because the applicant/registrant may have a valid explanation for why it is not currently licensed by the state, which would not necessarily support either revocation of an existing registration or the denial of an application. For example, the state licensing authority may have a large backlog in issuing its licenses, the applicant/registrant's application may have been lost or misplaced, there may be minor compliance issues which the applicant/registrant is in the process of correcting and which have delayed the issuance of the license but which would not necessarily warrant a denial or revocation (as the case may be) by DEA, or the applicant/registrant may have simply forgotten to renew its license on time. However, because other than in the case of practitioners, the possession of state authority is not an independent requirement for registration, what is clear is that an applicant/registrant is entitled to rebut the Government's *prima facie* case by showing that its conduct is not sufficiently egregious to warrant denial or revocation and what remedial measures it has undertaken to correct the problem. Thus, upon a proper showing by a respondent, summary disposition would be unwarranted and the respondent would be entitled to put on evidence.

In this matter, it is noted that in his July 14, 2011 filing, Respondent's owner claimed that it had filed for a renewal of its state license. However, since then, Respondent has produced no evidence that it has obtained a new state license. In addition, Respondent failed to comply with the ALJ's order for prehearing conference and failed to respond to the Government's renewed motion for summary disposition. As the First Circuit has noted in language that applies with equal force to administrative proceedings, '''[l]itigants must act punctually and not casually or indifferently if a judicial system is to function effectively.''' *McKinnon* v. *Kwong Wah Restaurant,* 83 F.3d 498, 504 (1st Cir. 1996) (quoted in *Kamir Garces-Mejias,* 72 FR 54931, 54933 (2007) (holding that registrant's failure to respond to ALJ's orders constituted waiver of her right to a hearing)). I therefore conclude that Respondent has waived its right to present evidence regarding its compliance with applicable laws. *See Garces-Mejias,* 72 FR at 54932–33; *see also Pamela Monterosso,* 73 FR 11146, 11147 (2008).

In addition, as I noted in the remand order, Respondent applied for a distributor's registration, and paid the fee for this category of registration (and not the fee for a manufacturer's registration).[7] However, it is clear from Respondent's application that it sought to engage in the ''Preparation 5% Solution (Lugol's Solution)'' and then noted that it intended to manufacture iodine in the dosage formulation of ''8 ml each.'' This constitutes manufacturing activity under the CSA. *See* 21 U.S.C. 802(15) (defining manufacturing to include ''the production, preparation . . . or processing of a drug or other substance, either directly or indirectly . . . and includes any packaging or repackaging of such substances or labeling or relabeling of its container'').

Under the CSA, ''[p]ersons registered . . . to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration.'' *Id.* § 822(b). Under DEA regulations, the manufacturing and distribution of list I chemicals are activities which ''are deemed to be independent of each other'' and while the holder of a manufacturer's registration can engage in the distribution of a list I chemical, the holder of a distributor's registration cannot engage in manufacturing. 21 CFR 1309.21(c); *id.* 1309.22(b) & (d). Accordingly, Respondent's proposed activity would not be lawful under the registration it seeks.

Based on Respondent's failure to obtain the required state permit or license, as well as that its proposed activity would not be lawful under the registration for which it applied, I find that the record supports a finding under factor two that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h). Accordingly, Respondent's application will be denied.[8]

[7] In his letter requesting a hearing, Respondent's owner stated that it required a DEA registration ''to manufacture iodine 5% solution, called Lugol Solution.'' Letter of Paul Anand, Ph.D., to Administrator (June 23, 2011). However, according to Respondent's application, it sought registration as a Chemical Distributor and not as a Chemical Manufacturer; consistent with this, it paid the fee for the former and not the latter. Respondent's Application, at 1, 3. Moreover, in Section 3B of the application, which applies to ''Manufacturers Only,'' Dr. Anand wrote: ''Preparation 5% Solution (Lugol's Solution),'' and in Section 3C, he checked the box for bulk iodine. *Id.* at 1–2.

Under DEA's regulation, the manufacturing of list I chemicals is deemed to be an activity which is independent of distribution (although a registered manufacturer can lawfully engage in distribution), and thus requires a manufacturer's registration. *See* 21 CFR 1309.22. Because Respondent did not apply for the required registration, its application should have been rejected as defective. *See id.* § 1309.34(a).

