (Tr. 209.) DI Albert further testified that both Mr. Leadingham and Mrs. Leadingham stated during the May 17, 2011 interview:

> Dr. John Temponeras had filled in and had seen [Respondent's] patients and that there were prescriptions that patients brought to the dispensary with [Dr. John Temponeras'] name on them. And Darryl Leadingham told me that at some point he figured out that it was no longer—or that they shouldn't be doing that and that he had told [Respondent] that her father needed to get his own DEA registration for that location.

(Tr. 213.)

DI Albert testified that based on information contained within the Ohio Automated Rx Reporting System (OARRS),[14] the only prescriptions filled at the dispensary were issued by Respondent or Respondent's father. (Tr. 209.) DI Albert testified that OARRS data reflected that from November or December 2008 until 2011, Respondent's dispensary filled approximately 3,397 prescriptions issued by Respondent's father for controlled substances, ''mostly oxycodone products and Xanax or the Schedule IV.'' (Tr. 210–11.) Regarding prescriptions issued by Respondent, DI Albert testified in April 2010 alone, Respondent ''filled 500 prescriptions at her dispensary, which came out to—after I compared that to other pharmacies, it was over eighty-three percent of her prescriptions were filled by herself.'' (Tr. 211.) DI Albert did not know why eighty-three percent of the patients chose to go to Respondent's dispensary and no cost analysis of pharmacies in the region was conducted by DI Albert. (Tr. 231.)

DI Albert next testified that as part of her investigation of Respondent, she reviewed ARCOS system data pertaining to ''all the oxycodone products [Respondent] ordered'' from the opening of the dispensary in 2008 until her last order in May 2011, finding a total of ''approximately 1.6 million dosage units'' of oxycodone, a Schedule II controlled substance. (Tr. 206–07.) DI Albert testified that she recalled the presence of various drugs at the dispensary on May 17, 2011, described as ''mostly controlled substances, oxycodone, OxyContin, benzos,[15] Xanax, Valium.'' (Tr. 204.) DI Albert believed there may have been a small quantity of hydrocodone and ''a couple

[11] DI Kresnak's testimony was further qualified by his statement that ''[w]e found invoices that reflect some of these.'' (Tr. 83.) Additionally, DI Kresnak explained that ARCOS reports indicated shipments of the relevant controlled substances to Respondent. (Tr. 134–36.)

[12] 21 CFR1300.03. DI Kresnak explained that CSOS is only for Schedule II controlled substances and is ''used to eliminate paper flow.'' (Tr. 194.)

[13] No audit was produced at hearing.

[14] DI Albert testified that OARRS is a prescription monitoring system run by the Ohio Board of Pharmacy based on information submitted by pharmacies. (Tr. 209–10.) *See also* Ohio Admin. Code R. 4729–37–03 (2011).

[15] DI Albert explained her use of the term ''benzos'' was short-hand for benzodiazepines, a Schedule IV controlled substance. (Tr. 205.)

of other Schedule II substances, such as morphine.'' (Tr. 204–05.)

DI Albert further testified that she has reviewed the originals of the DEA Form 222s reflected in Government Exhibit 6, which were seized from Respondent's dispensary on May 17, 2011, and did not remove any attachments from the originals nor was she aware of any other DEA personnel removing attachments. (Tr. 215.) DI Albert testified that she reviewed and compared distributor copies of the Form 222s with copies retained by Respondent, and found discrepancies between what the distributors indicated they shipped and what Respondent reported receiving. (Tr. 216–17.) DI Albert elaborated:

> I believe there were times where … on the distributor's copy, or the one that [the distributor] provide[d] to DEA, it indicates that they actually shipped a different quantity or they voided out the line, where, in fact, the copy that we found in the dispensary will show that they received a quantity and the distributor says that [the distributor] voided it.

(Tr. 218; Gov't Ex. 6.)

Finally, DI Albert testified that she reviewed various prescriptions for controlled substances issued to Patient [IM] by Respondent, dated between August and November 2006, and determined that the prescriptions were missing the address of the patient, as required by regulation. (Tr. 220–21, 249–50; Gov't Ex. 7.)

Agent Kinneer testified that he has been employed with the Ohio Board of Pharmacy as a Compliance Agent for approximately seventeen years.[16] Agent Kinneer further testified that he was familiar with Respondent's professional practice, explaining that in December 2010, Respondent applied for a Terminal Distributor license,[17] which would allow for the purchase of prescription drugs and controlled substances. (Tr. 301–02.)

Agent Kinneer next testified that based on Respondent's application for a Terminal Distributor license, he conducted an inspection of Respondent's location on February 9, 2011. (Tr. 303.) As a result of the inspection, Agent Kinneer determined that the dispensary was operated by Mr. Leadingham, who had been introduced as the dispensary manager. (Tr. 307.) Agent Kinneer further determined that for the past two years, Respondent had no role in the physical delivery of controlled substances to her patients. (Tr. 307, 334.)

Agent Kinneer explained that during his inspection, he observed a dispensing practice that failed to properly document the filling of prescriptions. ''What would happen is, you had one prescription that had all three labels on it * * * [a]nd then the other two had no labels at all. So there was no way to document that those prescriptions had actually been filled.'' (Tr. 313.)

Agent Kinneer testified that he requested an opening inventory and none was produced. Instead, Mr. Leadingham stated that ''one had not been done.'' (Tr. 314.) Mr. Leadingham was also unable to produce a biennial inventory. (Tr. 315.) Agent Kinneer further testified that he conducted a series of audits of individual drugs using a running inventory from the computer in Respondent's dispensary. (Tr. 316–17.) He determined a slight overage for two controlled substances and a shortage of two other controlled substances. (Tr. 317.) Agent Kinneer testified that ''our demonstration was to show Mr. Leadingham that you cannot rely on a running inventory. There actually needs to be a hard copy. And the purpose of it was to show that those things can be off.'' (Tr. 317.) The running audit also revealed that ''[t]here was drugs [sic] that were dead on.'' (Tr. 318.) Agent Kinneer further testified that there was no way to tell whether Respondent's dispensary had significant shortages or overages, since the absence of a starting point for the audit precluded a true inventory of controlled substances within Respondent's dispensary.

> Remember, this [running inventory] was just a tool to show Darryl Leadingham and Sue Leadingham that they cannot rely on the running inventory as a true inventory, that they needed an opening inventory as well as their DEA inventory. In order for me to do an audit I need a starting point. And that's what I am trying to express to them.

(Tr. 373–75.)

Agent Kinneer also reviewed DEA Form 222s during his inspection, specifically requesting the production of ''their blue copy where they actually receipted the medication.'' (Tr. 318.) Based on a review of a two to three inch stack of DEA Form 222s on the counter at the dispensary, Agent Kinneer testified that none had been ''receipted,'' explaining that none ''had a date or quantity on a filled-out line for those individual drugs that had been ordered and received.'' (Tr. 319, 362–63.) A review of DEA Form 222s kept in a vault within the dispensary also revealed that none had been receipted.[18] Agent Kinneer testified that Mr. Leadingham was unaware of the requirement to do so, instead indicating ''that he had been trained just to * * * do the invoices * * * [and] documenting it in the computer that they had received them.'' (Tr. 320.) Agent Kinneer further testified that he did not recall seeing invoices attached to the DEA Form 222s that he looked at, noting that it did not matter since that is not the requirement. (Tr. 320–21.) Agent Kinneer does not recall seeing staple marks on the DEA Form 222s that he reviewed, but explained he was not looking for staple marks. (Tr. 348.)

Agent Kinneer testified that controlled substances were ordered by the dispensary manager, Mr. Leadingham, using Respondent's DEA registration, but there was no indication that Respondent was active or accountable for the accuracy and completeness of the dispensary's records. (Tr. 321–22.) Agent Kinneer further testified that at the completion of the inspection, he informed Mr. Leadingham that ''from what we were witnessing he was running a pharmacy, which was illegal.'' (Tr. 323.) Agent Kinneer testified that Respondent's dispensary was not registered with the Ohio Board of Pharmacy as a pharmacy, nor were any personnel working in the dispensary licensed as pharmacists in Ohio. (Tr. 324–25.)

DI Burkhart was called in rebuttal by the Government, and testified in substance that she participated in the execution of a federal search warrant at Respondent's location on May 17, 2011, to include seizing the blue copies of DEA Form 222s. (Tr. 600–01.) Specifically, DI Burkhart testified that she seized and reviewed approximately fifty DEA Form 222s and only two blue copies had an invoice stapled to the back of them. (Tr. 601.) The fifty seized DEA Form 222s included the three reflected in Government Exhibit 6, which did not have any documents or invoices stapled to them at the time they were seized. (*Id.*) DI Burkhart further testified that she seized the DEA Form 222s from within the dispensary vault and in other places in the dispensary. (Tr. 607–08.)

I find the foregoing witness testimony fully credible in that each of the witnesses presented testimony that was internally consistent and evidenced a

[16] Agent Kinneer's duties include inspection of entities licensed by the Ohio Board of Pharmacy, to include physicians, pharmacies, pharmacists, dentists, and paramedics. Agent Kinneer's duties further include investigation of drug diversion. (Tr. 300.)

[17] The license was for Respondent's dispensary, Unique Relief, located within the same building as Respondent's medical practice. (Tr. 308.)

[18] Agent Kinneer testified that his inspection did not focus on how many dispensary orders were electronic as compared with orders using hand-written Form 222's with an accompanying blue copy. ''We were solely looking at the blue copies.'' (Tr. 360.)

reasonable level of memory for past events. Each witness presented testimony in a professional manner and the material portions of the testimony were consistent with other credible evidence of record, as discussed more fully below.

C. Respondent's Evidence

Respondent's evidence included testimony from two witnesses: Mrs. Leadingham and Mr. Leadingham. Respondent also introduced a letter dated April 27, 2010, from the Director of the Ohio Department of Health.[19] Mrs. Leadingham testified in substance as to her background and experience, to include having worked for approximately five years at an assisted living center before beginning work in Respondent's dispensary in or about November 2008. (Tr. 385, 390.) Prior to working for Respondent, Mrs. Leadingham had no prior working experience dispensing drugs at a pharmacy. (Tr. 457.) Mrs. Leadingham testified that when hired in November 2008, she worked for Ken Days (Mr. Days) in Respondent's dispensary. (Tr. 390–91.) Mrs. Leadingham described her duties to include counting pills, labeling medicine bottles, helping with inventory, filing, and handling invoices and DEA Form 222s. (Tr. 391.) Mrs. Leadingham further testified that she loved working for Respondent, who she described as caring and ''the best employer I have ever had.'' (*Id.*) Mrs. Leadingham explained that Respondent's dispensary operated like a pharmacy to include the use of pharmacy software called Rx30, as well as printed prescriptions, labeled drugs, and the filling of prescriptions, all consistent with that of a pharmacy. (Tr. 473.) Mrs. Leadingham testified that the dispensary filled controlled substance prescriptions for Respondent and Respondent's father, on a regular basis between 2008 and late 2010, when Respondent's father stopped issuing prescriptions. (Tr. 485.)