[8] As found above, on November 2, the Government filed its second motion for summary disposition by mailing it to Respondent's owner, at its address in Brea, California; on November 9, the ALJ issued his recommended decision noting that ''Respondent had 'until 4:00 p.m. EDT three business days after the date of service of any motion to file a responsive pleading' and that '[i]n the absence of good cause, failure to file a written response to the moving party's motion after three business days will be deemed a waiver of objection.''' ALJ II, at 4. The ALJ apparently deemed service to have been effectuated with mailing. *See id.* (noting that ''[a]s of November 9, 2011, five business days after service of the Government's [motion], Respondent had not yet filed a response''). While courts frequently deem service of a pleading to have occurred on mailing and not upon receipt by the opposing party, *see, e.g.,* F.R.C.P. r. 5(b)(2)(C), due regard must be given to the respective locations of the parties and the vagaries of the mail. While an ALJ is entitled to substantial discretion in managing his/her docket, the amount of time the ALJ allowed here for Respondent to file its responsive pleading was unduly limited and potentially a violation of Due Process.

However, because following issuance of the remand order, Respondent has not filed any pleadings including exceptions, I deem any such error harmless.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 28 CFR 0.100(b), I order that the application of Bio Diagnostic International, Inc., for a DEA Certificate of Registration as a distributor of list I chemicals, be, and it hereby is, denied. This Order is effective July 31, 2013.

Dated: June 21, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–15704 Filed 6–28–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sigrid Sanchez, M.D.; Decision and Order

On February 4, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sigrid A. Sanchez, M.D. (Respondent), of Sunrise, Florida. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a practitioner, on the ground that her ''registration would be inconsistent with the public interest.'' GX 7, at 1 (citing 21 U.S.C. 823(f)).

More specifically, the Show Cause Order alleged that on May 19, 2010, Respondent had surrendered her previous DEA registration, and that on July 29, 2010, she had applied for a new registration. *Id.* The Show Cause Order further alleged that on April 30, 2010, the Florida Department of Health had conducted ''a dispensing practitioner's

inspection'' at Respondent's former registered location, the Mercy Wellness and Recovery Center of Fort Lauderdale, Florida, finding violations of both federal and state law. *Id.*

The Order alleged that the federal violations included, *inter alia,* failing to provide adequate supervision over employees who had access to controlled-substance storage areas, failing to store controlled substances in a securely locked cabinet, taking possession of controlled substances at the clinic upon commencing her employment while failing to conduct an inventory of the controlled substances, failing to supervise the dispensing of controlled substances by clinic employees, authorizing an employee to order schedule II controlled substances without executing a Power of Attorney, and not having ''an adequate system for monitoring the receipt, distribution and disposition of controlled substances.'' *Id.* at 1–2 (citing 21 CFR 1301.71(a), (b)(11), (b)(14); 1301.75(b); 1304.21(a); 1304.22).

With respect to the state violations, the Show Cause Order alleged that ''by the transfer of controlled substances,'' Respondent violated various provisions of Floria law. *Id.* at 2 (citing Fla. Stat. Ann. §§ 499.0051(1), 499.006(10), and 499.0121(6) (all 2010)). The Order also alleged that Respondent's ''failure to supervise and review the dispensing of controlled substances'' violated both Florida statutes and regulations. *Id.* (citing Fla. Stat. Ann. § 893.04(1)(b) (2010); Fla. Admin. Code Ann. r. 64B16–27.1001(3) & (4) (2010); *id.* r. 64B16–28.140(3) (2010)). Finally, the Show Cause Order alleged that Respondent also violated state controlled substance recordkeeping requirements. *Id.* (citing Fla. Stat. Ann. §§ 893.07(1)(a) & (b); 893.07(2)).[1]

In a letter dated February 16, 2011, Respondent acknowledged service of the Show Cause Order. In her letter, Respondent further stated that she was waiving her right to a hearing but submitting a ''written statement regarding [her] position on the matters of fact and law involved.'' GX 6. *See also* 21 CFR 1301.43(c). Respondent's statement was made a part of the record. *See* GX 6. On September 20, 2011, the record was forwarded to my Office for Final Agency Action.

Having considered the entire record (including Respondent's statement), I conclude that granting Respondent's application would be inconsistent with the public interest. Accordingly, Respondent's application will be denied. I make the following findings.