Mrs. Leadingham next testified that Respondent's role in the dispensary included stopping by every morning and evening to answer questions or discuss issues. (Tr. 400.) ''She had a monitor in her office that she watched us the whole time we were at work. She could see everything we did at any given time.'' (*Id.*) Mrs. Leadingham later contradicted this testimony, admitting that Respondent could not watch the dispensary while she was examining patients throughout the day. (Tr. 478.) No monitors were present in patient examination rooms. (Tr. 469.) Mrs. Leadingham further testified to the physical layout of the dispensary, to include security measures. (Tr. 403–04.)

Mrs. Leadingham testified that the dispensary kept detailed daily inventories, and also completed a biennial inventory every two years that was kept ''in a file in the vault.'' (Tr. 407.) Other than working from a computerized printout, Mrs. Leadingham testified that she did not document anything from the biennial inventory. (Tr. 481–82.) Mrs. Leadingham further testified that she believes the physical copy of the inventory was seized by DEA on May 17, 2011, since the folder was gone from the dispensary after that date. (Tr. 408, 412.)

Mrs. Leadingham testified that she worked in Respondent's dispensary until April 2009, when she was fired along with Mr. Leadingham. (Tr. 419.) Mrs. Leadingham testified that she returned to work at Respondent's dispensary on July 1, 2009, along with Mr. Leadingham, explaining the circumstances of why Respondent asked them to return to work:

> [Respondent] was very, very concerned with the way the dispensary was being run. She was allowed no access to the dispensary itself in these two months that we were gone. When we got back, I know we got a lot of complaints from the patients that there was pills missing, they weren't treated well, * * *.''

(Tr. 421.) Mrs. Leadingham further testified that upon her return to Respondent's dispensary in July 2009 she observed pills that had been put in unmarked vials, to include some pills that appeared to have been crushed. (Tr. 427.)

Mrs. Leadingham also testified as to her understanding and practice with regard to DEA Form 222s, stating in substance that she always stapled the invoices for incoming controlled substances to the Form 222. (Tr. 428.) Mrs. Leadingham further testified that most controlled substance orders were placed electronically, but approximately fifty paper copies of DEA Form 222s would have been present in the dispensary within folders identified by suppliers. (Tr. 440–41.) Prior to February 2010, the dispensary practice was not to put the date and amount of controlled substances received on DEA Form 222s, but rather to staple the invoice for controlled substances to the form. (Tr. 462–63.) Mrs. Leadingham testified that following the Ohio Pharmacy Board inspection of the dispensary in February 2011, she personally wrote the amount and date received on DEA Form 222s. (Tr. 464–65.)

Mrs. Leadingham next testified to completing pill counts within the dispensary to ensure that the numbers on hand matched the computer records, and does not recall any significant discrepancies of greater than one percent. (Tr. 446.) Mrs. Leadingham further testified that Respondent has been present in the dispensary on at least one occasion and counted medications which were matched with inventories. Additionally, Respondent received daily inventories from the dispensary. (Tr. 453–54.)

Mrs. Leadingham was called by Respondent in rebuttal, and testified in substance that she had separated existing DEA Form 222s from the invoices two to three weeks prior to May 16, 2011, in order to prepare copies for submission to the Ohio Medical Board. (Tr. 629.) Mrs. Leadingham further testified that during the week prior to May 16, 2011, she stapled the DEA Form 222s and invoices together again, and filed them in the dispensary vault. (Tr. 631.)

Mr. Leadingham testified in substance as to his background and experience, to include work in Respondent's dispensary, Unique Relief, beginning in November 2008. (Tr. 513.) Unique Relief was a separately operated business from Respondent's medical practice, Unique Pain Management. (Tr. 572.) The dispensary's sole purpose was to fill prescriptions issued by Respondent and Respondent's father. (Tr. 572–73.) Mr. Leadingham testified that he worked as the manager of the dispensary, to include pricing, printing labels for prescriptions, and ordering. (*Id.*) Mr. Leadingham testified that he received no training prior to dispensing controlled substances from Respondent's dispensary, other than to travel to an existing pharmacy to observe a pharmacist for approximately two hours. (Tr. 576, 580.) Mr. Leadingham explained that he worked for Mr. Days and Respondent, describing his relationship with Mr. Days as ''very contentious'' because Mr. Days kept telling Mr. Leadingham what to tell Respondent to do, which Mr. Leadingham would not. (Tr. 514–15.) In April 2009, Mr. Leadingham and Mrs. Leadingham were fired by Mr. Days. (Tr. 517.)

Mr. Leadingham testified that he returned to work for Respondent in July 2009, after the departure of Mr. Days. (Tr. 520.) Upon return, Mr. Leadingham testified that he completed an inventory, which was placed in a folder and ''we had written on it that it was for a DEA biennial.'' (*Id.*) A similar inventory was

[19] Resp't Ex. 6. This was the only exhibit offered by Respondent at hearing.

done in February 2011, and marked ''DEA Biannual Report.'' (Tr. 521.) Mr. Leadingham testified that the two files were present in the dispensary on May 17, 2011, but following that date ''[t]here was no paperwork left in the vault.'' (Tr. 522.) Mr. Leadingham testified that between July 2009 and May 17, 2011, there were never any large amounts of drugs missing, and with regard to oxycodones, Mr. Leadingham did not believe variances existed of ''even one-tenth of a percent.'' (Tr. 561.)

Mr. Leadingham testified that with regard to his compliance with federal regulations for the operation of Respondent's dispensary, he received legal advice that ''we were doing it perfectly.'' (Tr. 545.) Mr. Leadingham further testified that he later questioned the legal advice he was getting with regard to filling prescriptions issued by Respondent's father and looked up the DEA rules ''that stated there had to be a DEA license address for the [d]octor at that address, with that address, if there was a Schedule II narcotics there.'' (Tr. 559–60.) Mr. Leadingham testified that he provided a printout of the rules to Respondent, who then applied to DEA for a license for her father at Respondent's address. (Tr. 560.) Mr. Leadingham testified, however, that he did not see the DEA regulation that DEA Form 222s had to be kept separate from all other records, and the dispensary was ''[a]pparently not'' complying with that regulation. (Tr. 568.)

Respondent's witnesses presented their testimony in a professional and serious manner, but as more fully explained in the discussion section below, I find it only partially credible in several material respects.

IV. Discussion

A. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act (CSA) provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[20] ''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner'' with a corresponding responsibility on the pharmacist who fills the prescription.[21] It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of their professional practice.[22] It is also unlawful to refuse or negligently fail to make, keep or furnish required records.[23]

B. The Public Interest Standard

The CSA, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Administrator may revoke a DEA COR if she finds that the continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). Pursuant to 21 U.S.C. 823(f), the Administrator may deny an application for a DEA COR if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Administrator is required to consider the following factors:

(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.[24]

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: The Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989). Application of the public interest factors requires an individualized determination and assessment of prescribing and record-keeping practices that are ''tethered securely to state law * * * and federal regulations.'' *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009). Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[25] The burden of proof shifts to the respondent once the Government has made its prima facie case.[26]

C. The Factors to Be Considered

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid, unrestricted medical license in Ohio. Although not dispositive, Respondent's possession of a valid unrestricted medical license in Ohio weighs against a finding that Respondent's registration would be inconsistent with the public interest. *See Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (state license is a necessary, but not a sufficient condition for registration, and therefore, this factor is not dispositive).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie,* 68 FR at 15,230, weighs against a finding that Respondent's registration would be inconsistent with the public interest.

Factors 2 and 4: Respondent's Experience in Handling Controlled Substances and Compliance with Applicable State, Federal or Local Laws Relating to Controlled Substances

In this case, there is indeed evidence that Respondent has failed to remain in compliance with applicable federal and state law relating to controlled substances, and that her past experience in handling controlled substances and compliance with applicable laws is inconsistent with the public interest.

1. Respondent's Dispensing Practices

Federal law requires every person who dispenses (including prescribing) any controlled substance to obtain a registration from the Attorney

[20] 21 U.S.C. 802(10), 822(a)(2).

[21] 21 CFR 1306.04(a).

[22] 21 U.S.C. 844(a).

[23] 21 U.S.C. 842(a)(5).

[24] In addition, I conclude that the reference in 21 U.S.C. 823(f)(5) to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in Section 824(a). *See Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (DEA 1993).

[25] *See* 21 CFR 1301.44(e).

[26] *See Medicine Shoppe—Jonesborough,* 73 FR 364,380 (DEA 2008); *see also Thomas E. Johnston,* 45 FR 72,311, 72,311 (DEA 1980).

General.[27] Additionally, a separate registration must be obtained for each principal place of practice where a registrant dispenses controlled substances and a registrant must report any change of address by applying to modify her registration, which shall be treated as an application for registration.[28] The Code of Federal Regulations delineates the procedures a registrant must follow to request a change in registered address.[29] Federal regulations also mandate that a ''prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.'' [30]

Ohio law requires ''[e]ach person * * * who sells dangerous drugs [31] at retail for delivery or distribution to persons residing in this state, shall be licensed as a terminal distributor of dangerous drugs pursuant to sections 4729.54 and 4729.55 of the Revised Code.'' Ohio Rev. Code Ann. § 4729.551 (2011). It further requires that to operate a pharmacy, a ''person not a pharmacist, who owns, manages, or conducts a pharmacy, shall employ a pharmacist to be in full and actual charge of such pharmacy, * * * .'' Ohio Rev. Code Ann. § 4729.27 (2011).

Various provisions of Ohio law authorize a licensed health professional, including a physician,[32] to prescribe, administer, or personally furnish controlled substances to a patient, or ''[c]ause * * * controlled substances to be administered under the prescriber's direction and supervision.'' Ohio Rev. Code Ann. § 3719.06 (2011).[33] Furthermore, Ohio law exempts, under defined circumstances, a business practice with a sole shareholder who is a licensed health professional from the requirement of obtaining a terminal distributor license. Ohio Rev. Code Ann. § 4729.51 (B)(1)(j) (2011) (effective September 2008). The parameters of this exemption are set forth in a guidance document published by the Ohio State Board of Pharmacy:

> [S]ection 4729.51(B)(1)(j) which will now allow registered wholesale distributors of dangerous drugs to sell dangerous drugs to a business practice that is a corporation, limited liability company, or professional association if the business practice has a *SOLE SHAREHOLDER* who is a licensed health professional authorized to prescribe drugs (prescriber) and is authorized to provide the professional services being offered by the practice.
>
> This means that if the business practice has a single prescriber (M.D. * * *) who *is the sole shareholder, member, or owner* of the practice, then this business practice is not required to be licensed as a Terminal Distributor of Dangerous Drugs with the Ohio Board of Pharmacy. Previously, this exemption was only for a prescriber who practiced as a Sole Proprietor.