Findings

Respondent previously held a DEA Certificate of Registration as a practitioner in schedules II through V. GX 1, at 1. On April 7, 2010, Respondent changed her registered address to 2001 N E 48th St., Fort Lauderdale, Florida. *Id.* This address was the location of the Mercy Wellness and Recovery Center (hereinafter, Mercy), a pain management clinic. GX 5, at 59. On or about April 13, 2010, Respondent, who is board certified in internal medicine, became the clinic's medical doctor. *Id.* at 1, 48, 60. According to a sworn statement Respondent gave to Investigators of the Florida Department of Health (DOH), in December 2009, she became a Dispensing Practitioner under Florida law, which authorized her to sell medicinal drugs to patients in her office. *Id.* at 60–61.

On April 30, 2010, DOH Investigators went to the Mercy Wellness clinic to conduct a dispensing practitioner inspection; at the same time, the Ft. Lauderdale Police Department executed a search warrant at the clinic. GX 4, at 1. Upon their arrival, the DOH Investigators observed that the clinic had an armed security guard at both the front and back entrances and that it had ''a large waiting area filled with patients.'' GX 5, at 47.

DOH Investigators interviewed several employees as well as Respondent. According to an affidavit of one of the DOH Investigators, at the time of the inspection a different doctor, M.W., was listed in DOH's records as the dispensing practitioner of record and was ''the intended subject of the inspection.'' GX 5, at 47. However, upon arriving at the clinic, the Investigators determined that Dr. M.W. had stopped working there on April 2nd and that Respondent ''was the dispensing practitioner.'' *Id.*

According to the Investigator's affidavit, the clinic had ''one examination room and a room directly adjacent to it which'' was identified ''as the 'Pharmacy.''' *Id.* The Pharmacy had a ''teller like window where the prescription drug products [were] dispensed and sold to the patient'' and the room was ''accessible to all [clinic] personnel.'' *Id.* Inside the dispensing room were two safes, one of which was open and contained drugs; ''[t]here were also unlabeled bottles of prescription drug products located on a table in the [dispensing room] which [J.F., a pharmacy technician] had been preparing to be dispensed to patients.'' *Id.* at 55. Inside the dispensing room, the Investigators also observed R.H., who was printing out prescriptions from the patient charts on a computer. *Id.* at 48.

During her interview, Respondent ''admitted that she [did] not verify [or] check the medications that [were] dispensed and sold to any of the patients'' as this was done by J.F. *Id.* While Respondent stated that she had signed at least three order forms (DEA–222) for schedule II controlled substances, and admitted that she had ''no knowledge of the amount of prescription drug products [that were] being ordered,'' the forms were completed by the pharmacy technician and then signed by her. *Id.* at 52. Respondent stated, however, that she did not know ''when or how often [the] drugs [we]re delivered to the facility,'' and ''who receive[d] them.'' *Id.* In addition, Respondent did not know how the invoices were paid or the combination to the safe where the drugs were stored.[2] *Id.*

During her interview, Respondent initially stated that J.F. was the pharmacist and in charge of the pharmacy. *Id.* at 61. However, Respondent then acknowledged that J.F. was only a pharmacy technician. *Id.*

The DOH Investigators further noted that Dr. W. had left prescription drug products at the clinic when he left its employment and that these were ''allegedly transferred to'' Respondent. Moreover, Respondent admitted that on April 20, 2010, she signed a DEA 222 form to take possession of the controlled substances left by Dr. W. *Id.* at 37. However, according to a DOH Investigator, ''there was no documentation to support that Dr. [W.] authorized such a transaction either personally or through power of attorney.'' *Id.* at 7. In addition, the DOH Investigator determined that ''DEA 222 forms revealed that C–II prescriptions drugs were received between 04/02/10

[1] The Show Cause Order also notified Respondent of her right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for electing either option, and the consequences for failing to do so. GX 7, at 3.