(Emphasis in original).[34]

The credible evidence at hearing demonstrated that Respondent established, solely owned, and operated two limited liability companies, Unique Pain Management (medical practice) and Unique Relief (dispensary), both of which are located at 418 Center Street, Wheelersburg, Ohio. (Tr. 48–49, 302–03.) Respondent's medical practice, which included her office and patient examination rooms, was physically separate from the dispensary, although a system of security cameras allowed some level of observing the dispensary operation by Respondent from a monitor located in her medical practice office. (Tr. 400.) The dispensary filled prescriptions issued by Respondent, as well as by Respondent's father, Dr. John Temponeras. The evidence of record reflects that between November 2008 and May 2011, a total of approximately 1.6 million dosage units of oxycodone, a Schedule II controlled substance, were ordered by Respondent, among other controlled substances. (Tr. 206–07.) The evidence further reflects that Respondent's father issued a large number of prescriptions for controlled substances while working at Respondent's medical practice at least one day a week from 2008 until late 2010, a significant portion of which were filled at Respondent's dispensary. (Tr. 181, 484–87.) Respondent's father was registered with DEA as an individual practitioner in Portsmouth, Ohio, but was not registered at Respondent's practice location. (Tr. 214.)

To the extent Ohio law permits a sole practitioner to dispense or personally furnish controlled substances directly to a patient without a Terminal Distributor license, Respondent's dispensing practices were well outside of those parameters. Respondent established a distinctly separate legal entity to fill prescriptions that was physically separate from Respondent's medical office. Furthermore, Respondent's dispensary was not limited to filling prescriptions issued only by Respondent, but also routinely filled prescriptions issued by Respondent's father, notwithstanding the fact that Respondent did not have a Terminal Distributor license as required by state law. Compare Ohio Rev. Code Ann. § 4729.551, with § 4729.51(B)(1)(j) (2011). Respondent's dispensary was not registered with DEA as a pharmacy and none of the dispensary employees was licensed in Ohio as a pharmacist, as required by state and federal law.[35] (Tr. 103–04.)

In addition to the foregoing violations, Respondent also failed to directly monitor or supervise the dispensing activities of her employees, none of whom were licensed, trained, or qualified to handle and dispense controlled substances in Ohio. Rather, Respondent's employees operated in large measure as an independent pharmacy filling prescriptions for Respondent and Respondent's father. The weight of the evidence demonstrated that Respondent and her father were not personally administering, dispensing, or furnishing controlled substances to their patients, but rather issued prescriptions for patients to be filled either at Respondent's dispensary or at other pharmacies. (Tr. 210–11.) The fact that patients had the option to fill prescriptions at other locations, which occurred to some extent, is inconsistent with personally administering or furnishing controlled substances.[36] While the majority of prescriptions issued by Respondent or her father were filled at Respondent's dispensary, there is no credible evidence of record that Respondent or her father had any personal role or supervision of that process. Instead, the process was left to Respondent's employees, who were unlicensed, untrained, and unqualified to handle or distribute controlled substances.

I do not find the testimonial evidence with regard to cameras in the dispensary and a monitor within Respondent's office credible insofar as establishing, consistent with Ohio law, that Respondent effectively supervised her employees dispensing or furnishing of

[27] 21 U.S.C. 822(a)(2).

[28] 21 U.S.C. 822(e), 827(g); 21 CFR 1301.51.

[29] *See* 21 CFR 1301.51.

[30] 21 CFR 1306.06

[31] Dangerous drugs under Ohio law includes any ''drug that may be dispensed only upon a prescription.'' Ohio Rev. Code Ann. § 4729.01(F) (2011).

[32] Ohio Rev. Code Ann. § 4729.01(I)(4) (2011).

[33] *See also* Ohio Rev. Code Ann. §§ 4729.29, 4729.291 (2011).

[34] Ohio State Board of Pharmacy, Licensing Issues for Prescribers (Updated July 2008), *http://www.pharmacy.ohio.gov/Licensing_Issues_for_Prescribers_07252008.pdf.*

[35] 21 CFR 1306.06 (2011); Ohio Rev. Code Ann. § 4729.27 (2011).

[36] A sampling of data for a one month time period in April 2010 revealed that Respondent filled approximately eighty-three percent of her prescriptions, with the remainder filled at other pharmacies. (Tr. 211.)

controlled substances. For example, Mrs. Leadingham testified that Respondent could not monitor the dispensary while treating patients in the examination rooms, nor did the screen on the monitor allow for the reading of labels on prescription bottles. (Tr. 471, 478.) The evidence of record establishes at most a system of cameras that was designed for security of the premises, rather than Respondent's direct supervision of the dispensing or furnishing of controlled substances. Moreover, Mrs. Leadingham testified that upon her return to work at Respondent's dispensary in July 2009, Respondent was very concerned with the way the dispensary had been run, to include complaints from patients and missing pills. (Tr. 421.) Respondent ''was allowed no access to the dispensary itself in these two months that we were gone.'' (*Id.*) The fact that Respondent continued to operate a dispensary from April to July 2009, with admittedly no access at all, is fully consistent with other credible evidence of record, to include testimony by Agent Kinneer, that Respondent had for significant periods of time essentially no role in the physical delivery of controlled substances to her patients. (Tr. 307.)