[2] Respondent also stated that she saw 60 to 65 patients a day, to whom she prescribed oxycodone 30mg and 15mg, muscle relaxants such as carisoprodol, and Xanax (alprazolam), a combination of drugs which this Agency has encountered in investigations of physicians engaged in blatant drug dealing. *See, e.g., Paul H. Volkman,* 73 FR 30630 (2008); GX 5, at 63–64 (Respondent's sworn statement to Investigators that she would issue two to four prescriptions to a patient; ''It is a combination, anti-inflammatory, muscle relaxers, pain killers. I really believe in them. You know the combination is the key.''). Yet the Government made no allegation that Respondent issued prescriptions outside of the usual course of professional practice and lacking a legitimate medical purpose, 21 CFR 1306.04(a), and produced no evidence that any prescription she issued was unlawful.

and 04/13/10 at which time no licensed practitioner was working who could legally possess the prescription drugs.'' *Id.* Moreover, because there were no pedigree documents for any of the drugs, the DOH Investigators determined that the drugs were adulterated under Florida law and seized them in place. *Id.* at 9, 38. According to various records, DOH seized several thousand dosage units of controlled substances including oxycodone (in both 30mg and 15mg strength), hydrocodone, alprazolam, diazepam, as well as carisoprodol, a drug which was then controlled under Florida law but not Federal law. *Id.* at 69–72.

Respondent further admitted to a DOH Investigator that she ''never completed an inventory of the medication present and did not know of any inventory ever [having been] taken by others.'' *Id.* at 38. Respondent also told a DOH Investigator that she did not ''know until today that [J.F.] was not a pharmacist—[she] thought he was.'' *Id.* However, when the Investigator then told Respondent that ''an 8 ½ x 11 printout stating that [J.F.] is a Registered Pharmacy Technician [was] on the wall immediately inside her dispensing room,'' Respondent replied that she had ''never been in that room.'' *Id.*

During the inspection, Respondent agreed to voluntarily surrender her DEA registration. Respondent completed a DEA Form 104 evidencing her agreement. GX 5, at 67. On July 29, 2010, Respondent applied for a new registration. GX 1.

As noted above, following service of the Show Cause Order, Respondent submitted an unsworn written statement of position. GX 6. Therein, Respondent stated that she had been placed at Mercy by All Care Staffing, a temporary staffing agency and had started work there on April 13, 2010. GX 6, at 1. Respondent further stated that she had previously obtained work through All Care and that at the time of her placement at Mercy, she had interviewed with two internal medicine groups and while she was doing due diligence on them, contacted All Care. *Id.* According to Respondent, ''All Care assured [her] that [Mercy] was stable and ran an above-board, legitimate, compliant practice.'' *Id.* Respondent also stated that because her time at Mercy ''was the first time in [her] professional career that [she] had been a dispensing practitioner, [she] was *completely* unaware that [she] had run afoul of the laws governing dispensing practitioners.'' *Id.*

Respondent then addressed the various violations found by the DOH Investigators. First, she asserted that ''[t]o the best of [her] knowledge, the prescription drugs at [Mercy] were at all times stored and otherwise locked in a safe . . . and that access was restricted, in compliance with 21 CFR 1301.75.'' *Id.* at 2. She asserted that when she asked whether she should have the safe's combination, the owners told her that this ''was not a legal requirement'' and that she ''could inspect the safe at any time.'' *Id.* She also maintained that she ''believed that [Mercy] employed a pharmacist who was responsible for and addressed all pharmacy and prescription issues'' and that ''[i]t seemed reasonable . . . to rely upon the owners of [Mercy] to employ properly trained and credentialed personnel in the pharmacy.'' *Id.*

Respondent further stated that ''upon the initial date'' of her employment at Mercy, she ''did order medications pursuant to a form DEA 222'' and did so because she was told that she ''could not use the medications that had been ordered by'' Dr. W., the previous doctor. *Id.* Respondent maintained that she ''was provided with the DEA 222 form by [clinic] personnel, but was unfortunately unaware of my obligations regarding the DEA 222 form at the time.'' *Id.* She then explained that she ''was informed that Dr. [W.] was responsible for addressing the medications that he left behind as well as the DEA 222 forms associated with him,'' and therefore, she ''did not address them or to [her] knowledge dispense any medications that had previously been ordered by Dr. [W.]'' *Id.* However, Respondent then stated that Mercy ''refused to make Dr. [W.] available to [her], so in hindsight, proper transfer may not have been possible.'' *Id.*

Respondent stated that because she ''worked three days a week for a three week period of time, [she] did not do an inspection or complete an inventory.'' *Id.* She then stated that ''no prior inventories or logs were made available to'' her. *Id.*