Respondent also offered at hearing one documentary exhibit, namely a letter from the Ohio Department of Health, dated April 27, 2010, which apparently was in reply to a document submitted by Respondent entitled: ''Policy and Procedure for Initial Intake, Screening, Verification of Identity and Medical Records, Monthly Processing of Patient.'' (Resp't Ex. 6; Gov't Ex. 8.) The reply letter in relevant part complimented Respondent and her staff ''on your thoroughness and intense efforts for security in preventing prescription drug abuse.'' (*Id.*) For purposes of this recommended decision, I have given this letter little weight. While the document facially confirms that Respondent had a written policy related to prevention of drug abuse, it does not address or rebut the specific evidence of Respondent's noncompliance with various provisions of state and federal law related to her handling of controlled substances alleged in the OSC/IS. Additionally, there is no credible evidence of record to suggest that the Ohio Department of Health, through Alvin D. Jackson, Director, was aware in April 2010 of the evidence of Respondent's specific misconduct which forms the basis of the instant proceeding, a significant portion of which became known to state and federal authorities after April 2010.

I find by a preponderance of the evidence that Respondent dispensed or directed and authorized the dispensing of controlled substances from an unregistered location on numerous occasions between November 2008 and May 2011, in violation of 21 U.S.C. 841 and 822(a)(2) and (e), as well as 21 CFR 1306.06.[37] I further find that Respondent's dispensing practices and lack of supervision of employees during that time period violated applicable state law. Ohio Rev. Code Ann. §§ 4729.551, 4729.27, and 3719.06 (2011).

2. Respondent's Record-Keeping Practices

Pursuant to 21 CFR 1304.03(b), 1304.21(a), 1304.22(a)(2)(iv), 1304.22(a)(2)(ix) and 1304.22(c), a registered individual practitioner is required to maintain records of controlled substances in Schedules II through V that are dispensed and received, including the number of dosage units, the date of receipt or disposal and the name, address and registration number of the distributor. It is unlawful to refuse or negligently fail to make, keep or furnish required records.[38] DEA regulations require that ''each registered individual practitioner required to keep records'' shall maintain inventories and records of Schedule II controlled substances ''separately from all of the records of the registrant;'' inventories and records of Schedule III through V controlled substances ''shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.'' [39] DEA registrants are required to maintain ''a complete and accurate record of all controlled substances on hand * * * .'' [40] They must ''take a new inventory * * * at least every two years.'' [41] The inventory ''must be kept by the registrant and be available[] for at least 2 years'' from the date of its creation.[42] ''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.'' [43]

Under longstanding Agency precedent, ''the failure to comply with record keeping requirements is a basis for revoking a registration.'' *Alexander Drug Co.,* 66 FR 18,299, 18,303 (DEA 2001) (citing *Singer-Andreini Pharmacy, Inc.,* 63 FR 4,668 (DEA 1998); *Arthur Sklar, d/b/a King Pharmacy,* 54 FR 34,623 (DEA 1989); *Summer Grove Pharmacy,* 54 FR 28,522 (DEA 1989); and *The Boro Pharmacy and Bell Apothecary,* 53 FR 15,151 (DEA 1988)). The CSA's emphasis on record-keeping constitutes '' 'an attempt to regulate closely the distribution of certain substances determined by Congress to pose dangers, if freely available, to the public at large.' '' *United States* v. *Poulin,* 926 F. Supp. 246, 250 (D. Mass. 1996) (quoting *United States* v. *Averi,* 715 F. Supp. 1508, 1510 (M.D. Ala. 1989)).

One mandatory record-keeping vehicle is DEA Form 222, the ''official triplicate order form[] used by physicians to order scheduled narcotics'' and other controlled substances.[44] A menu of federal regulations specifies procedures relating to DEA Form 222, such as obtaining, 21 CFR 1305.11, executing, § 1305.12, filling, § 1305.13, and endorsing DEA Form 222, § 1305.14, among other procedures.[45] In addition, 21 CFR 1305.03 requires that a DEA Form 222 be used for each distribution of a controlled substance listed in Schedules I or II, and Section 1305.17 provides that these order forms must be maintained separately from all other records and that they ''are required to be kept available for inspection for a period of 2 years.''

The evidence at hearing reflected numerous record-keeping violations by Respondent. The evidence credibly reflects that Respondent did not properly prepare or maintain DEA Form 222s as required by law. The evidence also demonstrated with regard to Respondent's dispensary, that Schedule II controlled substance records were improperly commingled with other controlled substance records, contrary to 21 CFR 1304.04.

Respondent's evidence did not deny the record-keeping violations with regard to DEA Form 222 alleged by the Government in the OSC/IS. Respondent's witnesses admitted that paper copies of DEA Form 222 were not properly maintained with required

[37] The OSC/IS alleged misconduct beginning on January 1, 2007, but the undisputed evidence of record established that Respondent opened her dispensary in or about November 2008, and no other relevant evidence was offered by the Government pertaining to ''unauthorized distributions of controlled substances'' by Respondent prior to that date. *See* ALJ Ex. 1, at 1.

[38] 21 U.S.C. 842(a)(5).

[39] 21 CFR 1304.04(g), (f)(2).

[40] 21 CFR 1304.11(a).

[41] 21 CFR 1304.11(c); *see also* 21 CFR 1304.04(a) (''every inventory * * * must be kept by the registrant and be available * * * for at least two years from the date of such inventory'').

[42] 21 CFR 1304.04(a).

[43] 21 CFR 1304.11(a).

[44] *Robert L. Dougherty, Jr., M.D.,* 60 FR 55,047, 55,048 (DEA 1995).