Respondent ''acknowledge[d] that [she] did not personally check and certify filled prescription[s] for accuracy prior to [the] patient receiving'' them. *Id.* Respondent reiterated that she ''believed that there was [a] pharmacist employed at [Mercy] that ensured compliance with these issues'' and that because of her belief, she ''was not always present when medications were dispensed nor did I initial all prescription labels.'' *Id.* Regarding the DOH report's statement that she had denied having been in the ''Pharmacy'' room, Respondent stated that she ''had been in the dispensing room and had seen the technician enter information into the . . . computer system, prepare labels, count pills and place them in prescription bottles for dispensing.'' *Id.* She also stated that she is now aware that she had ''an obligation to verify that the personnel where I was providing services were properly licensed to perform certain duties.'' *Id.*

Respondent further stated that following the inspection, she terminated her employment at Mercy. However, she again reiterated that she ''was improperly led to believe that [Mercy] was properly running its practice, with the appropriate personnel, licenses, and permits,'' and that the dispensing of drugs was being ''done properly and in full compliance with the law'' but that she had concluded that the ''many compliance breaches in this matter clearly existed long before [her] locum tenens assignment to'' Mercy. *Id.* at 2–3. Respondent further stated that she has ''been practicing medicine for twenty-five years, and prior to this, had an unblemished record'' and that ''[t]he inspection and [her] very brief relationship with [Mercy] has been a very painful and embarrassing learning process for'' her. *Id.* at 3. Respondent also stated that the DOH ''inspection report evidences that [she] was not evasive and fully answered all the questions asked from the participants of the inspection.'' *Id.*

Respondent stated that she ''believed that it was not improper for [her] to provide services [for Mercy] and that the practice was operated appropriately'' and that she ''simply was not fully aware of the obligations discussed in the paragraphs above and believed [she] was in compliance with the laws.'' *Id.* Finally, Respondent stated that ''[t]his was the first time in [her] professional career that [she] had been a dispensing practitioner and [that she is] not interested in dispensing again after the experience [she] had with'' Mercy. *Id.*

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration . . . would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

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

(2) The applicant's experience in dispensing . . . controlled substances.

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

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

(5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to deny an application. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005)).

In the case of a practitioner, the Government has the burden of proving with substantial evidence that granting an application would be inconsistent with the public interest. However, where the Government makes out a *prima facie* case to deny an application, the burden shifts to the applicant to show why granting the application would be consistent with the public interest.[3]

In this matter, I conclude that the Government's evidence with respect to factors four and five establishes a *prima facie* case to deny Respondent's application.[4] While I have considered Respondent's statement of position, I conclude that she has not provided substantial evidence to show why, at this time, she can be entrusted with a new registration.

Factors Four and Five—Compliance With Applicable Laws Related to Controlled Substances and Other Conduct Which May Threaten Public Health and Safety

Based on the DOH Inspection, the Government alleges that Respondent committed multiple violations of the CSA, its implementing regulations, as well as Florida law and regulations. These violations include her failure to conduct an initial inventory of the controlled substances, her failure to institute sufficient security/diversion controls, and her improper execution of a DEA 222 form for the transfer of controlled substances from the clinic's prior doctor.

The CSA provides in relevant part that ''every registrant . . . shall . . . as soon . . . as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances . . . make a complete and accurate record of all stocks thereof on hand.'' 21 U.S.C. 827(a)(1).[5] Respondent acknowledged that she failed to comply with this provision. This was also a violation of Florida law. *See* Fla. Stat. Ann. § 893.07(1)(a).

The Government further argues that Respondent ''could not specify what quantity of drugs she received from Dr. [W.'s] stock of controlled substances, thus violating 21 CFR 1304.22.'' Req. for Final Agency Action, at 5. This, however, is simply the same violation as set forth in the preceding paragraph.[6]

The Government also contends that Respondent violated Federal regulations because she allowed other persons to order controlled substances on her behalf and did not issue a Power of Attorney. The Government argues that although Respondent signed several Schedule II order forms which were ''completed by another individual, she did not order the medications and she was not notified when controlled substances were ordered on her behalf.'' *Id.* at 5; *see also* Show Cause Order ¶ 2d (citing 21 CFR 1305.05(a)). As found above, Respondent admitted that she did not know the amount of the drugs that were being ordered under her registration. Yet other evidence establishes that the DEA 222 forms were completed by the pharmacy technician and then signed by Respondent.

Under the CSA, a schedule II controlled substance can only be distributed pursuant to ''a written order of the person to whom such substance is distributed, made on a form . . . issued by the Attorney General [DEA–222].'' 21 U.S.C. 828(a). DEA regulations further provide, in relevant part, that ''[o]nly persons who are registered . . . under section 303 of the [CSA] to handle Schedule I or II controlled substances . . . may obtain and used DEA Form 222 . . . for these substances. Persons not registered to handle Schedule I or II controlled substances . . . are not entitled to obtain Form 222.'' 21 CFR 1305.04(a). A registrant may, however, ''authorize one or more individuals . . . to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual.'' *Id.* 1305.05(a).

The evidence does not, however, establish that Respondent violated either the CSA or the Agency's regulations by signing the order forms because the evidence shows that the forms were completed by the pharmacy technician and then signed by Respondent. Thus, because Respondent signed the form, she and not the pharmacy technician issued the orders,

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[3] Where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '''present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.''''' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *accord Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

In addition, ''DEA properly considers the candor of the physician and his forthrightness in assisting in the investigation and admitting fault important factors in determining whether the physician's registration'' is consistent with the public interest.'' *Hoxie,* 419 F.3d at 483.

[4] The only evidence in the record as to factor one (the recommendation of the state licensing board) is the approximately one year old DOH report which shows that Respondent still had a state license at that time. However, DEA has repeatedly held that while the possession of state licensure is a fundamental condition for obtaining and maintaining a practitioner's registration, it is not dispositive of the public interest inquiry.

As for factor three, the Government raises no contention that Respondent has been convicted of a federal or state law offense related to controlled substances. However, because there are multiple reasons why an applicant or registrant may not have been convicted or even prosecuted for such an offense, the absence of such a conviction ''is of considerably less consequence in the public interest inquiry.'' *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied* 2011 WL 6739420 (10th Cir., Dec. 23, 2011). *See also Jayam Krishna-Iyer,* 74 FR at 459, 461 (2009); *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007), *pet. for rev. denied* 533 F.3d 828 (DC Cir. 2008). Accordingly, this factor is not dispositive.

[5] While the CSA exempts from the recordkeeping requirements ''the prescribing of controlled substances . . . by practitioners acting in the lawful course of professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual,'' 21 U.S.C. 827(c)(1)(A), the evidence shows that Respondent was not only prescribing but also dispensing controlled substances.

[6] The Government also alleges that Respondent violated Federal law when she ''signed a DEA Form 222 to take possession of controlled substances that were abandoned by a former practitioner at the clinic.'' Show Cause Order at 2. As noted above, in an affidavit, a DOH Investigator stated that ''there was no documentation to support that Dr. [W.] authorized such a transaction either personally or through [a] power of attorney.'' GX 5, at 53. Given the Government's assertion that the drugs ''were abandoned,'' it is not clear why it was necessary for Dr. W. to authorize the transaction and why Respondent violated Federal law by signing a Form 222. The Government makes no further argument that it was unlawful for Respondent to acquire possession of the controlled substances that were at the clinic when she commenced her employment there because the clinic owners were not registered and could not lawfully distribute the drugs to her.

and Respondent was not required to execute a power of attorney form.

However, Respondent admitted that she did not know what controlled substances were being ordered under her registration as well as when they were being received, and the evidence shows that other scheduled drugs including hydrocodone, alprazolam, and diazepam (which do not require the execution of a Form 222 to order) were found at the clinic. Moreover, other evidence establishes that the clinic did dispense controlled substances (notwithstanding that Respondent had been at the clinic for only seventeen days at the time of the inspection) which were ordered under her registration. Under DEA's regulations applicable to all registrants, a practitioner is required to institute and maintain an adequate system ''for monitoring the receipt . . . distribution, and disposition of controlled substances.'' 21 CFR 1301.71(b)(14). Respondent did not comply with this requirement.

The CSA also requires that ''every registrant . . . manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him.'' *Id.* § 827(a)(3). Florida law imposes a similar obligation on persons engaged in the dispensing of controlled substances. *See* Fla. Stat. Ann. § 893.07(b). However, the record does not establish whether the clinic was maintaining the invoices documenting the receipt of controlled substances or a proper dispensing log.