[45] *See, e.g.,* 21 CFR 1305.15–.19.

information, or in separate locations from other records. Rather, the testimony focused on whether the improperly completed DEA Form 222s had distributor invoices stapled to them in an apparent attempt to comply with the substance and spirit of the applicable DEA regulations.

As a factual matter, the testimony from Respondent's witnesses that invoices were routinely stapled to DEA Form 222s was directly contradicted by physical evidence at hearing, namely three purchaser copies of Form 222 seized from Respondent's dispensary on May 17, 2011, none of which was accompanied by an invoice. (Tr. 64–65; Gov't Ex. 6.) Additionally, all of the Government witnesses were consistent in describing the absence of stapled invoices in the vast majority of DEA Form 222s observed and seized from Respondent's dispensary.

Agent Kinneer credibly testified that during his February 9, 2011 inspection of Respondent's dispensary he reviewed a two to three inch stack of Form 222s on the dispensary counter with no attached invoices, noting that ''none of them had a date or quantity on a filled-out line for those individual drugs that had been ordered and received.'' (Tr. 319.) Agent Kinneer also testified that he reviewed a box kept in the dispensary vault with folders full of blue Form 222s, and none of them had the requisite receipt information, to include date or quantity received. (Tr. 319–20.) With regard to attached invoices, Agent Kinneer testified that he did not go through all of the forms in the box, but none of those he recalls reviewing had an invoice attached. (Tr. 320.)

Consistent with Agent Kinneer's testimony, DI Burkhart credibly testified that she participated in the execution of a federal search warrant at Respondent's dispensary on May 17, 2011, resulting in the seizure of approximately fifty blue purchaser copies of DEA Form 222, among other items. (Tr. 600–01.) Of the fifty, only two had an invoice stapled to the back of them. (Tr. 601.)

In light of the foregoing testimony credibly demonstrating that on February 9, 2011, and May 17, 2011, the vast majority of DEA Form 222s present in Respondent's dispensary did not have accompanying invoices attached, I do not find credible the testimony of Respondent's witnesses to the contrary. Even if there had been credible evidence offered to establish that Respondent routinely attached invoices to DEA Form 222s, such evidence would ''not obsolve [a registrant] from its obligation to adhere to the law.'' *Alexander Drug Co.,* 66 FR at 18,303.

> The efficacy of the closed system of distribution for controlled substances and certain chemicals mandated by Congress through the Controlled Substances Act depends upon strict adherence by all registrants to all record keeping requirements including those set forth at 21 U.S.C. [§§] 827, 828, 829, and 830, and all implementing regulations found in Title 21 Code of Federal Regulations, as well as all applicable state laws and regulations.

(*Id.*)

The evidence at hearing also demonstrated that Respondent did not take an initial inventory or biennial inventories, contrary to applicable regulations. 21 CFR 1304.11(b) and (c). Agent Kinneer credibly testified that during his February 9, 2011 inspection, he requested an opening inventory but was informed by Mr. Leadingham that ''one had not been done.'' (Tr. 314.) Nor was a biennial inventory produced during the inspection. DI Kresnak credibly testified that as a result of the May 2011 search of Respondent's dispensary, documents related to inventories were found, none of which reflected a ''biennial inventory.'' For example, there is evidence of record that documents were seized from Respondent's dispensary reflecting ''biannual inventories,'' and one marked ''opening inventory'' which ''indicated that the date that they opened the dispensary there was a zero inventory.'' (Tr. 83.)

Respondent's evidence with regard to inventories centered primarily on testimony by Respondent's dispensary employees that frequently during ''down time'' they would count on-hand drugs, including controlled substances, to ensure a match with computer records. Mrs. Leadingham testified that the dispensary kept detailed daily inventories, and completed a biennial inventory every two years, which was kept in the dispensary vault. (Tr. 407.) Later contradicting that testimony, Mrs. Leadingham testified that the process to conduct a biennial inventory consisted of Mr. Leadingham using a computer printout while she physically counted the controlled substances, adding that she did not ''document anything'' from the inventory. (Tr. 481–82.) The lack of documentation undermines the credibility of Mrs. Leadingham's assertions that detailed inventories were kept. Of significance, no invoices, DEA Form 222s, or dispensing logs were used to conduct the biennial inventory. (Tr. 480–82.) Nor is there any credible evidence that Respondent participated in the inventory process in any meaningful way to ensure an accurate inventory was taken and proper records maintained.[46] Instead, the credible evidence of record reflects that Respondent delegated that task to employees who were neither trained nor properly supervised to perform the task.

The evidence at hearing unequivocally demonstrates that Respondent's employees, however well-intentioned, lacked the qualifications, training, or supervision to conduct an appropriate initial or biennial inventory, as required by applicable law and regulation. The fact that no compliant initial or biennial inventory was produced by Respondent or her employees during the February 9, 2011 inspection, nor seized during the May 17, 2011 search, amply demonstrates Respondent's blatant non-compliance with this important record-keeping requirement. As Agent Kinneer succinctly testified, a ''running inventory'' is no substitute for a true inventory, since in ''order for me to do an audit I need a starting point.'' (Tr. 373–74.) There is no evidence that such a starting point existed within Respondent's dispensary records, nor any other compliant inventory records.

Contrary to Respondent's assertion that the foregoing represents ''highly technical paperwork errors,'' (Resp't Br. At 7), the failure by Respondent to properly maintain required records prevented investigators, as well as Respondent, from determining whether Respondent's dispensary had significant shortages or overages. (*See, e.g.,* Tr. 375.) The sheer volume of controlled substances handled by Respondent, which between November 2008 and May 2011, totaled approximately 1.6 million dosage units of the Schedule II controlled substance oxycodone alone, demonstrates that overages or shortages had the potential to be quantitatively significant. (*See* Tr. 375.) Nor was the risk of diversion purely speculative with regard to Respondent's dispensary given, for example, the testimony by Mrs. Leadingham that during May and June 2009, Respondent was not allowed access to her own dispensary. (Tr. 421.) Additionally, Mrs. Leadingham testified that when she returned to work in Respondent's dispensary in July 2009, she observed crushed pills and pills in unmarked vials, and received complaints from customers of missing pills. (Tr. 421, 427.) Rather than being technical paperwork errors, I find

[46] I have carefully considered and reject as not credible testimony by Respondent's employees that Respondent actively participated or supervised the inventory process. (*See, e.g.,* Tr. 453–54.) Even if such testimony was found to be credible, the methodology used to conduct the inventory, with or without the Respondent, was clearly contrary to law.

Respondent's blatant disregard for fundamental record-keeping requirements, among other violations, to be significantly at odds with the public interest.

Accordingly I find by a preponderance of the evidence that Respondent unlawfully failed to make, keep or furnish required records relating to her handling of controlled substances, during the time period from November 2008 to May 2011, in violation of applicable federal law.[47]

3. Respondent's Issuance of Prescriptions Without Required Information

Pursuant to 21 CFR 1306.05(a), ''[a]ll prescriptions for controlled substances shall * * * bear the full name and address of the patient * * * [and] directions for use * * *.'' The evidence of record included approximately eleven prescriptions issued by Respondent for various controlled substances to a single patient covering the time period August to November 2006. (Tr. 219–20; Gov't Ex. 7.) Each of the eleven prescriptions was deficient by failing to include the patient's address. (Tr. 220–21; *see* Gov't Ex. 7.)

Additionally, the Government introduced testimony by DI Kresnak that he reviewed approximately twelve prescriptions seized from a Portsmouth, Ohio pharmacy that Respondent had issued for controlled substances to more than one patient between 2005 and 2006. Of the twelve reviewed, DI Kresnak testified that eleven lacked a patient address. (Tr. 53–55, 123–24.) None of these prescriptions were introduced by the Government at hearing, and DI Kresnak was uncertain if any of the prescriptions he recalled reviewing from the Portsmouth, Ohio pharmacy were the same as those identified in Government Exhibit 7. Nor could DI Kresnak recall any of the patient names from memory without reviewing copies of the prescriptions.[48] (Tr. 118.) In light of this testimony, I give little overall weight to the testimony offered by the Government with regard to the eleven prescriptions seized from the Portsmouth, Ohio pharmacy, since those prescriptions may or may not be the same as those contained within Government Exhibit 7. ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith* v. *Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt* v. *Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)).

Accordingly, I find by a preponderance of the evidence that Respondent issued approximately eleven prescriptions between August and November 2006 for controlled substances without providing a patient address, in violation of applicable federal regulations.

All of the above findings regarding Respondent's violation of applicable law and regulation as it pertains to her prescribing practices, record-keeping, and dispensing from an unregistered location weigh heavily against a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be consistent with the public interest.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the Administrator is authorized to consider ''other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). The Agency has accordingly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola,* 74 FR 20,727, 20,734 (DEA 2009).[49] A ''[r]espondent's lack of candor and inconsistent explanations'' may serve as a basis for denial of a registration. *John Stanford Noell, M.D.,* 59 FR 47,359, 47,361 (DEA 1994).

In this case Respondent was called by the Government to testify, but refused to answer questions by invoking her Fifth Amendment privilege. ''It is well established that the Agency may draw an adverse inference from a respondent's failure 'to testify in response to probative evidence offered against' [her].'' *Surinder Dang, M.D.,* 76 FR 51,417, 51,422 (DEA 2011) (citing *Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976)). I find it appropriate on the facts of this case to draw an adverse inference against Respondent where the Government presented evidence of misconduct involving Respondent's prescribing, dispensing, and record-keeping practices, yet Respondent failed to testify and respond to this evidence. Additionally, Respondent presented no evidence of acceptance of responsibility for past misconduct, nor any evidence demonstrating that she will not engage in future misconduct, which weighs heavily against a finding under Factor Five of 21 U.S.C. 823(f) that Respondent's continued registration would be consistent with the public interest.

V. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's DEA COR BT5598214, based on Factors Two, Four and Five of 21 U.S.C. 823(f). Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72,311 (DEA 1980). The record reveals that Respondent has not sustained her burden in this regard. In light of the foregoing, Respondent's evidence as a whole fails to sustain her burden to accept responsibility for her misconduct and demonstrate that she will not engage in future misconduct.

I recommend revocation of Respondent's DEA COR BT5598214 as a practitioner, and denial of any pending applications for renewal or modification, on the grounds that Respondent's continued registration would be fully inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

Dated: December 15, 2011.

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2012–18749 Filed 7–31–12; 8:45 am]

BILLING CODE 4410–09–P

[47] *See* 21 U.S.C. 827(a), 842(a)(5); 13 CFR 1304.11 (b) and (c), 1305.13(e).

[48] The Government did not seek to refresh DI Kresnak's recollection with any documents, nor were the prescriptions at issue introduced at hearing. *See supra* note 9.

[49] *See also Hoxie* v. *DEA,* 419 F.3d 477, 484 (6th Cir. 2005) (decision to revoke registration ''consistent with the DEA's view of the importance of physician candor and cooperation'').

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–364]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: DEA is announcing a new DEA-approved certification process for Electronic Prescriptions for Controlled