The Government also alleges that ''Respondent failed to store [the] controlled substances in a securely locked cabinet'' and that DOH Investigators observed that multiple employees had access to the drug dispensing room. Req. for Final Agency Action, at 4 (citing 21 CFR 1301.71(b)(11) and 1301.75(b)). As for the failure to store the controlled substances in a securely locked cabinet, the DOH Investigators stated that drugs were observed both in an open safe and on a table in the pharmacy area. It is not clear why this would constitute a violation if the clinic was then open and preparing prescriptions for dispensing.

As for the observation that multiple employees had access to the dispensing room, under DEA regulations, ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a). Among the factors which DEA considers is ''[t]he adequacy of *supervision* over employees having access to manufacturing and storage areas.'' *Id.* at 1301.71(b)(11) (emphasis added). While the affidavits state that multiple employees had access to the dispensing room, the record is devoid of evidence establishing whether the supervision of these employees was adequate.[7]

The evidence also shows that clinic personnel (including Respondent) violated various provisions of State law. More specifically, the evidence showed that the clinic employee who filled the prescriptions and dispensed them was not licensed as a pharmacist, but rather only as a pharmacy technician, and that Respondent, who was registered as a dispensing physician, admitted that she did not verify the prescriptions that were dispensed to the patients. Under Florida law in effect at the time of the events at issue here, ''[a] person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.'' Fla. Stat. § 465.0276(1).[8] *See also* Fla. Admin. Code r.64B16–27.1001(3) (''Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.'').

In her written statement, Respondent repeatedly asserted that she believed that the pharmacy technician was actually a licensed pharmacist. I do not find this credible because the affidavit of one of the DOH Investigators establishes that ''on the wall immediately inside the dispensing room,'' there was an 8½ by 11 printout stating that the employee who did the dispensing was a Registered Pharmacy Technician. *See also* Fla. Admin. Code r.64B16–27.100(4) (''The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment.''). In his affidavit, the Investigator further stated that when Respondent said that she did not ''know until today that [J.F.] was not a pharmacist,'' he confronted her with the information regarding the printout, to which Respondent replied that she had ''never been in that room.''

However, in her written statement, Respondent stated that she had been in the dispensing room and seen the technician prepare the labels, count the pills and place them in the bottles for dispensing. Unexplained by Respondent is how she could then have been unaware that J.F. was not a licensed pharmacist. I thus reject Respondent's contention that she believed that J.F. was a pharmacist and could lawfully dispense medications. Moreover, it is a violation of the Florida Medical Practice Act to ''delegat[e] professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them.'' Fla. Stat. Ann. § 458.331(w).

The DOH Investigators further found that the clinic did not have pedigree documents for any of the drugs that were on hand. As noted above, Respondent admitted that drugs were ordered under her DEA registration during her time there. Florida law provides in relevant part that ''[a] drug or device is adulterated . . . [i]f it is a prescription drug for which the required pedigree paper[9] is nonexistent.'' *Id.* § 499.006(10). Moreover, under state regulations, ''[a] copy of the pedigree paper must be maintained by each recipient,'' Fla. Admin Code r. 64F–12.012(3)(d), and for a ''permittee[] located in the state . . . must be readily available and immediately retrievable, i.e., subject to inspection at the

[7] Agency regulations explicitly require that non-practitioner registrants limit access to storage areas. *See* 21 CFR 1301.72(d) (security requirements for non-practitioners; ''The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees.''). There is, however, no similar requirement applicable to practitioners.

[8] In addition, under Florida law, ''[a] person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section duties, tasks, and functions that do not fall within the purview of s. 465.003(13).'' Fla. Stat. § 465.014(1). However, ''[a]ll such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision.'' *Id.* A dispensing practitioner ''must . . . [c]omply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to'' chapter 465, which regulates the practice of pharmacy. *Id.* § 465.0276(2)(b).

[9] The pedigree paper ''must include either the proprietary name or generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates.'' Fla. Admin Code r. 64F–12.012(3)(a)1. In addition, ''[t]he pedigree paper must clearly identify the invoice to which it relate[s].'' *Id.*

permitted establishment during the inspection.'' *Id.* r.64F–12.012(6)(b).

As the forgoing demonstrates, Respondent failed to comply with a variety of federal and state controlled substance laws and regulations as well as state pharmacy laws and rules. As for the latter, while these laws and rules are applicable to all prescription drugs and not just controlled substances, these violations are properly considered under factor five as other conduct which may threaten public health and safety for two reasons. First, the violations involved the dispensing of controlled substances. Second, violations of state pharmacy rules and food and drug safety provisions are relevant (even if the conduct did not involve controlled substances) in assessing the likelihood of an applicant's future compliance with the CSA. *See Paul Weir Battershell,* 76 FR 44359, 44368 (2011); *Wonderyears, Inc.,* 74 FR 457, 458 n.2 (2009).

On the other hand, the record in this matter establishes that Respondent's record of non-compliance with the CSA was limited to a seventeen-day period. While it may be that this conduct would have continued but for the DOH inspection, Respondent stated in her letter that following the inspection she terminated her relationship at the clinic and there is no evidence disputing this.[10]

It is also acknowledged that Respondent's letter demonstrated some degree of contrition. However, I do not find credible Respondent's numerous assertions that she believed that JF was a licensed pharmacist. In addition, while Respondent emphasizes that her employment at Mercy ''was the first time in [her] professional career that [she] had been a dispensing practitioner,'' and that she ''was completely unaware that [she] had run afoul of the laws governing dispensing practitioners,'' GX 6, at 1, ignorance of the law is no excuse. *See Patrick W. Stodola,* 74 FR 20727, 20735 (2009) (quoting *Hageseth* v. *Superior Ct.,* 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007) (a ''licensed health care provider cannot 'reasonably claim ignorance' of state provisions regulating medical practice'')). Indeed, in her statement, Respondent explained that at the time she took her position, she ''was doing due diligence'' on two internal medicine groups. One must wonder why she did not make a similar effort to familiarize herself with the various requirements applicable to the dispensing of controlled substances under both the CSA and state laws, as well as the manner in which Mercy's business was operated.

DEA can, of course, consider deterrence interests in determining whether to grant or deny an application. *See Joseph Gaudio,* 74 FR 10083, 10094 (2009) (citing *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007)). As I have previously explained, '''even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.''' *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504 (citing *Butz v. Glover Livestock Commission Co., Inc.,* 411 U.S. 182, 187–88 (1973)). ''The '[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest,''' which is manifested in both 21 U.S.C. 823(f) and 824(a)(4). *Gaudio,* 74 FR at 10094 (quoting 72 FR at 36504).

All registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules. Moreover, those registrants who contemplate employment in circumstances in which their registrations are used to operate clinics owned by non-registrants need to recognize that there are serious consequences for failing to comply with the Act and that they remain strictly liable for all activities which occur under the authority of their registrations. *See, e.g., Robert Raymond Reppy,* 76 FR 61154, 61157–58 (2011); *Paul Weir Battershell,* 76 FR 44359, 44368 (2011); *Paul Volkman,* 73 FR 30630, 30643–44 (2008), *pet. for rev. denied* 567 F.3d 215 (6th Cir. 2009). It is no excuse that the practitioner is not the employer of those persons who perform controlled substance activities and lacks the power to hire or fire the employee.

Accordingly, having considered the record as a whole, I conclude that Respondent has not sufficiently demonstrated why she should be entrusted with a new registration. I therefore hold that granting Respondent's application would, at this time, be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). However, given that the violations proved on this record were limited in both their scope and duration, a new application should be given favorable consideration if submitted no earlier than one year from the date of this Order, provided that Respondent meets the following conditions: (1) That she does not engage in any further misconduct, and (2) that she takes a certified Continuing Medical Education course on controlled substance handling and dispensing.

[10] Hanging over this matter is the dark cloud of evidence that Mercy was a pain clinic and that Respondent was seeing some 60 to 65 patients a day to whom she was prescribing such drugs as oxycodone 30mg and 15mg, muscle relaxants such as carisoprodol, and Xanax (alprazolam). However, evidence which creates only a suspicion of wrongdoing does not constitute substantial evidence. *See NLRB v. Columbian Enameling & Stamping Co., Inc.,* 306 U.S. 292, 299–300 (1939). I therefore do not rely on it.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Sigrid Sanchez, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This order is effective July 31, 2013

Dated: June 20, 2013.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Mylan Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on March 8, 2013, Mylan Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Remifentanil (9739)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled