extended the release of augmentation flows on an emergency basis for a longer duration (and higher magnitude) than in prior years based on the emergency criteria established for the releases. In 2014 the total volume released was 64 TAF. As in prior years of implementing flow augmentation, and despite the unprecedented high incidence of infection, no significant mortalities of fish occurred. In 2014 due to the rapid worsening of conditions in the lower Klamath River and the documented occurrence of disease, NEPA compliance was implemented through the ''Emergency'' provisions as identified by the Council of Environmental Quality.

In response to the need to provide augmentation flows in several of the past years, and the indication that such flows will be needed in future years, Reclamation committed to developing a long-term plan to address this need along with the appropriate NEPA compliance. Reclamation has determined an EIS is the appropriate level of NEPA compliance for the Long-Term Plan, and will serve as the Lead Agency.

Additional Information

The purpose of the scoping process is to solicit early input from the public regarding the development of reasonable alternatives and potential environmental impacts to be addressed in the EIS for the lower Klamath River Long-Term Plan. Written comments are requested to help identify alternatives and issues that should be analyzed in the EIS. Federal, State and local agencies, Tribes, and the general public are invited to participate in the environmental review process.

Special Assistance for Public Scoping Meetings

Requests for sign language interpretation for the hearing impaired and all other special assistance needs to participate in the meetings may be submitted by any of the following methods at least five working days before the meeting:

- *Email to:* Mr. Paul Zedonis, *sha-slo-klamath-LTP@usbr.gov*.
- *U.S. Mail to:* Mr. Paul Zedonis, Northern California Area Office, Bureau of Reclamation, 16349 Shasta Dam Boulevard, Shasta Lake, CA 96019.
- *Telephone:* Mr. Paul Zedonis, 530–275–1554.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 12, 2015.

Pablo R. Arroyave,

Deputy Regional Director, Mid-Pacific Region.

[FR Doc. 2015–17208 Filed 7–13–15; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–15–021]

Government in the Sunshine Act Meeting Notice; Change of Time to Government in the Sunshine Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE: July 16, 2015.

ORIGINAL TIME: 2 p.m.

NEW TIME: 3 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.35(d)(2)(i), the Commission hereby gives notice that the Commission has determined to change the time of the meeting of July 16, 2015, from 2 p.m. to 3 p.m.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier notification of this change was not possible.

By order of the Commission.
Issued: July 10, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–17378 Filed 7–10–15; 4:30 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–62]

Odette L. Campbell, M.D.; Decision and Order

On October 26, 2010, an Agency Administrative Law Judge issued the attached Recommended Decision.[1] Therein, the ALJ rejected, as unsupported by substantial evidence, the Government's allegations that: (1) Respondent had unlawfully prescribed methadone to a patient for the purpose of treating the patient's opioid addiction; (2) Respondent had issued a controlled substance prescription to an employee for the purpose of obtaining the controlled substance for her own use; and (3) Respondent could not account for 13 bottles or 390 dosage units of Suboxone. R.D., at 32–43.

However, the ALJ also found that the Government had proved several allegations. These included that: (1) Respondent possessed controlled substances at an unregistered location when she moved her office without obtaining a modification of her registration; (2) Respondent occasionally allowed patients to return controlled substances to her if they did not like the medication or had an adverse reaction to it; and (3) Respondent failed to keep required records (including DEA Form-222s) for her receipts of Demerol, a schedule II controlled substance, as well as both inventories and dispensing logs for Ambien (zolpidem) and Provigil (modafinil), both being schedule IV controlled substances.[2] *Id.* at 30–32; 44; 46–49.

With respect to the latter finding, the ALJ noted that while recordkeeping violations alone can support an order of revocation, Respondent's violations ''occurred over a comparatively short period of time, with substantially fewer controlled substances [than in those cases where revocation was ordered], and with no evidence of actual diversion of any controlled substances.'' *Id.* at 52. The ALJ thus concluded that while ''Respondent's errors and conduct clearly were neglectful and serious during the relevant time period,'' he then reasoned that they were ''likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft'' and that an order of revocation would be disproportionate to the misconduct which was proved. *Id.*

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

[2] The ALJ also noted that ''the evidence indicates that Respondent did not follow adequate security procedures'' in that the controlled substance were not stored ''in a securely locked, substantially constructed cabinet'' and ''Respondent did not maintain control over the key.'' R.D. at 45. However, the ALJ declined to consider the evidence on the ground that the Government did not provide adequate notice in either the Show Cause Order or its Prehearing Statement, notwithstanding that Respondent did not object to the testimony. While the record arguably support a finding that the issue was litigated by consent, *see CBS Wholesale Distributors,* 74 FR 36746, 36750 (2009), the Government did not take exception to the ALJ's ruling. I therefore do not consider the evidence.

The ALJ did not explain why these issues prevented Respondent from maintaining proper records for all of the controlled substances she obtained and dispensed or for ensuring that she obtained a new registration after she moved into her new office.

The ALJ further found that ''Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omission with regard to a revocation penalty.'' *Id.* However, he then found that her ''explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration.'' *Id.*

The ALJ thus recommended that Respondent's registration not be revoked and that she be granted a registration subject to the conditions that she submit, no later than one year after issuance of a new registration, documentation reflecting that she had successfully completed ''accredited training . . . in the proper maintenance, inventory, and recordkeeping requirements for controlled substances.'' *Id.* at 52–53. The ALJ also recommended that Respondent's registration be subject to the condition that for one year after the issuance of a new registration, she submit a log of all controlled substances ''received, maintained and dispensed'' by her each quarter. *Id.* at 53.

The Government filed an Exception to the ALJ's decision. Thereafter, the record was forwarded to this Office for final agency action.

On review, it was noted that Respondent's registration was due to expire on August 31, 2010, one week after the hearing in this matter was conducted. GX 1. Moreover, at the hearing, the Government argued that the proceeding was moot because under an agency regulation, Respondent was required to file her renewal application at least 45 days before her registration expired in order for her registration to remain in existence past its expiration date. Tr. 9. The Government further argued that Respondent had not filed a renewal application for a Texas Controlled Substances Registration with the Texas Department of Public Safety (DPS), and thus, even if Respondent prevailed in the DEA hearing, she would not be entitled to be registered because she lacked state authority as a result of her failing to file for a renewal of her DPS registration.[3] *Id.* at 9–10.

Respondent disputed the Government's contention, asserting that she had filed an application with DPS six months earlier as well as the day before the hearing; she also asserted that she could not obtain a new DPS registration without a DEA registration. *Id.* at 10.

The Government then noted that Respondent had not even attempted to submit a renewal application. *Id.* The Government further argued that because Respondent would still not possess a state license after the DEA proceeding was concluded, there were no collateral consequences which would preclude a finding of mootness. *Id.* at 11. Respondent then offered to ''file a DEA application today after the hearing.'' *Id.* at 12. The ALJ then denied the Government's motion and proceeded to conduct a hearing.

Several months later, Respondent's counsel faxed to the ALJ a copy of a printout from the DPS's Web site which showed that on November 15, 2010, Respondent had been granted a new DPS registration. However, because there was no evidence that Respondent had filed a renewal application, the Administrator ordered the parties to address whether the case was moot. Order, at 2. (June 28, 2011).

Also, having taken official notice that on August 27, 2010, the Texas Medical Board had issued a formal complaint against Respondent charging her with multiple violations of Texas laws based on her prescribing of controlled substances to 19 patients,[4] the Administrator ordered the parties to address the status of the Board proceedings. *Id.* Thereafter, the Government notified this Office that Respondent had, in fact, finally filed a renewal application on November 19, 2010, seven days after it filed its Exception and before the ALJ forwarded the record. Gov. Submission in Response to Order, at 2. The Government further notified this Office that the Medical Board matter was still pending and had gone to mediation, but that further mediation had been postponed and that a date had not been set for further mediation. In her filing, Respondent denied having engaged in non-therapeutic prescribing and asserted that the State's allegation were ''unsubstantiated.''

In its filing, the Government further notified this Office that Respondent had been indicted for health care fraud and was schedule to go to trial in October 2011. Gov.'s Submission at 2 n.1. This Office subsequently determined that on August 19, 2010—approximately one week before the DEA hearing—Respondent was indicted on 30 counts of Health Care Fraud, as well as five counts of altering records during a federal investigation. *See* Docket Sheet at 1, *United States* v. *Campbell,* No. 4:10cr182 (E.D. Tx.).[5]

[3] This proceeding commenced with the issuance of an Order to Show Cause and Immediate Suspension of Registration. Thereafter, both the Texas Medical Board and the Texas Department of Public Safety suspended Respondent's medical license and state controlled substance registration. Accordingly, the Government moved for summary disposition on the ground that because she lacked state authority, she could not be registered with DEA, and thus, her DEA registration should be revoked. The ALJ granted the Government's motion, recommended that her DEA registration be revoked, and thereafter forwarded the then-existing record to this Office for final agency action.

While the matter was under review, Respondent submitted a letter to the ALJ (which was then forwarded to this Office) asserting that the medical board had reinstated her medical license. The Government argued, however, that Respondent was still without state authority because her DPS registration had been revoked and she had not filed a new application. Respondent then submitted a letter in which her counsel asserted that she could not be reinstated by the DPS unless DEA reinstated her registration.

While the parties had engaged in an exchange of letters with each other and the ALJ, neither party filed a motion seeking relief from this Office notwithstanding that the record had since been forwarded to it. The Administrator therefore ordered that if the Government still sought a final order based on Respondent's lack of state authority, it should file a properly supported motion seeking such relief and serve it on Respondent.

Thereafter, the Government filed a request for final agency action, noting that Respondent's DPS registration had not been reinstated, which it supported with appropriate evidence. In opposition, Respondent argued that it was fundamentally unfair and a denial of due process to revoke her DEA registration based on the DPS's action, because the DPS's action was based on the unsubstantiated allegations of the DEA Immediate Suspension Order.

On review, the Administrator noted that it appeared that under Texas law and regulations, Respondent was not entitled to a hearing before the DPS to challenge either the DPS's suspension or the denial of her application for a new registration. *See* Tex. Health & Safety Code § 481.063(e)(3) & (h); *id.* § 481.066(g); *see also* Tex. Admin Code § 13.272(h). Because, if this was so, revoking her registration based on her lack of state authority would preclude her from ever being able to challenge the basis of the Immediate Suspension Order, the Administrator remanded the case to the ALJ with the instruction to first determine whether the DPS would provide her with a hearing on the allegations. The Administrator further instructed that if the DPS had provided or would provide a hearing, the Government could renew its motion for summary disposition; however, in the event DPS would not provide a hearing, the ALJ was to conduct a hearing on the allegations of the Order to Show Cause and Immediate Suspension of Registration.

[4] While the Medical Board had restored Respondent's medical license in October 2009, on August 30, 2010, the Board had filed a formal complaint against her which charged her, *inter alia,* with engaging '' 'in a pattern of non-therapeutic prescribing of controlled substances and/or dangerous drugs.' '' Respondent's Resp. to the Govt's Req. for Status Update, at 6 (quoting Complaint at 2, *In re Campbell,* No 10–6060.MD (Tex. Med. Bd., Aug. 27, 2010)). This proceeding was, however, resolved through mediation and dismissed on the motion of the Texas Medical Board. *See* Order No. 3, *In re Campbell* (Tex. SOAH. Mar 19, 2012).

[5] This Office has also taken Official Notice of the Docket Sheet Entries in this proceeding, as well as

Continued

Under 42 U.S.C. 1320a–7(a)(3), had Respondent been convicted of even a single count of Health Care Fraud, she would have been subject to mandatory exclusion ''from participation in any Federal health care program.'' Moreover, just as a mandatory exclusion is a ground to suspend or revoke an existing registration, it is also ground to deny an application. *See* 21 U.S.C. 824(a)(5) (authorizing suspension or revocation of a registration ''upon a finding that the registrant . . . has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–(7)(a) of Title 42''); *see also Pamela Monterosso,* 73 FR 11146, 11148 (2008) (noting that ''the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303'') (citing cases). Accordingly, this case was held in abeyance pending the final disposition of the Health Care Fraud charges against Respondent.

On March 27, 2013, the United States Attorney offered Respondent a pre-trial diversion agreement, pursuant to which prosecution of the charges would be deferred for a period of 12 months provided she complied with the agreement. The United States Attorney further agreed that upon her ''fulfilling all the terms and conditions of the Agreement'' for the 12-month period, the charges would be dismissed. The Government does not dispute that Respondent complied with the agreement and even submitted a copy of the Certification of Completion of Pretrial Diversion Program, which recommended that the charges against her be dismissed when the diversion agreement expired on March 26, 2014. However, months later, the case still remained open according to the district court docket sheet.

Moreover, during the preparation of this decision, this Office determined that on September 19, 2014, the Texas Medical Board filed a new formal complaint against Respondent seeking the revocation of her medical license. The complaint was based in part on the 2010 indictment for health care fraud and her subsequent entrance into the pre-trial diversion agreement, as well as the results of a July 2013 Lifeguard assessment which found that she ''lacked the fitness to safely practice medicine'' in that she ''displayed a less than adequate knowledge base with many of the practice-based competencies tested, as well as deficiencies in prescriptive practices.'' Mediated Agreed Order, at 1 & 4; *In re Campbell,* (Tx. Med. Bd. Feb. 13, 2015). Because possessing state authority to dispense controlled substances is a prerequisite for holding a DEA registration, *see* 21 U.S.C. 802(21) & 823(f), this proceeding was again held in abeyance pending the resolution of the Board proceeding.

Thereafter, the matter was referred to mediation, and on February 13, 2015, the Board and Respondent entered into a Mediated Agreed Order. *Id.* Therein, the Board found that Respondent has successfully completed the pre-trial diversion agreement, that she had ''complied with all recommendations made as a result of the Lifeguard assessment,'' and that she had ''produced evidence of her ongoing efforts to advance her medical knowledge.'' *Id.* Respondent was thus allowed to retain her state license.

The Government's Exception

As noted above, the Government filed an Exception to the ALJ's Recommended Decision. Because Respondent had allowed her registration to expire and had not filed a renewal application, the Government argued that the Agency should reject the ALJ's ultimate recommendation that Respondent's registration should not be revoked and that she should be granted a restricted registration. Exception, at 2. Noting that the ALJ cited no precedent for maintaining a DEA registration beyond its expiration date where the registrant failed to file a timely renewal application, the Government argued that ''the only possible recommendation to be made by the ALJ is whether the Deputy Administrator should affirm the Immediate Suspension Order issued simultaneously with the Order to Show Cause.'' *Id.* at 1–2. However, as found above, Respondent filed an application for a new registration prior to the ALJ's forwarding of the record to this Office. Thus, notwithstanding that Respondent's registration expired on August 31, 2010, there is an application to act upon.

The Government further contended that ''the issuance of the Immediate Suspension Order'' should be affirmed ''for the reasons discussed in the Government's Post-Hearing Brief.'' Exception, at 2. While Respondent did not file her application until after she received the ALJ's largely favorable decision and the Government filed its Exception, I assume that the Government would likewise seek denial of the application ''for the reasons discussed in the Government's Post-Hearing Brief.'' *Id.*

However, the Agency regulation on Exceptions is quite specific in requiring that a ''party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcripts and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66(a). The purpose of Exceptions is to allow a party to identify the specific factual findings and legal conclusions of the ALJ which it believes to be erroneous. *Cf. The Attorney General's Manual on the Administrative Procedure Act* 87 n.5 (1947) (quoting *Final Report of the Attorney General's Committee on Administrative Procedure,* at 52) (''Too often . . . exceptions are blanket in character, without reference to pages in the record and without in any way narrowing the issues. They simply seek to impose upon the agency the burden of complete reexamination. Review of the hearing commissioner's decision should in general and in the absence of clear error be limited to grounds specified in the appeal.'').

Here, the ALJ previously considered the Government's post-hearing brief and found its evidence unpersuasive on several critical issues, including the allegations that Respondent had issued a prescription to an employee that was actually for her own use and that Respondent was prescribing methadone to treat opioid addiction. With respect to each allegation, the Government relied on unsworn hearsay statements, which the ALJ found were not sufficiently reliable when weighed against the testimony of witnesses which he found credible and the documentary evidence. Because the Government has failed to identify in its Exception why the ALJ erred in reaching these findings, I adopt the ALJ's findings.

As noted above, the ALJ also rejected the Government's evidence regarding the accountability audit. Here again, the Government has failed to identify in its Exception why the ALJ erred in reaching his finding. Indeed, the Government did not even submit the audit computation chart, let alone such documentation as the closing inventory taken by the Investigator. Thus, I must reject the Government's contention.

The ALJ did, however, find that Respondent relocated her practice and possessed and distributed controlled substances at her new location without

Document #27, which sets forth the disposition of an October 6, 2011 hearing conducted by the district court on Respondent's violation of the conditions of her pretrial release, wherein the Court modified the conditions of her release to prohibit her from writing any controlled substance prescriptions.

being registered there. R.D. at 30–32. The ALJ found that this conduct constituted a violation of 21 U.S.C. 822(e) and 827(g), as well as 21 CFR 1301.51. *Id.* at 32. The ALJ found, however, that there was evidence that mitigated the violations as Respondent had notified the Texas DPS that she had changed her practice location and concluded that her failure to notify the Agency of her address change was not ''intentionally deceitful'' but the result of an ''omission.'' *Id.*

The ALJ further found that Respondent admitted that she occasionally accepted controlled substances from patients which she then destroyed, notwithstanding that no provision in the CSA or DEA regulations permits this. R.D. at 44. However, the ALJ also found that there was no evidence that this was a frequent occurrence or evidence that the drugs were diverted; rather, ''the un-rebutted testimony was that the drugs were destroyed.'' *Id.* Be that as it may, it is still a violation of the CSA. *See* 21 U.S.C. 844(a) (''It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter.'').

Next, the ALJ found that Respondent failed to keep proper controlled substance records. Specifically, the ALJ credited the testimony of the Diversion Investigators that Respondent's records showed that she had dispensed Demerol, a schedule II controlled substance. R.D. at 47. Because it is a schedule II drug, Respondent was required to document her purchases and receipts of the drug on DEA Form 222. 21 CFR 1305.04(a); *id.* § 1305.12; *id.* § 1305.13(a) & (e). She was also required to retain a copy of the form for at least two years from the date of the order. *Id.* § 1305.17; 21 CFR 1304.04(a). However, during a search of Respondent's registered and non-registered locations (as well as her home), no Form 222s were found. R.D. at 47. Nor were there any invoices for the Demerol.

Moreover, while the Investigators found that Respondent was dispensing other controlled substances, including Ambien (zolpidem) and Provigil (modafinil), each of which is a schedule IV drug, *see* 21 CFR 1308.14 (c) & (e); there were no inventories or dispensing logs for either drug. R.D. at 47.

In mitigation, the ALJ credited Respondent's testimony that she had never been the subject of a prior DEA investigation; that she had been evicted from her office at the time of the events at issue; that she also had issues with employees, ''to include alleged misuse of prescription pads, theft, and related financial matters''; and that she was a workaholic. R.D. at 49. While finding her testimony to be generally credible, the ALJ concluded that the Government had made out a *prima facie* case, noting that ''[o]n balance . . . Respondent's recordkeeping violations, handling of returned controlled substances and failure to properly change her registered address weigh significantly in favor of revocation'' or the denial of her application. *Id.* at 50.[6]

Turning to whether Respondent had produced sufficient evidence to rebut the Government's *prima facie* case, the ALJ noted that under the Agency's rule, ''where a registrant has committed acts inconsistent with the public interest, a 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 10083, 10094 (2009). Moreover, in setting the appropriate sanction, the Agency also considers the egregiousness of the proven misconduct and the need to deter future violations by both the Applicant and members of the regulated community. *Fred Samimi,* 79 FR 18698, 18713 (2014) (citing *Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011)).

As for her failure to update her registered address, the ALJ noted that Respondent had updated her address with the Texas DPS and had ''made various efforts to do so with DEA.'' R.D. at 51. However, the ALJ found that Respondent's explanation for her recordkeeping violations was ''less specific.'' *Id.* Noting her testimony that Respondent ''believed she 'had very effective oversight' of controlled substances,'' the ALJ found that her ''belief is contradicted by [her] own testimony.'' *Id.* Specifically, the ALJ noted that ''Respondent testified that she relied heavily on her staff with regard to inventory and maintenance of controlled substances and . . . did very little herself.'' *Id.* While the ALJ concluded that her ''testimony as a whole demonstrated that she understood the seriousness and importance of recordkeeping requirements,'' *id.,* at no point in her testimony did she acknowledge that as a DEA registrant, she was the person ultimately responsible for maintaining the required records.

[6] As explained above, as of the date of the hearing, Respondent had not filed a timely renewal application and her registration expired one week after the hearing and before the record was forwarded.

Noting that Respondent's recordkeeping violations ''occurred over a comparatively short period of time, with substantially fewer controlled substances, and with no evidence of actual diversion,'' the ALJ rejected the Government's contention that revocation was the appropriate sanction, reasoning that it was disproportionate to her misconduct. *Id.* at 52. However, he also found that while ''Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omissions . . . [her] explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration.'' *Id.*

Indeed, Respondent offered no plan to avoid future recordkeeping violations. And while I agree that the *proven* misconduct would not support a sanction of revocation (in the event she had not allowed her registration to expire), consistent with other cases it does support a period of outright suspension. *See Kenneth Harold Bull,* 78 FR 62666, 62676 (2013) (imposing six-month suspension based on physician's failure to maintain records where his dispensing activity appeared to be limited and there was no evidence of diversion); *see also Paul Weir Battershell,* 76 FR 44359, 44368–69 (2011). Moreover, while the ALJ explained that ''[t]he Respondent's errors were neglectful and serious during the relevant time period, and likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft,'' R.D. at 52, none of these explain why she was missing records documenting her controlled substance activities even months after her eviction and when she was continuing to possess and dispense controlled substances.[7]

The ALJ recommended that Respondent be granted a restricted registration subject to the conditions that: (1) ''no later than one (1) year after issuance'' of a registration, she provide documentation that she has successfully completed a course in controlled substance recordkeeping, and (2) that she submit to the nearest DEA Field Division Office, on a quarterly basis, a

[7] While Respondent maintained that she was locked out of her first location (4851 I–35 East, Denton, TX.), she also testified that her staff had packed up the medical records prior to her eviction. Tr. 200. Moreover, in her testimony, Respondent stated that the judge in the eviction case granted her ''a brief period of time'' to retrieve her medications. *Id.* Unexplained is why she would not have also retrieved any controlled substance records at this time.

log of all controlled substances received, maintained and dispensed.

I reject these conditions as insufficient to protect the public interest. As explained above, Respondent offered no plan to address the recordkeeping violations that were proved on the record. In the absence of evidence that Respondent has successfully completed a course in controlled substance recordkeeping, allowing Respondent to possess, dispense and administer controlled substance would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f).

Accordingly, while I will grant Respondent's application, upon the issuance of her registration, it shall be suspended for a period of six months. I will further order that her registration be restricted to authorize her to engage in only the prescribing of controlled substances. Respondent shall not be allowed to possess any controlled substance unless she obtains it pursuant to the lawful order of a practitioner to treat a legitimate medical condition. Moreover, Respondent may not accept any manufacturer's or distributor's sample of any controlled substance other than those provided to her by a duly authorized medical professional in the course of treating her for a legitimate medical condition.[8]

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 Odette L. Campbell, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, granted subject to the conditions set forth above. I further order that upon the granting of the application, the registration shall be suspended for a period of six months. This Order is effective August 13, 2015.

Dated: July 6, 2015.

Chuck Rosenberg,

Acting Administrator.

Larry P. Cote, Esq., for the Government.
Jeffrey C. Grass, Esq., for Respondent.

[8] In the event Respondent provides evidence that she has completed a course in controlled substance recordkeeping, these conditions will be removed from her registration one year from the effective date of this Order. However, in the event Respondent is granted authority to possess, administer and dispense controlled substances, she shall provide, on a quarterly basis, a log of all controlled substances she receives, possesses, dispenses, or otherwise disposes of, to the nearest DEA Field Division Office. Said log shall be submitted no later than ten (10) calendar days following March 31st, June 30th, September 30th, and December 31st. This requirement shall remain in effect for the duration of the initial period of re-registration. However, if Respondent fully complies with this condition, this requirement shall be removed upon the renewal of her registration.

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

Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* to determine whether Respondent's Certificate of Registration (COR) with the Drug Enforcement Administration (DEA) should be revoked and any pending applications for renewal or modification of that registration should be denied. Without this registration, Respondent, Odette L. Campbell, M.D., of Denton, Texas, would be unable to lawfully possess, prescribe, dispense or otherwise handle controlled substances.

On August 4, 2009, the Deputy Administrator of the DEA immediately suspended Respondent's registration on grounds that Respondent had failed to comply with a standard referenced in 21 U.S.C. 823(g)(1) and that her continued registration during the pendency of these proceedings would constitute an immediate danger to the public health and safety. The Deputy Administrator simultaneously issued an Order to Show Cause (OSC) why DEA should not revoke Respondent's DEA COR as a practitioner pursuant to 21 U.S.C. 824(a)(4) because her continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f) and (g)(2)(E)(i). The OSC further alleged, in substance, that:

1. Respondent is currently registered with the DEA as a practitioner in Denton, Texas. Respondent is also authorized to treat no more than thirty narcotic-dependant patients at any one time with Schedule III through V narcotic controlled substances that are approved by the Food and Drug Administration for that indication. Respondent's current DEA registration was set to expire by its own terms on August 31, 2010.

2. Respondent moved her practice to another location in Denton without notifying the DEA and possessed and dispensed controlled substances at an unregistered location in violation of Federal law.[1]

3. On January 30, 2009, Respondent prescribed the Schedule II controlled substance methadone to an individual to treat opioid addiction.[2]

4. In March 2009 Respondent prescribed controlled substances to an employee for other than legitimate medical purposes.[3] At Respondent's request a local pharmacy filled the prescription and the controlled substances were returned to Respondent for her personal use.[4]

5. An accountability audit conducted at Respondent's medical office in April 2009 revealed an unexplained shortage of approximately thirteen bottles, or 390 dosage units, of Suboxone. Respondent's dispensing log indicated that she dispensed other controlled substances, such as Demerol, but she was unable to provide investigators with records showing receipt of these controlled substances.[5]

The Order to Show Cause and Immediate Suspension of Registration (OSC/IS) advised Respondent of her right to a hearing in this matter, and further advised that if she requested a hearing, it would be held on September 21, 2009, at DEA headquarters in Arlington, Virginia. Respondent timely filed a request for a hearing on the issues identified in the OSC/IS and referred all future correspondence to counsel.

On September 8, 2009, counsel for the Government filed a motion for summary disposition, asserting, in substance, that Respondent currently lacked authority to handle controlled substances in Texas, the jurisdiction in which she is licensed to practice medicine and in which she holds a DEA registration, and that the DEA does not have statutory authority to maintain a registration if the registrant does not have state authority to handle controlled substances in the state in which she conducts business.[6] Counsel for the Government further asserted that even if the suspension of Respondent's Texas medical license is temporary or there is the potential for Respondent's state controlled substance privileges to be reinstated, ''summary disposition is warranted because revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement.'' [7] Counsel for the Government attached to his motion a copy of an Order of Temporary Suspension (Without Notice of Hearing) dated August 19, 2009, in which a Disciplinary Panel of the Texas Medical Board suspended Respondent's medical license. (ALJ Ex. 10.)

On September 11, 2009, counsel for Respondent[8] entered his appearance in this matter and filed a response to the Government's motion. Counsel for Respondent asserted that the Texas Medical Board action required that Respondent's DEA registration be suspended, but requested a stay in the instant proceedings pending resolution of the state proceedings.

On September 14, 2009, Administrative Law Judge (ALJ) Mary Ellen Bittner[9] issued an Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (Recommended Decision), which granted the Government's motion for summary disposition and recommended that Respondent's DEA registration be revoked and any pending applications denied on the basis that Respondent's state medical license had been suspended and she was therefore

[1] Citing 21 U.S.C. 841(a)(1), 822(3) and 827(g).

[2] Citing 21 U.S.C. 823(g)(1); 21 CFR 1306.04(c).

[3] Citing 21 CFR 1306.04.

[4] Citing 21 U.S.C. 843(a)(3).

[5] Citing 21 CFR 1304.21.

[6] Citing *Roy Chi Lung, M.D.,* 74 FR 20,346 (DEA 2009); *Michael Chait,* 73 FR 40,382 (DEA 2008); *Shahi Musud Siddiqui, M.D.,* 61 FR 14,818 (DEA 1996); *Michael D. Lawton, M.D.,* 59 FR 17,792 (DEA 1994); and *Abraham A. Chaplan, M.D.,* 57 FR 55,280 (DEA 1992).

[7] ALJ Ex. 10 at 2 (citing *Stuart A. Bergman, M.D.,* 70 FR 33,193 (DEA 2005); *Roger A. Rodriguez, M.D.,* 70 FR 33,206 (DEA 2005)).

[8] Richard Alley, Esq.

[9] ALJ Bittner was designated the presiding officer in this matter from August 28, 2009, until June 8, 2010.

without state authority to handle controlled substances. (ALJ Ex. 3.)

On October 29, 2009, Government counsel submitted a letter to the ALJ noting Respondent's request that the matter be set for hearing because Respondent's medical license had been restored by the Texas Medical Board. While the Government conceded the medical license had been restored, the Government maintained that Respondent ''nonetheless still does not have authority to prescribe controlled substances in Texas'' because ''Respondent's state controlled substance registration was revoked by the Texas Department of Public Safety on August 4, 2009, and that there are no applications currently pending for Respondent.'' (ALJ Ex. 12.)

On November 3, 2009, Counsel for Respondent again requested a hearing, noting that ''in speaking with the Texas Department of Public Safety (DPS) . . . attorneys, they have stated that Dr. Campbell cannot be reinstated unless DEA reinstates her license . . . [o]bviously this reasoning is a tautological chicken and the egg quandary and denies Dr. Campbell her due process rights.'' (ALJ Ex. 13.)

On January 19, 2010, the Deputy Administrator issued an Order outlining the procedural history of the matter and inviting the parties to submit a motion, properly supported, that seeks the particular relief requested. (ALJ Ex. 4.)

On January 29, 2010, Government filed a Request for Final Agency Action and on February 8, 2010, Respondent filed her Response. (ALJ Exs. 14, 15.)

On May 11, 2010, the Deputy Administrator remanded the matter to the ALJ for further proceedings. The Deputy Administrator found that although Respondent's Texas medical license had been restored, Respondent's state controlled substance registration was terminated on August 4, 2009, and Respondent was therefore without state authority to handle controlled substances. The Deputy Administrator further found that the applicable Texas statutes and regulations may not permit Respondent to challenge the termination of her state controlled substance registration because the termination was based on the immediate suspension of Respondent's DEA registration. If that is the case, Respondent will be denied the opportunity to challenge the revocation of her DEA registration and her state controlled substance registration, which will effectively deny Respondent her right to due process. The Remand Order therefore directed the ALJ to determine what action the Texas Department of Public Safety (DPS) has taken on Respondent's application for a state registration and whether the DPS has provided or will provide Respondent with a hearing; if not, Respondent is entitled to an expedited hearing on the allegations of the OSC/IS. (ALJ Ex. 5.)

I. Procedural Issue

What action the Texas Department of Public Safety (DPS) has taken on Respondent's application for state registration to handle controlled substances and whether the DPS has provided or will provide Respondent with a hearing; and, if the DPS has determined that Respondent is not entitled to a hearing, to conduct an expedited hearing on the allegations of the OSC/IS served on Respondent on August 4, 2009.

A. The Government's Contentions

The Government first contends that Respondent's alleged due process violations and the failure of the Texas DPS to provide Respondent with a hearing regarding the revocation of her state controlled substance license are beyond the jurisdiction of this agency to adjudicate and would properly be heard by the Texas courts and the DPS.

The Government further argues that because Respondent currently lacks authority to handle controlled substances in Texas, the jurisdiction in which she is licensed to practice medicine and in which she holds a DEA registration, ''any fact-finding proceeding regarding the original basis for the Order to Show Cause [is] moot.'' [10] Citing 37 Tex. Admin. Code § 13.274(b), the Government contends that the DPS will not automatically restore Respondent's controlled substances registration even if Respondent prevails in these proceedings because the DPS will not reinstate a revoked registration sooner than one year from the date of the final revocation and upon filing of a new application for registration. According to the Government, these proceedings are therefore moot because, if Respondent's DEA registration is reinstated, the Government would have to immediately reinitiate proceedings by issuing an OSC on the ground that Respondent lacks authority to handle controlled substances in Texas.

The Government also asserts that Texas law does provide Respondent a mechanism to seek reinstatement of her DPS registration under Texas Health & Safety Code § 481.066(j) but Respondent has failed to seek a reinstatement under that authority. Under Texas Health & Safety Code § 481.066(j), the Governments contends that Respondent should be able to show good cause for reinstatement of her DPS registration based on the Texas Medical Board finding that ''rejected the Government's allegations serving as the basis of the suspension of Respondent's DEA registration.'' (ALJ Ex. 18.)

B. Respondent's Contentions

Respondent first contends that the allegations contained in the OSC/IS are untrue and, therefore, her DEA registration should not be ''permanently revoked.'' Respondent argues that 37 Tex. Admin. Code § 13.274(b)(1)(B) provides that within one year after a DPS revocation becomes final, the DPS will consider a request for reinstatement if Respondent demonstrates by a preponderance of the evidence that Respondent's DEA registration has not been permanently revoked. Respondent further contends, however, that it will be pointless to request a DPS hearing on the matter until after the DEA has issued a final order because the sole basis for the DPS revocation is the fact that the DEA suspended Respondent's DEA registration.

[10] (ALJ Ex. 18 at 3.)

Respondent similarly contends that the DPS will not provide a hearing on the matter of reinstatement one year after revocation under 37 Tex. Admin. Code § 13.274(b)(2)(A) because there is no question of fact regarding whether DPS has taken adverse action against Respondent. Again, Respondent argues that such a hearing request will not be granted because the only issue pertains to the status of Respondent's DEA registration. Respondent contends that the restoration of her DEA registration is the only evidence necessary or sufficient to negate the basis of the revocation of her DPS registration and, therefore, only a DEA hearing can result in the resolution of the matter with Texas and with the DEA.

Respondent also argues that Respondent has exhausted her attempts at reinstatement of her DPS registration under a showing of good cause. (ALJ Ex. 19.)

C. Discussion and Conclusions

The parties' contentions and the Remand Order essentially concern two procedural issues: (1) whether Respondent has been afforded due process under federal law; and (2) whether the fact that Respondent does not possess state authority to handle controlled substances renders this proceeding moot.

(1) Federal Due Process and Mootness Doctrine

The Supreme Court of the United States has held that the ''Due Process Clause of the Fifth Amendment prohibits the United States, as the Due Process Clause of the Fourteenth Amendment prohibits the States, from depriving any person of property without 'due process of law.' '' *Dusenbery* v. *United States,* 534 U.S. 161, 167 (2002). ''The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.' '' *Mathews* v. *Eldridge,* 424 U.S 319, 333 (1976) (citations omitted).

In analyzing procedural due process issues, courts have generally engaged in a ''two-step inquiry: (1) Did the individual possess a protected interest to which due process protection was applicable? (2) Was the individual afforded an appropriate level of process?'' *Ward* v. *Anderson,* 494 F.3d 929, 934 (10th Cir. 2007) (citations omitted).

As to the first step, a license has consistently been held to be a property interest entitled to due process protection. *Barry* v. *Barchi,* 443 U.S. 55, 64 (1979).

The second step of the analysis in this case rests significantly on the interrelationship between the DEA-initiated OSC/IS and the relevant Texas statutes and regulations pertaining to the regulation of controlled substances by practitioners. The United States Court of Appeals for the Fifth Circuit has held that the DEA's revocation of a registration based on a state agency action ''would only be invalid if the alleged state agency errors rose to the level of a federal due process violation . . . .'' *Maynard* v. *DEA,* 117 Fed. App'x 941, 945 (5th Cir. 2004). The DEA's revocation of a COR amounts to the deprivation of a property interest and therefore must comport with the requirements of federal due process. *See Mathews,* 424 U.S. at 333. At a minimum,

federal due process requires that a respondent be afforded adequate notice and opportunity to be heard ''at a meaningful time and in a meaningful manner.'' *Id.; see also Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 313 (1950).

Agency precedent has consistently held that where, for example, a state action precedes a DEA OSC or OSC/IS, the DEA need not inquire into the validity of a state licensing agency's decision. *George S. Heath, M.D.,* 51 FR 26,610 (DEA 1986). Similarly, where there is an independent basis for the state action, the DEA has relied on the state authority without further inquiry. *See Joseph Baumstarck, M.D.,* 74 FR 17,525 (DEA 2009); *Michael D. Lawton, M.D.,* 59 FR 17,792 (DEA 1994); *George S. Heath, M.D.,* 51 FR 26,610 (DEA 1986); *Hezekiah K. Heath, M.D.,* 51 FR 26,612 (DEA 1986). Summary disposition based on suspension of a respondent's state authority, of even a temporary nature, has been consistently upheld. *E.g., Roger A. Rodriquez, M.D.,* 70 FR 33,206 (DEA 2005). The Controlled Substances Act (CSA) requires that a practitioner be currently authorized to handle controlled substances in ''the jurisdiction in which he practices'' in order to maintain a DEA registration.[11] Therefore, because ''possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,'' the DEA has repeatedly held that ''the CSA requires the revocation of a registration issued to a practitioner whose State license has been suspended or revoked.'' *See Scott Sandarg, D.M.D.,* 74 FR 17,528 (DEA 2009) (citing *David W. Wang, M.D.,* 72 FR 54,297 (DEA 2007); *Sheran Arden Yeates, M.D.,* 71 FR 39,130 (DEA 2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104 (DEA 1993); and *Bobby Watts M.D.,* 53 FR 11,919 (DEA 1988)).

A review of agency precedent, however, reveals no instance where a respondent's registration has been the subject of a final revocation by summary disposition where state action was triggered *solely* by the DEA suspension process, and the respondent was afforded no opportunity to be heard ''at a meaningful time and in a meaningful manner.'' *Mathews* v. *Eldridge,* 424 U.S 319, 333 (1976) (citations omitted). To the contrary, the DEA has recently rejected a due process argument by a respondent claiming the state action was based on the DEA's order immediately suspending his registration, stating: ''Respondent ignores, however, that the State's suspension order did not rely solely on my Order. Rather, the State Board also relied on Respondent's indictment by a federal grand jury . . . . [T]he board clearly conducted its own independent evaluation of the evidence against him and did not simply piggyback on my Order of Immediate Suspension.'' *Joseph Baumstarck,* 74 FR 17,525, 17,527 (DEA 2009) (internal citations omitted); *see also Oakland Medical Pharmacy,* 71 FR 50,100, 50,102 (DEA 2006*)* (rejecting the contention that it is circular for DEA to rely on a state suspension order to revoke a registration where the State did not rely solely on the DEA order in suspending a practitioner's state license).

The Texas authorities in the instant case did ''piggyback'' solely on the OSC/IS to suspend Respondent's state registration on August 4, 2009, and relied exclusively on the DEA action to suspend Respondent's state authority.[12]

The Government also argues in substance that the ultimate issue in this case is ''moot'' given Respondent's current lack of state authority.[13] Additionally, as of the hearing date, Respondent's registration was due to expire by its terms on August 31, 2010, and there is no evidence of record indicating that Respondent has submitted an application for renewal.[14] The Government's mootness argument with regard to Respondent's current application status is misplaced because this proceeding began as an immediate suspension. To find otherwise would be contrary to the applicable regulation and agency precedent.[15]

In *William R. Lockridge, M.D.,* 71 FR 77,791 (DEA 2006), the agency declined to apply the mootness doctrine to a case in which the respondent's registration had expired several months before the hearing and a renewal application had not been timely filed. In that decision, the Agency concluded that

> a case remains a live dispute when 'collateral consequences' attach to a proceeding which otherwise would be moot . . . . As several courts have noted in cases involving sanctions against licensed professionals such as attorneys, even a temporary suspension followed by a reinstatement does not moot a challenge to the initial suspension because the action 'is harmful to a [professional's] reputation, and 'the mere possibility of adverse collateral consequences is sufficient to preclude a finding of mootness.'

Id. at 77,797 (internal citations and formatting omitted). Additionally, ''the issuance of an immediate suspension creates collateral consequences beyond those that are present when the Government serves a Show Cause Order but allows the registrant to continue to handle controlled substances throughout the litigation.'' *Id.*

Consistent with the rationale set forth in *Lockridge,* I find that application of the mootness doctrine to Respondent's case is unwarranted and would deny both Parties an opportunity to resolve the evidentiary issues, as well as prejudice the public interest. Additionally, there is no indication that Respondent intends to suspend her medical practice or not seek restoration of her registration. *See Meetinghouse Community Pharmacy, Inc.,* 74 FR 10,073 (DEA 2009). Absent an opportunity to be heard ''at a meaningful time and in a meaningful manner'' under the Texas statutory scheme, reliance on agency precedent, including the mootness doctrine, to support summary disposition in this instance is entirely misplaced.

(2) The Texas Statutory and Regulatory Scheme

The Texas Controlled Substances Act (Texas CSA), Tex. Health & Safety Code § 481.001 et. seq., governs the registration of practitioners to dispense controlled substances in Texas. Pursuant to § 481.066(b), ''[t]he director may cancel, suspend, or revoke a registration, place on probation a person whose license has been suspended, or reprimand a registrant for cause described by Section 481.063(e).'' In addition, Section 481.063(e)(3) authorizes the denial of an application for a state registration ''to manufacture, distribute, analyze, [or] dispense . . . controlled substance[s]'' if the applicant's DEA registration has been ''suspended, denied, or revoked'' under the Federal Controlled Substances Act defined as 21 U.S.C. Section 801 *et seq.*[16]

The Texas regulatory structure for practitioners is further governed by the Texas Administrative Code, Title 37, Part 1, Ch 13. A ''registration terminates: . . . (3) when a regulatory board or DEA accepts a voluntary surrender, or denies, suspends, or revokes a license or a federal controlled substance registration. . . .'' [17] Of significance, the Texas Administrative Code states that the ''director will revoke a registration if the registrant: (1) violates a ground of denial described in the Act, § 481.063(e).'' [18] The Code further provides that upon revocation under this section, ''the registrant may request a hearing, *unless otherwise stated in the Act.''* [19] The state due process requirements for licenses, set forth at Tex. Gov't Code Ann. § 2001.054, do not apply to suspensions and revocations pursuant to Texas CSA §§ 481.063(e)(2)(A) or (B), (e)(3), (e)(4) or (e)(9). *Maynard* v. *DEA,* 117 Fed. App'x 941 (5th Cir. 2004); *see* Tex. Health & Safety Code Ann. § 481.063(h).

The applicable Texas statutes and regulations contemplate a right to a hearing pursuant to the Texas APA in certain enumerated circumstances, but not where the initial suspension or revocation was based solely on federal action.[20] Consistent with the foregoing, the Respondent has not been afforded a hearing in Texas nor is one contemplated. The procedural due process available to Respondent under Texas law

[11] *See* 21 U.S.C. 802(21).

[12] (*See* Gov't Ex. 5; Gov't Ex. 6; Gov't Ex. 7; Resp't Ex. 2.)

[13] (ALJ Ex. 18 at 3.)

[14] At hearing, the Government represented that ''there's no indication in the DEA system that an attempt was even made to submit a renewal application.'' The Respondent questioned the requirement ''to do meaningless acts if it's going to be kicked back,'' but indicated she would file a DEA application immediately. (Tr. 10–12.)

[15] 21 CFR 1301.36(h) states that ''[a]ny suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.'' This section is distinguishable from the extension requirements for an ''applicant . . . who is doing business under a registration . . . not revoked or suspended . . . .'' 21 CFR 1301.36(i).

[16] *See* Tex. Health & Safety Code Ann. § 481.002(18) (identifying the federal Controlled Substances Act).

[17] 37 Tex. Admin. Code § 13.30 (2010).

[18] *Id.* § 13.274.

[19] *Id.* § 13.274(d) (emphasis added).

[20] I have also carefully considered the ''informal hearing'' provisions pursuant to § 13.301, but do not find that provision adequate to afford Respondent a meaningful right to a hearing, consistent with due process.

simply cannot support summary disposition on the facts of this case. Accordingly, I find that Respondent is entitled to a federal administrative hearing on the substantive issues alleged in the OSC/IS.

II. Substantive Issue

Whether the record establishes that Respondent's DEA COR BC0181999 as a practitioner should be revoked and any pending applications for renewal or modification of that registration should be denied because her 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. Findings of Fact

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

A. Stipulated Facts

Respondent is registered as a practitioner in Schedules II–V under DEA registration number BC0181999.

B. General Overview

Respondent's State Medical License and Controlled Substance License

The Texas Medical Board issued an Order of Temporary Suspension (without Notice of Hearing) on August 19, 2008, thereby rendering Respondent's Texas medical license temporarily suspended. (Gov't Ex. 6; Tr. 33.) On October 16, 2009, the Texas Medical Board issued an Order Denying Temporary Suspension or Restriction of Texas Medical License, thereby reinstating Respondent's Texas medical license. (Gov't Ex. 7; Tr. 33.) The Texas Department of Public Safety revoked Respondent's Controlled Substances Registration on August 4, 2009, based solely on the Drug Enforcement Administration's immediate suspension of Respondent's Controlled Substance Registration.[21] (Resp't Ex. 2.). Respondent was previously disciplined by the Texas Medical Board on three separate occasions between December 2000 and April 2009; each action resulted in a monetary fine.[22]

Dr. Odette Louise Campbell (Respondent)

Respondent attended the College of William & Mary in Williamsburg, Virginia. She received a master's degree in psychology from Virginia Commonwealth University and attended medical school in Virginia. Respondent completed internal medicine and oncology residency programs in Philadelphia and remained at the hospital as an attending physician. She relocated to Galveston, Texas, and then to Dallas, Texas, where she has practiced medicine since approximately 1991. (Tr. 110.) Between 1999 and 2002, Respondent built four cancer centers. She built a fifth cancer center in 2005 at 4851 South I–35 East, Corinth, Texas. (Tr. 112.) She has been involved in multiple research projects regarding lymphoma, central nervous system lymphoma and the method of delivery of fentanyl to cancer patients. (Tr. 114.)

Dr. Robert James Babuji (Dr. Babuji)

Dr. Babuji is a practicing physician. He completed his basic medical degree at Stanley Medical College in Madras, India in 1986; he completed general internal medicine training in the United Kingdom from 1987 until 1991; from 1991 until 1992, Dr. Babuji conducted basic research in cardiology; in 1994, he relocated to the United States and completed residency training at the University of Utah in Salt Lake City, Utah; he completed an advanced heart failure and transplantation fellowship in Salt Lake City, a cardiology fellowship at the University of Virginia in Charlottesville and Salem, Virginia, and then a cardiology fellowship in San Francisco, California; in 1999, Dr. Babuji returned to the United Kingdom where he practiced cardiology and internal medicine; in 2002, he returned to the U.S. to start in private practice in Florida and then later in Dallas, Texas, where he has practiced in cardiology, internal medicine, and primary care for the last three years. (Tr. 265.) Dr. Babuji is not certified in pain management but based on his training and experience is familiar with the procedures involved in pain management, based in part on his treatment of patients with numerous pain conditions. Dr. Babuji further testified that he is familiar with the standard of care required to treat patients with chronic pain syndrome. (Tr. 266.)

C. DEA Investigations

(a) DEA Diversion Investigator Joel Lynn Dunn (DI Dunn)

DI Dunn has been a DEA Diversion Investigator for six years. He is assigned to the Dallas Field Division. DI Dunn received training as a diversion investigator at the DEA training academy. (Tr. 15.)

(b) DEA Diversion Investigator Anita Chalmers (DI Chalmers)

DI Chalmers has been a DEA Diversion Investigator for ten years. She is assigned to the Dallas Field Division, where she has been employed for twenty years. (Tr. 91.)

(c) DEA Diversion Investigator Richard Leakey (DI Leakey)

DI Leakey has been a DEA Diversion Investigator for approximately seven years. He is assigned to the Dallas Field Division. (Tr. 98.)

(d) Respondent's Registered Location

Respondent's DEA-registered location is the Corinth Medical Group, 4851 I–35 East, Denton, Texas. Respondent was evicted from that location in late 2008 and moved to a temporary location (Collier Street) for an unknown length of time and then to a permanent location at 431 Mesa Drive on or about February 1, 2009. (Tr. 160.) Respondent did not move any controlled substances from the Denton location and the medications were destroyed prior to Respondent's eviction. (Tr. 197–98.) DI Dunn testified that Respondent was practicing at 431 Mesa Drive in April 2009, when the FBI executed a search warrant of that location; that Respondent was not authorized to possess controlled substances at that location; and that controlled substances were found there. (Tr. 52, 53.) DI Dunn further testified he was unaware of any requests from or attempts made by Respondent to modify the address of her registered location but that Respondent has updated her registered location in the past and Respondent did not have a practice at 4851 I–35 East. (Tr. 85, 87.)

Respondent did update her new Mesa Drive registered address with the Texas Department of Public Safety and the Texas Medical Board. (Tr. 85, 160.) Respondent testified that she contacted the DEA seeking copies of records and provided her new address at that time. Respondent further stated that she believed she had fulfilled her requirement to change her registered address because she received documents from the DEA at 431 Mesa Drive. (Tr. 160.)

Respondent stated in a written request for hearing dated August 27, 2009, that

[m]y office administrator notified the Dallas office of the DEA in the third week of February 2009 informing them of my new office address. At the time of the notification, my office had requested a copy of a prior report of a theft which occurred in January 2009 be sent to our new office address. In addition, my new office address had been sent to the Texas Medical Board and the Texas DPS office in Austin, Texas. My Duplicate prescriptions reflected my new office address which led me to believe that I had fulfilled the Federal law requirements. I did not also send my new address to the Arlington, Virginia office. I did not know that this additional notification was required until August 4, 2009. I have been unable to complete my change of address successfully on the DEA internet site after multiple attempts prior hereto . . . .

(ALJ Ex. 2.)

(e) Respondent's Issuance of Methadone to Opioid-Addicted Patients

(i) [JF]

DI Dunn testified that a physician must be registered with the DEA as a narcotic treatment program to prescribe methadone; Respondent is not registered with the DEA as a narcotic treatment program. (Tr. 21.) DI Dunn further testified that he did not consult with a physician regarding the standard of care applied when a physician treats a methadone patient with Suboxone but that he does consult the Code of Federal Regulations (CFR) which allows a physician to prescribe Suboxone. (Tr. 70.)

DI Dunn further explained that he was contacted by Lori Price, Director of the Denton Treatment Program, a narcotic treatment program that is registered by the DEA to administer methadone to narcotic addicts; that Ms. Price was concerned because she was aware of a number of

[21] *See* Tex. Health & Safety Code §§ 481.066(b), 481.063(e)(3); 37 Tex. Admin. Code § 13.274(a).

[22] In December 2000, Respondent was cited for substandard chart documentation resulting in a monetary fine, chart monitoring and eight hours of continuing education in medical recordkeeping; Respondent received a monetary fine for failure to timely notify the Texas Medical Board of the relocation of her practice from Corinth to Denton (date not reflected in record but assumed to be prior to April 2009); and in March or April 2009, Respondent received a monetary fine in relation to missing fentanyl. (Tr. 185.)

patients who left the clinic to be treated by Respondent; and that he asked Ms. Price to speak with the patients to ask them to contact him to discuss their treatment. (Tr. 21.)

DI Dunn related that [JF] contacted him and they spoke on several occasions; that [JF] went to Respondent for only one reason: to get off methadone and start taking Suboxone, a Schedule III controlled substance (Tr. 22); and that Respondent never prescribed Suboxone to [JF]. DI Dunn stated that he had not seen [JF]'s medical chart as of the time of Respondent's suspension. (Tr. 67.)

The Government introduced at hearing an unsworn but witnessed statement signed ''[JF],'' [23] indicating that [JF] received from Respondent prescriptions for Valium and methadone and that ''[a]s a result of taking these prescription [sic] I ended up on life sapport [sic] for 30 days. I could not walk or move any part of my body.'' (Gov't Ex. 12.)

Respondent testified that the Denton Treatment Center provides methadone treatment for patients that have methadone addiction issues and that she spoke with Lori Price when she contacted the Center to request [JF]'s records. (Tr. 130.) Respondent further testified that she did prescribe to [JF] 10 mg methadone quantity 120 with instructions to take two tablets two times per day, a thirty-day supply, pursuant to Respondent's instructions, and 10 mg diazepam quantity 90 with instructions to take one tablet every eight hours. (Gov't Ex. 13 & 14.) The medical record for [JF] indicates that [JF] initially began taking methadone to treat chronic pain from ''chronic arthritics pain in [the] neck, lumbar spine and left knee.'' (Resp't Ex. 6, at 8.)

Respondent testified that [JF] was self-referred to Respondent, whose name she said she received from Lori Price, and that [JF] wanted to stop taking methadone and start taking Suboxone in order to save money because she did not have a lot of money to receive treatment from the methadone clinic. (Tr. 132, 141, & 220.) Respondent explained that in order to change a patient's medication from methadone to Suboxone, the physician must first counsel the patient regarding potential side effects and then the patient must detoxify from methadone before taking Suboxone. (Tr. 141.) Respondent further explained that Suboxone was a superior medication for [JF] because it has less of a respiratory depressant effect and [JF] was on oxygen twenty four-hours per day; the Suboxone for [JF] would be used for pain management and [JF] signed a pain management agreement; [JF] had to first detoxify from the methadone and then Respondent would prescribe Suboxone; and [JF] did detoxify from methadone. (Tr. 141; Resp't Ex. 6; Tr. 143.)

Respondent also testified that, during an office visit, she did not prescribe Suboxone because [JF] determined that she was unable to afford the Suboxone; Respondent could not send [JF] back to the treatment center to resume methadone because the center had stopped seeing patients for the day; Respondent provided [JF] with a very low pain management dose of methadone: 20 mg with instructions to take one two times per day; Respondent previously took 120 mg of methadone per day; and if the methadone clinic had been open that day, Respondent would have sent [JF] back. (Tr. 143, 220.) Respondent agreed to place [JF] on a list to receive free Suboxone because Respondent can sponsor two Suboxone patients per year and agreed that Respondent would maintain [JF] on methadone in the interim. (Tr. 144.)

Respondent testified that [JF] was hospitalized four days after [JF]'s visit with Respondent because [JF] had aspiration pneumonia and an upper GI bleed; that no drug screen was performed at the hospital; and it was impossible for [JF] to overdose from Respondent's prescriptions as written. (Tr. 145.)

Dr. Babuji testified the normal course of treatment when starting a patient on Suboxone is to wean the patient off methadone first and then start prescribing Suboxone. (Tr. 267.) Dr. Babuji explained that Suboxone is used to treat opioid addiction and as a pain management tool and that Suboxone would be an appropriate treatment for [JF]. (Tr. 291.) Dr. Babuji further testified that, because [JF] was unable to afford the Suboxone, [JF] was maintained on a smaller dose of methadone to stop further withdrawal and allow a slow withdrawal of the methadone, which would be helpful for chronic pain syndrome, and that there was no reason for [JF] to return to the Denton Treatment Center because [JF] was already on methadone and being weaned off with the intent of starting on Suboxone. (Tr. 268.)

Based on his review of [JF]'s medical records, Dr. Babuji found that [JF] presented to Respondent with pain in the right foot, left knee, the lumbar region and the neck area. (Tr. 267.) Dr. Babuji testified that he reviewed the discharge summary from [JF]'s hospital visit; that the visit was the result of the exacerbation of chronic obstructive pulmonary disease which led to pneumonia; and that there was no evidence of a drug overdose. (Tr. 269, 290.)

(ii) [MM]

DI Dunn testified that he received [MM]'s patient file pursuant to a search warrant executed on the premises of Respondent's practice. (Tr. 43.) A review of the patient file indicated that [MM] was receiving methadone and that [MM]'s previous physician was a narcotic treatment program. (Tr. 41.)

DI Dunn further testified that he spoke with [MM], who told him that [MM] was a lifelong heroin addict; [MM] was seeing Respondent for narcotic treatment because the methadone from Respondent was less expensive than what [MM] received through the narcotic treatment program; and that although [MM] did sign a pain management agreement with Respondent, [MM] was not seeing Respondent for pain management. (Tr. 41.)

[MM] signed an unsworn, but witnessed statement indicating that [MM] was a recovering alcoholic and used heroin; [MM] relapsed and went to the methadone clinic ten years ago; in or around April 2009, after [MM] started receiving Medicaid and Social Security disability, [MM] heard that Respondent would accept Medicaid and prescribe methadone; and [MM] saw Respondent for addiction treatment, not pain treatment. (Gov't Ex. 18.)

[MM]'s patient file indicates [MM] signed a pain management agreement on April 15, 2009; [MM] wrote that [MM]'s reason for visiting Respondent's office was ''methadone, osteoporosis, ativane, and smoking patch''; that [MM]'s previous physician was the Brentwood clinic where [MM] received methadone; and [MM] had complaints and history of back pain and leg pain. [MM]'s patient file also reflects that Respondent noted that [MM] suffered from shoulder and leg pain, opioid addiction, anxiety, depression, chronic back pain and arthritis. (Gov't Ex. 16.)

Respondent testified that [MM] told her that she had been diagnosed with osteoporosis; that she explained to [MM] that she helps patients get off methadone and that she doesn't do methadone maintenance for patients with only addiction problems but she may use methadone to treat chronic pain; that [MM] said [MM] did have chronic pain; that Respondent reviewed the pain management contract with [MM]; and that [MM] presented as a dual-diagnosis patient suffering from both chronic pain and addiction. (Tr. 172.)

(iii) [TR]

DI Dunn testified that [TR]'s patient file was seized pursuant to a search warrant executed at Respondent's practice. DI Dunn has not spoken with [TR]. (Tr. 46.)

Respondent testified that [TR] described [TR]'s condition as back pain, sciatica and severe pain; that [TR] had been on methadone for pain; and that Respondent reviewed the pain management agreement with [TR] and subsequently placed [TR] on methadone with good results. (Tr. 171.)

The patient file for [TR] indicates that [TR] signed a pain management agreement on June 10, 2009; that [TR] stated the reason for [TR]'s visits to Respondent was a need for a new doctor, to resolve ''a lot of female problems and back problems'' and for pain management of severe back and leg pain; that [TR] had a history of or complaints of back pain and arthritis; and that [TR] had received 120 mg of methadone daily from a clinic. (Gov't Ex. 17.)

(f) Respondent's Possession of a Prescription Written in the Name of an Employee

DI Dunn testified that [HM] was an employee of Respondent; that diazepam, written in [HM]'s name, was recovered when a search warrant was executed at Respondent's home. (Tr. 29.) DI Dunn related that he spoke with [HM] regarding the diazepam found in Respondent's home and that [HM] stated that Respondent asked if she could write a prescription in [HM]'s name and then take the medication back from [HM] because Respondent could not write prescriptions in her own name. (Tr. 29.)

DI Dunn conceded that the sole basis for his conclusion that Respondent received a prescription written in [HM]'s name is [HM]'s statement and the recovery of the medication from Respondent's home. (Tr. 83.)

[23] [JF] was not called by either party, nor is there any evidence of record to indicate that [JF] was not otherwise available as a witness.

DI Leakey testified to assisting in the execution of the search warrant at Respondent's residence; that a bottle containing approximately fifty tablets of diazepam was found in the master bedroom's bathroom medicine cabinet; and that DI Leakey participated in DI Dunn's interview of [HM]. (Tr. 99, 100, 105–06.) [HM] signed an unsworn, but witnessed statement indicating that [HM] became a patient of Respondent in November 2008; that [HM]worked for Respondent until April 2009; that in early March Respondent asked [HM] to fill a prescription for her for diazepam and for hormones because Respondent did not have time to see her own doctor; that [HM] filled at CVS the prescription written by Respondent and then provided the medication to Respondent. [HM]'s statement said ''I have *never* taken Valium *ever* . . . .'' (Gov't Ex. 11) (emphasis in original). [HM] concluded by stating, ''[a]fter the FBI did the search of [Respondent's] house she called me to tell me they found the Valium RX in my name & she told them that I kept it at work & it must have fallen in a box of files she brought home. She asked me to tell everyone that story.'' (Gov't Ex. 11 at 2.)

A CVS pharmacy patient prescription record introduced in evidence by Respondent for [HM] indicates that [HM] received 10 mg diazepam quantity 10 on February 27, 2001, from Dr. [VS]. (Resp't Ex. 13.)

Respondent testified that [HM] was initially a patient who had depression, generalized anxiety disorder, morbid obesity, severe rheumatoid arthritis and multiple back surgeries; and that [HM] was taking Xanax and Effexor for anxiety disorder. (Tr. 149; Resp't Ex. 8.) Respondent also testified that [HM] was scheduled for back surgery, in preparation for which Respondent was transitioning [HM] from Xanax to Valium, which she considered to be a safer medication and which was the reason Respondent wrote [HM] the prescription for Valium. (Tr. 150.)

Respondent further testified that [HM] brought into the office the Valium written to [HM] by Respondent and left the bottle sitting on a desk in a room that was being painted; that Respondent, upon seeing a painter in the room with the unsecured medication, feared the medication would be stolen and placed the bottle in her lab coat pocket; Respondent then took her lab coat home and likely placed it in the laundry, as she typically does; Respondent has no further recollection regarding the whereabouts of the medication. (Tr. 153.)

Respondent explained that her relationship with [HM] deteriorated because [HM] intended to sue Respondent over a medical procedure performed by another doctor in Respondent's office. (Tr. 154.)

Debra Allinger testified that she worked in Respondent's office from March until August 2009; that on her second day of work she was asked to clean out [HM]'s belongings from an office that was to be painted; and that upon seeing a prescription bottle in the office, she told Respondent, who then put the bottle in her lab coat. (Tr. 297.)

Shelley Franks-Chapa testified that she was employed by Respondent from February 2009 to about June 2009, and began employment before February 14, 2009. (Tr. 310, 319.) Ms. Franks-Chapa further testified that she was familiar with an employee named [HM], also known as [GM]. (Tr. 312.) Ms. Franks-Chapa recalled being present in Respondent's office on an unknown date but during her period of employment, and overheard [HM] ask that her prescription of Valium be faxed out. (Tr. 312.) Ms. Franks-Chapa further recalled on cross-examination that the conversation took place in an end office which was about to be painted within a few days and that [HM] was present in the office working. (Tr. 316–17.)

(g) The DEA's Accountability Audit of Respondent's Practice and Respondent's Handling of Controlled Substances

DI Dunn testified that in May 2008, he launched an investigation of Respondent based on theft and loss reports related to the theft or loss of experimental fentanyl; the investigation revealed reports had not been completed properly, DI Dunn instructed Respondent as to the proper filing of the report form and no further action was taken and that investigation was unrelated to the instant matter. (Tr. 17, 55.) DI Dunn has been trained in how to conduct an audit at a registered location. (Tr. 16.) DI Dunn testified that he obtained Respondent's Demerol log from the FBI, who seized the log pursuant to an April 2009 search warrant. (Tr. 48.)

Respondent testified she believed that an employee, Marie Lopez, was stealing or forging prescriptions so she eventually fired Ms. Lopez. (Tr. 115, 116.) Respondent further testified that she believes that Ms. Lopez stole the fentanyl that was reported to the DEA as lost. (Tr. 196.)

Respondent described how, after the first theft from her office, she acquired two safes for the Mesa Drive location and placed one under the sink in the triage room and one in Respondent's office. (Tr. 119.) Respondent explained that some Schedule IV controlled substances were stored in cabinets in the triage room and that Suboxone, Demerol, probably Ambien, and sometimes Provigil, were stored in a safe under the sink, but that some Provigil was in the cabinet. (Tr. 192.) Respondent further testified that she believed that the safe in the triage room was opened with both a combination and a key and that Respondent did not have a key to the safe but a member of her clinical staff would keep the key during the day, and lock the key in the triage room at night. Respondent maintained the key to the triage room and was always the last person out of the office at night. (Tr. 193.) Respondent further explained that in late 2008, her office was broken into and a safe containing triplicate prescriptions and possibly two bottles of Suboxone was stolen; and Respondent reported the theft to the local police and the DEA. (Tr. 119, 196 & 199.)

Respondent testified her office procedure for documenting the receipt of controlled substances was as follows: certain employees were authorized to receive delivery of medications or office supplies; all medications were taken to the triage room, where there was a safe for storing controlled substances, and the delivery receipt was placed in the appropriate manual for the particular medication. (Tr. 120, 205.) Respondent further testified that because fentanyl was part of an investigational study, the medication was signed into a book upon receipt; each pill was counted by an independent person who was part of the investigational study. (Tr. 120.)

Respondent further testified that when her safe was stolen in late 2008, the Suboxone manual was damaged and Respondent later requested that Dendrite (a pharmaceutical supply company), send copies of receipts of all deliveries of Suboxone to her office. (Tr. 121, 123; Resp't Ex. 11.) Respondent then obtained from Community Pharmacy copies of receipts of medical supplies ordered by her office. (Resp't Ex. 9.)

Respondent testified that she typically purchased Demerol through Community Pharmacy and she requested copies of receipts from Community Pharmacy in an effort to account for the Demerol in her office. (Tr. 125.) Respondent testified that when she moved her practice from 7851 South I–35 East to 431 Mesa Drive, scheduled medications were destroyed, not moved. (Tr. 200.)

DI Dunn testified that an audit occurred after search warrants were executed on Respondent's registered and unregistered locations and home in April 2009, and that he did not participate in the execution of the search warrants. (Tr. 20, 33.) DI Dunn further testified that at a later time, he conducted an audit of Respondent's Suboxone 8 mg for the period beginning July 18, 2008, and ending April 9, 2009; the audit was conducted from materials located at DEA and FBI offices, based on Respondent's inventory records and dispensing logs that were seized pursuant to the execution of search warrants at Respondent's office; as well as from distributor records, ARCOS records, and a count of drugs that were identified during the execution of the search warrants; and approximately fifteen bottles of Suboxone were found to be missing. (Tr. 36; *see* Gov't Ex. 4.) DI Dunn testified that he had no recollection of seeing a report regarding, or being informed of, a break-in at Respondent's office. (Tr. 64.)

DI Dunn testified that Respondent had records indicating the dispensing of Demerol but not the receipt; because Demerol is a Schedule II controlled substance, it can only be transferred between registrants pursuant to a DEA Form 222, which Respondent did not have; and that DI Dunn did not request Respondent's DEA Form 222 because he was not present when the search warrant was executed. (Tr. 35, 65.)

DI Chalmers testified that she was present at the execution of the search warrant at Respondent's practice location; she conducted a search in the medication room and a location in the back of that room that may have been Respondent's office; DI Chalmers found controlled substances (Suboxone, Provigil, and possibly Ambien) in an unlocked cabinet; she inventoried but did not seize the controlled substances that she found; and that drug logs were among the documents seized from the medication room. (Tr. 92–93.)

Respondent further testified she did not recall having copies of DEA Form 222 for Demerol at the time of the April 2009 search,

stating ''I would guess that we did, but I'm not going to . . . .'' [24] (Tr. 126–27.) Respondent explained that during the relocation from the Corinth office to the temporary Denton office, medications were not transferred, so she ''didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' After moving to the permanent office ''on Mesa, we had to get those little 222s, because we . . . had to order them.'' (Tr. 197.)

IV. The Parties' Contentions

A. The Government

The Government first contends that there is ''no viable DEA registration to revoke in the matter'' because Respondent failed to file a renewal application and her registration expired by its terms on August 31, 2010. The Government argues that any discussion regarding revocation of Respondent's DEA registration is moot because Respondent does not currently possess a valid DEA registration. In the alternative, the Government argues that if the Deputy Administrator finds that collateral consequences require the issuance of a Final Order, then the Deputy Administrator should affirm the immediate suspension order on the grounds that Respondent's continued registration is inconsistent with the public interest.

The Government argues, in substance, that Respondent's ''experience in dispensing controlled substances and record of compliance with applicable controlled substances laws is abysmal.'' (ALJ Ex. 16, 10.) The Government supports its position with allegations that Respondent dispensed a controlled substance prescription for other than a legitimate medical purpose; Respondent prescribed a Schedule II controlled substance for the purpose of opioid addiction treatment; Respondent acted as a reverse distributor without proper authorization by accepting from patients and destroying controlled substances; Respondent illegally possessed controlled substances at an unregistered location; an accountability audit revealed that approximately fifteen bottles of Suboxone were missing from Respondent's office; and Respondent's substandard record-keeping prevented the DEA from performing audits of additional controlled substances.

B. Respondent

Respondent argues, in substance, that she has never previously been the subject of ''an allegation related to the manufacture, distribution or dispensing of controlled substances'' and Respondent has no conviction record under State or Federal law. Respondent further contends that although the DEA has suggested that Respondent's arrest in Denton County, Texas, should be considered in determining whether Respondent's DEA COR should be revoked, this fact should not be considered because it did not result in an indictment or conviction and because 21 U.S.C. 824(a) was never meant to apply to physicians in this circumstance.[25] (ALJ Ex. 17, 12.)

Respondent next contends that Respondent did notify the local DEA of her change of address and was unable to complete an attempt to ''change the national registration database,'' and Respondent reasonably believed that she had complied with the DEA regulations regarding address changes. (ALJ Ex. 17, 14.)

With regard to the unauthorized prescribing of a Schedule II controlled substance for the purpose of treating opioid addiction, Respondent contends that the allegation applies to only one prescription and that Respondent was within the standard of care for prescribing such medication and did not violate any laws because Respondent provided the methadone prescription for pain management, which Respondent documented.

Respondent also contends that she did not take a patient or employee's Valium for her own use. Respondent asserts that she came into possession of the medication because she found the medication in the open and attempted to secure it; and that she subsequently forgot about the medication, which eventually ended up in her home, in her laundry pile.

Respondent argues that although the DEA contends that Respondent failed to properly maintain logs and receipts for controlled substances, the DEA never asked to review her controlled substances logs and never asked Respondent to provide receipts.

Respondent finally contends that a finding that Respondent's continued registration would be inconsistent with the public interest, would not be consistent with the finding of the state licensing authority, which refused to suspend or revoke Respondent's medical license, and that Respondent has at all times ''remained compliant with State and Federal law in her practice of medicine and prescribing controlled substances.'' (ALJ Ex. 17, 16.)

V. Discussion and Conclusions

A. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act 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.[26] ''A separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.'' [27] DEA regulations provide that any registrant may apply to modify his registration to change his address but such modification shall be handled in the same manner as an application for registration.[28]

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 his professional practice.[29] 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.[30]

B. Statement of Law and Discussion

The Controlled Substances Act, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a 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).[31]

Pursuant to 21 U.S.C. 823(f), the Deputy 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 Deputy 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.

As a threshold matter, the factors specified in Section 823 (f) are to be considered in the disjunctive: the Deputy 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).

Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[32] The burden of proof shifts to Respondent once the Government has made its *prima facie* case. *Medicine Shoppe—Jonesborough,* 73 FR 364 (DEA 2008); *see also Thomas Johnston,* 45 FR 72,311 (DEA 1980).

C. The Factors To Be Considered

Factor 1: The Recommendation of the Appropriate State Licensing Board

As described in the Procedural Section of these Recommended Rulings, Respondent does hold a valid state medical license but Respondent's state controlled substances

[24] Respondent's answer on direct examination was interrupted by Respondent's counsel, with a question on a different topic.

[25] I have specifically given no weight and find no relevance to any references or suggestions about ''arrests,'' ''criminal search warrants'' or similar statements appearing in this record.

[26] 21 U.S.C. 822(a)(2).

[27] 21 U.S.C. 822(e).

[28] 21 CFR 1301.51.

[29] 21 U.S.C. 844(a).

[30] 21 CFR 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c) & 1304.22(a)(2)(iv).

[31] 21 U.S.C. 824(a)(4).

[32] 21 CFR 1301.44(e) (2010).

registration has been suspended. Respondent, therefore, does not possess valid authority to handle controlled substances in the jurisdiction in which she is registered. Given that the Texas authorities relied exclusively on the DEA action to suspend Respondent's state authority, however, Respondent's lack of such authority is not dispositive and has no relevance in determining whether Respondent's continued registration would be inconsistent with the public interest.

There is evidence, however, that the Texas Medical Board has taken prior action against Respondent's medical license. Although the Government presented no evidence regarding the matter, Respondent did testify that she has been disciplined by the Texas Medical Board on three prior occasions: 1) in December 2000, Respondent was cited for substandard chart documentation resulting in a monetary fine, chart monitoring, and eight hours of continuing education in medical recordkeeping; 2) Respondent received a monetary fine for failure to timely notify the Texas Medical Board of the relocation of her practice from the City of Corinth to the City of Denton; and 3) in March or April 2009, Respondent received a monetary fine in relation to missing fentanyl. (Tr. 186–87.)

Although no additional detail is available, the Texas Medical Board action taken against Respondent with regard to Respondent's failure to timely notify the Texas Medical Board of the relocation of her practice appears to be similar to Respondent's failure to notify the DEA of a subsequent change of practice location. Accordingly, the fact that Respondent was previously disciplined by the Texas Medical Board does weigh in favor of revocation.

It is important to also note that the Texas Medical Board did temporarily suspend Respondent's medical license on August 19, 2009, and reinstate Respondent's medical license on October 16, 2009; the evidence indicates that Respondent's Texas medical license is currently active. The August 19, 2009, suspension order referenced the suspension action taken by the DEA; however, the order also referenced numerous other grounds which were apparently unrelated to the grounds upon which the DEA issued the OSC/IS; specifically, the Texas order addressed issues related to the issuance of prescriptions to Respondent's patients by another physician. (Gov't Ex. 6, 7.)

These issues were not raised in the OSC/IS but were addressed in the Government's Prehearing Statement. At hearing, however, the Government did not elicit testimony regarding the issues related to prescriptions written by another physician but did submit some limited documentary evidence on the matter. (*See* Gov't Ex. 3, 6 & 7.) The documentary evidence provided is not sufficient to warrant a review of an issue which the Government has failed to adequately pursue in the proceeding and the issue, therefore, will not be considered further.

The Texas Medical Board's October 16, 2009 Order reinstating Respondent's Texas medical license offers little substantive insight with regard to its own factual findings, which were found to be inconclusive. ''The Panel is unable to determine from the evidence presented that Respondent is a continuing threat to the health of Respondent's patients or a continuing threat to the public. . . .'' (Gov't Ex. 7.) Accordingly, the action and findings of the Texas Medical Board do not significantly weigh for or against Respondent with regard to the temporary suspension and later reinstatement. The current active status of Respondent's Texas medical license does, on balance, weigh against a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor 3: Respondent's Conviction Record

There is no evidence that Respondent has ever been convicted under any federal or state laws relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, weighs against a finding that Respondent's continued 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 no evidence that, prior to any action related to this matter, Respondent has failed to remain in compliance with applicable federal laws relating to controlled substances. The testimony and evidence does reveal, however, that Respondent failed to properly notify the DEA that she relocated her practice from her registered location to a new unregistered location, in violation of both state and federal law.[33] There is no evidence that, prior to the current circumstances, Respondent has failed to comply with the Controlled Substances Act. The Respondent has admitted to a March or April 2009, Texas Medical Board monetary fine in relation to missing fentanyl. There is no other independent evidence of record relating to the circumstances surrounding that issue.

(a) Respondent's Registered Location

It is undisputed that Respondent relocated her practice from her registered location, 4851 I–35 East, Suite 101, Denton, Texas 76210 (I–35 office), to a new location, 4310 Mesa Drive, Denton, Texas 76207 (Mesa office), on or around February 1, 2009. Respondent testified that she relocated her practice to the Mesa office because she was evicted from the I–35 office in late 2008.[34] Respondent maintains that she did not move controlled substances or acquire controlled substances for use at her temporary Collier street location. (Tr. 197–98.) The evidence does indicate, however, that Respondent did possess and distribute controlled substances from the unregistered Mesa office during the period beginning approximately February 1, 2009, and ending with the issuance of the OSC/IS on August 4, 2009.

Federal law requires every person who dispenses any controlled substance to obtain a registration from the Attorney General.[35] Additionally, a separate registration must be obtained for each principal place of practice where an applicant dispenses controlled substances and a registrant must report any change of address by applying to modify his or her registration to change his/her address, which shall be treated as an application for registration.[36] The CFR clearly states the procedures a registrant must follow to request a change in the registered address.[37]

In this case, the evidence indicates that Respondent failed to modify her registration to update her Mesa office practice address. Respondent testified she believed that she properly notified the DEA of her new address when she requested certain documents be sent to her new location. The evidence of record reflects that Respondent has previously successfully modified the address of her registered location at least three times [38] and therefore Respondent was fully aware of the proper procedure for requesting an address change. (Gov't Ex. 2.) Additionally, there was no evidence presented at hearing confirming that Respondent has even yet successfully updated the address of her practice location.

The search warrant executed by the FBI and the DEA in April 2009 reflected the presence of controlled substances from Respondent's unregistered Mesa Drive location. I therefore find that Respondent failed to properly notify the DEA of the change in address of her registered location and Respondent possessed and dispensed controlled substances from an unregistered location, in violation of 21 U.S.C. 822(e) and 827(g) and 21 CFR 1301.51.

In mitigation, the Respondent's actions with regard to notifying DEA do not appear to be intentionally deceitful, because the Respondent credibly testified that she notified the Texas DPS of her new Mesa office address, and no other evidence of record was offered by either party at hearing to the contrary. (Tr. 161–64.) Respondent also introduced as evidence prescription pads which reflected the address of 4310 Mesa Drive, Denton, Texas. (Resp't Ex. 5.) Clearly the evidence as a whole is consistent with Respondent's testimony that the failure to update her new address was due to an omission, notwithstanding the evidence of neglect by Respondent to ensure it had been properly done.

(b) Respondent's Issuance of Methadone to Opioid-Addicted Patients

The Government provided evidence, which Respondent corroborated, that Respondent

[33] Any registrant may apply to modify his or her registration to change his or her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. *Cf.* 21 CFR 1301.14 (2010). The request for modification shall be handled in the same manner as an application for registration. 21 CFR 1301.12 *et. seq.; see also* 37 Tex. Admin. Code § 13.23 (2010).

[34] Respondent testified that all controlled substances that remained at the I–35 location were destroyed, not relocated.

[35] 21 U.S.C. 822(a)(2).

[36] 21 U.S.C. 822(e), 827(g); 21 CFR 1301.51 (2010).

[37] *See* 21 CFR 1301.51 (2010).

[38] August 21, 2001; March 11, 2003; and September 16, 2004.

prescribed methadone to three (3) opioid-addicted patients [39] who were previously treated at an addiction treatment center. The Government, however, further alleged that Respondent's treatment of these patients amounted to the unauthorized treatment of narcotic-dependent patients by prescribing Schedule II controlled substances for the purpose of treating opioid addiction, which is inconsistent with 21 U.S.C. 823(g)(1) and 21 CFR 1306.04(c).

Federal law requires a separate registration for ''[p]ractitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment . . . .'' [40] A practitioner may, however, ''lawfully prescribe methadone to a patient for pain management purposes under his practitioner's registration.'' *Tony T. Bui, M.D.,* 75 FR 49,979 (DEA 2010) (citing 21 U.S.C. 823(f)). The Government presented evidence indicating that Respondent prescribed methadone to three patients who were previously treated with methadone at an addiction treatment center. (Gov't Exs. 12–14, 16–18.) The Government contends in part that Respondent was providing opioid addiction treatment because each of the three patients were already taking methadone when they first became patients of Respondent, and that each patient previously received methadone from a methadone clinic. This alone does not amount to substantial evidence indicating that Respondent was improperly prescribing a Schedule II controlled substance for the purpose of opioid addiction treatment.

Although the documentary evidence does indicate an opioid addiction in each of the three patients, this evidence consists of unsworn statements from patients [JF] and [MM], along with medical records relating to the three patients, which must be weighted accordingly. The allegation of improper prescribing of methadone is unsubstantiated by the documentary evidence and was, in fact, refuted by Respondent's expert witness; and, in each instance, Respondent has established an underlying purpose of pain management. ''While methadone is approved by the FDA, and has long been used, for the treatment of opioid addiction . . . the drug is also approved for the treatment of pain.'' *Bui,* 75 FR at 49,988. Moreover, the record contains no expert evidence showing that Respondent's prescribing of methadone was inconsistent with accepted medical practice for prescribing the drug for pain management.

The Government bears the burden on the issue of whether Respondent's prescribing of methadone ''was for the purpose of treating opioid addiction'' and not as part of an accepted medical practice for pain management. Similar to *Bui,* the Government has presented no expert evidence indicating such and relies solely on hearsay and unsworn statements. Respondent has testified that the treatment of the three patients in question was for pain management related to a number of underlying medical conditions, which are objectively documented in the medical records introduced at hearing by both parties. Additionally, the Respondent presented expert testimony from a medical doctor with experience treating chronic pain, even though not formally certified in pain management.

In *Calhoun* v. *Bailar,* 626 F.2d 145 (9th Cir. 1980), the court found that to constitute substantial evidence the probative value and reliability of hearsay evidence may be analyzed using many factors, such as: a consideration regarding the independence or possible bias of the declarant; the type of hearsay material presented; whether the statements are signed and sworn or anonymous, oral or unsworn; whether the statements are contradicted by direct testimony; whether the declarant is available to testify and, if so, whether the objecting party subpoenas the declarant or whether the declarant is unavailable and no other evidence is available; the credibility of the witness testifying to the hearsay; and whether or not the hearsay is corroborated. *Id.* at 149; *see also Richardson* v. *Perales,* 402 U.S. 389, 402–06 (1971).

DI Dunn credibly testified at hearing that his investigation revealed that Respondent treated several patients who previously had been treated for narcotic addiction at the Denton Treatment Center. DI Dunn obtained unsworn statements from two of those patients, [JF] and [MM], both indicating in substance that they did not consult Respondent for the purpose of pain management. That testimony and evidence, however, does not carry much weight based on the factors set forth in *Calhoun.*

The written patient statements presented by the Government were unsworn; there is no evidence that an attempt was made to subpoena the witnesses, and the Government provided no indication that the witnesses were unavailable to testify; no evidence was offered to explain why the statements were unsworn; there was no evidence presented to indicate whether the declarant witnesses are credible; and the statements provided are not corroborated by other record evidence.

For example, the patient files specifically refer to a number of objective medical findings and diagnoses that are inconsistent with the unsworn statements. In the case of [MM], the medical file reflects entries from April to August 2009, including patient complaints of osteoporosis left shoulder and leg; back, shoulder and leg pain at level seven, among other complaints; and diagnoses of chronic back pain; arthritis; opioid addiction; anxiety; depression; and weight management, among others; as well as positive physical findings on examination to include lumbosacral back pain. (Gov't Ex. 16.) In the case of [TR], the medical file reflects entries from June to August 2009, including patient complaints of back and left knee pain; ''lumbosacral back pain from scoliosis for several years. Pain 10/10 without meds.'' (Gov't Ex. 17, at 35.) The file reflects diagnoses of chronic back pain; left knee arthritis; anxiety; and depression, among others; as well as positive physical findings on examination to include positive lumbosacral back pain and bilateral hip pain, among other findings. (Gov't Ex. 17.) In the case of [JF], the medical file reflects entries from January to February 2009, including patient complaints of chronic pain complicated by history of opioid dependence resulting from chronic arthritic pain in the neck, back and left knee. Diagnoses included arthritis in the cervical and lumbar spine, chronic pain syndrome, and opioid dependence, among other findings.

In addition to the patient files, the unrebutted testimony and expert opinion of Dr. Babuji support a finding that the methadone was prescribed for pain management, not for opioid addiction. Although the Government did object to the testimony of Dr. Babuji at hearing on the grounds that he was not ''proffered as an expert,'' [41] that objection is misplaced.[42] The Government further argues in its post-hearing brief that Dr. Babuji's testimony be given no weight because he ''was not tendered and/or accepted as an expert witness . . . [and] [t]here is no indication from his testimony that [he] has any experience in pain management or addiction treatment.'' (ALJ Ex. 16, 6.) To the contrary, Respondent indicated in her Prehearing Statements that she was offering the witness as an expert, and I so find. Additionally, Dr. Babuji's testimony specifically included an admission that he was not certified in pain management, but he based his testimony in part on his experience treating his own patients with conditions of pain.

I find that Dr. Babuji was adequately proffered as an expert and I have evaluated his testimony as an expert witness with regard to the standard of care in treating patients with pain management conditions. Dr. Babuji is clearly qualified to testify regarding the general standard of care and treatment of patients with pain management issues, based on his education, training, and experience over twenty years, including practicing cardiology, internal medicine and primary care for the last three years in Dallas, Texas. (Tr. 265.)

Dr. Babuji's demeanor was serious and forthright throughout his testimony. The evidence reflected that Dr. Babuji has known the Respondent for between two and three years, having done cardiology consults in her Denton, Texas office approximately once per week. (Tr. 270.) Dr. Babuji's appearance and testimony at hearing was without benefit of financial compensation. On cross-examination the Government challenged the witness with regard to whether he had reviewed the entire [JF] file, suggesting that he had not, because the ''complete file . . . is approximately 700 to a thousand pages.'' [43]

[39] Referred to herein as [JF], [MM] and [TR].

[40] 21 U.S.C. 823(g) (2006).

[41] (Tr. 288.)

[42] The Government offers no authority in support this argument. While Respondent did offer Dr. Babuji as an expert witness, there is no formal requirement to either ''offer'' or ''accept'' an expert witness during hearing. *See United States* v. *Johnson,* 488 F.3d 690, 697–98 (6th Cir. 2007) (frowning on the practice of labeling the witness as an ''expert'' in the presence of the fact finder); *see also United States* v. *Rice,* No. ACM 30231, 1994 WL 164477 at *1 (AFCMR Apr. 22, 1994) (noting ''no requirement in either military or federal practice mandating that an expert witness be tendered (offered) and accepted before providing expert testimony.'')

[43] Government counsel asked the witness: ''Would it surprise you to learn that the complete

While there may be some doubt as to the exact number of pages reviewed by Dr. Babuji with regard to the [JF] medical file, he credibly maintained that he had sufficient information available to support his conclusion, noting his review of hundreds of pages of the medical file including the discharge summary. There is no other evidence to suggest the witness had a bias or interest in the outcome of the case.

I find that Dr. Babuji presented fully credible competent evidence within his stated area of expertise. The testimony is consistent with that presented by the Respondent, who credibly testified at hearing in detail as to the standard of care she used in treating the three patients at issue in this matter. The testimony of Dr. Babuji and the Respondent is also consistent with other documentary evidence of record including the relevant treatment records. Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent prescribed Schedule II controlled substances to patients for the purpose of treating opioid addiction in violation of 21 U.S.C. 823(a)(1) and 21 CFR 1306.04(c).

(c) Respondent's Possession of a Prescription Written in the Name of an Employee

The Government alleges that Respondent prescribed controlled substances for other than a legitimate medical purpose when she issued a prescription to a then-current employee and the controlled substance was later found in Respondent's home. Under DEA's regulations, a prescription for a controlled substance is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' [44]

At the hearing in this matter, the Government presented evidence consisting of photographs of a prescription bottle for diazepam 10 mg, quantity 90, issued in the name of [HM], which DI Dunn testified was found in Respondent's bathroom medicine cabinet and which the DEA had tested; photographs of tablets; an unsworn statement by [HM]; and the testimony of DI Leakey, who assisted in the search of Respondent's residence and seizure of the [HM] prescription containing an estimated fifty (50) pills.[45] Respondent provided evidence consisting of Respondent's medical records for [HM] and CVS pharmacy records for [HM] along with the testimony of Respondent, Debra Allinger and Shelley Franks-Chapa.

DI Dunn testified that [HM] was a patient and employee of Respondent and that the DEA found, in Respondent's home, a prescription bottle for diazepam issued in the name [HM]. (Tr. 29.) DI Dunn's testimony is supported by photographs of the prescription bottle and several loose pills along with the testimony of DI Leakey, and an unsworn statement from [HM].

Respondent has not argued that the diazepam was not found in her home, although there may be some discrepancy regarding the last location where Respondent recalls seeing it; that the medication found was not actually diazepam; or that she did not authorize the prescription for [HM]. There is no dispute that the DEA did find in Respondent's home a prescription bottle containing diazepam issued in the name of [HM]. I therefore find no reason to provide less than full weight to the testimony of DI Dunn or DI Leakey that the prescription bottle of diazepam was found in a medicine cabinet in Respondent's home containing approximately fifty (50) pills. I do find reason, however, to provide less weight to the unsworn written statement of [HM] given the sworn testimony of Respondent, Debra Allinger and Shelley Franks-Chapa regarding the origin of the single Valium prescription at issue in this case.

DI Dunn testified that he spoke with [HM] and that the statement [HM] gave him was consistent with the written statement provided by the Government. (Tr. 29; Gov't Ex. 11.) DI Dunn testified that [HM] told him that Respondent asked if [HM] could write a prescription in [HM]'s name and then get the medication back from [HM] because Respondent could not write a prescription to herself. (Tr. 29–30.) I find no reason to doubt the testimony of DI Dunn with regard to his interaction with [HM]. I do, however, find that, consistent with the factors set forth in *Calhoun,* [HM]'s statements are not reliable.

Respondent's testimony indicated a possibility of bias of [HM] in that [HM] is a former patient and employee and the relationship between Respondent and [HM] ended badly. (Tr. 154.) Respondent testified that [HM] intended to initiate a lawsuit against her because of poor results from a medical procedure performed by another physician in Respondent's office. The accuracy of this testimony was uncontested and I find it otherwise credible. As a result of this prior dispute, [HM] would certainly have some interest or bias in the outcome of any proceeding related to Respondent's practice of medicine.

[HM]'s statement is contradicted by objective evidence of record. [HM]'s statement asserts that [HM] has ''*never* taken Valium *ever* . . . .'' (Gov't Ex. 11) (emphasis in original). Respondent, however, submitted CVS pharmacy records for [HM] indicating that [HM] did fill a prescription on February 27, 2001, for 10 diazepam 10 mg, written by Dr. [VS]. [HM] has, therefore, at least received a prescription for diazepam in the distant past thereby contradicting her statement that she has never taken Valium.[46] The Government also implied that the Valium prescription for [HM] was written ''before [Respondent] even had a patient consult with [GM].'' (Tr. 320.) While Respondent's medical records for [HM] appear to support that implication, (*see* Resp't Ex. 8), a review of the record as a whole indicates otherwise.

Respondent's medical records for [HM] include a report of a consultation on February 6, 2009, which indicates that Respondent prescribed diazepam (Resp't Ex. 8.); [HM]'s prescription records, as provided by Respondent, indicate that the diazepam prescription was filled on February 8, 2009. (Resp't Ex. 13, at 3.) The Government has provided no evidence indicating the actual date that the prescription was written and is presumably relying on Respondent's testimony that the prescription was written on February 3, 2009. (*See* Tr. 221.) I find no need to determine the precise date upon which the diazepam prescription was actually written because there is evidence that Respondent had written prescriptions for [HM] as early as September 26, 2008, as evidenced by [HM]'s prescription records. (Resp't Ex. 13.) Given the fact that [HM] worked in Respondent's office and presumably had a patient-physician relationship with Respondent, the actual date upon which the prescription was written provides little or no value to the evidence regarding whether Respondent prescribed controlled substances for other than a legitimate medical purpose.

[HM]'s statement is also contradicted by the testimony of Respondent, Debra Allinger and Shelley Franks-Chapa. [HM] stated that Respondent called her after the FBI searched her home and asked her to tell people that Respondent came into possession of the diazepam because [HM] kept the medication at work (presumably at Respondent's practice) and ''it must have fallen in a box of files she brought home.'' (Gov't Ex. 11.) Respondent and Ms. Allinger both credibly testified that [HM] left the medication sitting on top of a desk in a room that was being painted and that Respondent, after seeing the medication, retrieved it from the desk and placed it in the pocket of her lab coat. (Tr. 153, 297.) Additionally, Ms. Franks-Chapa testified that she witnessed [HM] requesting prescriptions for Valium.[47] (Tr. 313.)

Respondent objected at hearing to the admission of [HM]'s statement on the grounds that the statement was unsworn, constituted hearsay, and was unduly prejudicial because Respondent was not able to cross-examine the declarant. (Tr. 31.) Neither party has shown that [HM] was unavailable to testify and the Government has provided no explanation as to why [HM] was not made available as a witness. Neither party attempted to subpoena the witness. As the court recognized in *Calhoun,* however, a respondent cannot complain of an inability to cross-examine a witness with regard to a written report when the respondent has failed to exercise her right to subpoena the witness. That said, the absence of sworn testimony by [HM] at hearing, weighed against other credible sworn testimony and credible documentary evidence, significantly discredits the reliability and probative value of [HM]'s statement.

file regarding [JF]'s hospital visit is approximately 700 to a thousand pages?'' (Tr. 287.) The factual basis for this question remains a mystery, since no other medical records relating to [JF] were received in evidence other than Respondent's exhibit six. Respondent's exhibit seven relating to [JF] was withdrawn and the Government presented no case in rebuttal.

[44] 21 CFR 1306.04 (2010).

[45] (Gov't Ex. 11, 15; Tr. 29–31, 37–38, 99 & 105.)

[46] I take official notice from the 2007 edition of the Physicians' Desk Reference that Valium is a brand name product containing the Schedule IV controlled substance diazepam, a benzodiazepine derivative.

[47] It is unclear whether [HM] requested the prescription from Respondent or her nurse but the incident apparently occurred in Respondent's office. (Tr. 317.)

I find [HM]'s unequivocal statements that [HM] had ''never'' taken Valium, ''ever,'' and that it was ''prescribed only this one time for her,'' were directly contradicted by objective uncontested evidence of a past prescription for Valium issued to [HM] and testimony by Ms. Franks-Chapa that she witnessed [HM] requesting a prescription for Valium. [HM]'s past adverse patient and employment history with Respondent also indicates [HM] had a reason to be biased against Respondent. In light of the foregoing, the unsworn statement of [HM], corroborated only by the prescription found at Respondent's home, is entirely discredited by the objective and sworn testimony to the contrary.

Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent prescribed controlled substances for other than a legitimate medical purpose to a then-current employee.

(d) The DEA's Accountability Audit of Respondent's Practice

The Government alleges in the OSC/IS that an accountability audit ''performed at your office in April 2009, revealed . . . an unexplained shortage of approximately 13 bottles of Suboxone, or 390 dosage units.'' The Government's Prehearing Statement filed on June 15, 2010, further states that an

''accountability audit was conducted on the Suboxone 8mg for the period of July 1, 2008, through April 9, 2009. Respondent's records show dispensation of 38 bottles (1,140 dosage units) of Suboxone. There were 11 bottles present on-hand on the day of the search warrant. Therefore, Respondent could only account for 49 bottles (1,470 dosage units) of Suboxone, leaving a shortage of 13 bottles (390 dosage units unaccounted for based on the records.''

The Government's Prehearing Statement further stated in part that DI Chalmers would testify about the ''accountability audit conducted on the Suboxone . . . .''

The Government's evidence at hearing with regard to the Suboxone audit consisted of a two page ARCOS [48] Transaction History Report and the testimony of DI Dunn, reflecting an audit period of July 18, 2008 to April 9, 2009. (Tr. 34–35.) DI Dunn's direct testimony regarding the audit is reflected in the following testimony:

Q: Now how did you conduct your audit of Suboxone?

A: With the Suboxone, she did have some records there that showed an inventory date. I used that date as a starting point from her own records. She had a log of dispensing of Suboxone, so I was able to utilize that as well. I then turned to ARCOS's subpoena and found out who the provider for the Suboxone was, the distributor, subpoenaed their records, used the ARCOS records, and then from account of the drugs that were on hand on the date of the search warrant, we were able to do an audit with those numbers on that one drug.

(Tr. 36.) DI Dunn testified that from the foregoing audit fifteen (15) bottles of Suboxone were missing, each containing thirty (30) pills, for a total loss of 450 pills. (Tr. 36.)

DI Chalmers testified on direct examination that she participated in the FBI search of Respondent's practice location on Mesa Drive in April 2009, as DI Dunn was out of town and could not participate. DI Chalmers further testified that her responsibilities during the search were to speak with the Respondent and assist with the search warrant. DI Chalmers searched the ''medication room at the clinic and another location at the back of the room believed to be Respondent's office setting.'' (Tr. 92.) DI Chalmers testified that she did not conduct an audit on the Suboxone or other drugs found in the specific location that she searched, nor did she seize any of the controlled substances at that time. (Tr. 93.) DI Chalmers also testified that rather than conduct an audit, she did an inventory of the controlled substances ''that she encountered'' and also seized documents from the medication room, to include a drug log. While the evidence is clear that DI Chalmers did not seize any drugs, there is no evidence of record reflecting whether any drugs were seized from the premises or if all drugs present were inventoried, since DI Chalmers's role in the search was limited to a narrow location and purpose.

The evidence of an audit in this case simply cannot support any credible findings of a shortage of Suboxone during the alleged time period. DI Dunn's testimony of a shortage of fifteen bottles of Suboxone as of the date of the April search appears to rest on the ''account of the drugs that were on hand on the date of the search warrant'' compared with the data obtained from the ''ARCOS records,'' and records from the distributor.[49] There was no documentary or testimonial evidence offered to indicate the search established an accurate count of the number of bottles of Suboxone present in Respondent's office, which is an essential component of the audit.[50] The testimony by DI Chalmers clearly indicates that she only inventoried the controlled substances that she encountered and there is no evidence whatsoever as to the number of other agents participating in the search, what other agents encountered, the scope of the search or the identity and total inventory of controlled substances found during the search.[51] There is no evidence of record to support the conclusions reached by DI Dunn regarding the audit, to include the details related to the search of Respondent's office, specific items seized or inventoried, the location of the items and related information as may be found in a search inventory.

Additionally, the reliability of the audit results is further undermined by the distributer records. (*See* Resp't Ex. 11.) As an example, the ARCOS data reflected in Government exhibit four reflects a transaction date of October 28, 2008, for the shipment of three (3) bottles of Suboxone, thirty (30) dosage units each, for a total of ninety (90) dosage units, from the supplier Dendrite. An invoice from Dendrite with a process date of October 28, 2008, reflects a shipment of ''6 SUBOXONE SUBLINGUAL 8MG CIII TABLETS–30 TABLETS PER BOTTLE.'' (Resp't Ex. 11, at 3 & 9.) While there may be an explanation for the discrepancy, none was offered at hearing nor is an explanation readily apparent from the limited evidence offered with regard to the audit. Evidence submitted by Respondent also indicates that some of the Suboxone shipments were returned during the relevant time period. (Resp't Ex. 11, at 4.)

Other discrepancies exist but it is unnecessary to elaborate further. While I find the testimony of DI Dunn and DI Chalmers generally credible, the limited evidence offered by the Government at hearing related to the audit of Respondent's handling of Suboxone for the time period of July 18, 2008 to April 9, 2009, is so lacking in specificity and reliability that it cannot support any credible findings or constitute substantial evidence.[52]

Accordingly, I find that the Government has not established by a preponderance of the evidence that Respondent cannot account for ''approximately 13 bottles of Suboxone or 390 dosage units.''

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[48] While neither party offered background information regarding ARCOS during hearing, it is noted that ''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).

[49] DI Dunn testified that he ''subpoenaed their records,'' meaning the distributor of the Suboxone. Government exhibit four indicates the source of the data is ARCOS rather than distributor records. DI Dunn was asked whether the subpoenaed distributor records ''matched up'' with the ARCOS report, and DI Dunn stated he ''believed so.'' (Tr. 36–37.) Remarkably, the Government submitted no audit report or any other supporting documentation with regard to distributor records, drug inventory reports compiled at the time of the April 2009 search of Respondent's office, or any other related documentation to factually support the audit results. The only distributor evidence with regard to the Suboxone shipments was offered by the Respondent. Additionally, no testimonial or other evidence was offered with regard to the definition, source, or reliability of ARCOS data.

[50] It is noteworthy that the OSC/IS and Government's Prehearing Statement recited specifically that thirteen bottles of Suboxone were missing for a total dosage count of 390, differing from the testimony at hearing that fifteen bottles of Suboxone were missing for a total dosage count of 450.

[51] The evidence at hearing suggested that the scope of the April 9, 2009 search warrant did not specifically relate to the search and seizure of controlled substances from any of the premises, but rather involved the search and seizure of records. (Tr. 93, 105.)

[52] The Government's post-hearing brief (ALJ Ex. 16) states ''DI Dunn's accountability audit of Suboxone is also uncontested.'' This ignores the fact that Respondent alleged in her Prehearing Statement discrepancies with the Suboxone audit. At hearing, Respondent further offered Respondent's exhibit eleven to rebut the audit results, which was admitted without objection. (Tr. 123.)

(e) DEA 222 Forms, Effective Controls and Disposal of Controlled Substances

The Government alleges in the OSC/IS that Respondent's ''dispensing log indicates that you dispensed other controlled substances, such as Demerol; however, you were unable to provide investigators with any records showing receipt of those controlled substances'' as required by 21 CFR 1304.21. The Government's Prehearing Statement further noticed: the absence of DEA 222 Official Order Forms accounting for Demerol purchases, and no receiving or distribution records for Provigil; and the ''Narcotic Logbook also showed receipt of controlled substances returned to Respondent by patients that did not want the medication. This activity is not specifically authorized by Respondent's registration.'' [53]

The DEA regulations require all applicants and registrants to provide ''effective controls and procedures to guard against theft and diversion of controlled substances.'' [54] In determining whether there has been substantial compliance with the required security standards, the Deputy Administrator may consider a number of factors, including, but not limited to: the type and form of activity conducted; the quantity of controlled substances handled; the type of storage system used; the adequacy of key control systems; the adequacy of supervision over employees with access to storage areas; and the adequacy of the registrant's system for monitoring the receipt, distribution and disposition of controlled substances.[55] A practitioner must store controlled substances listed in Schedules II–V in a ''securely locked, substantially constructed cabinet.'' [56] Additionally, a registrant must ''notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft'' and complete a DEA Form 106 regarding the theft or loss.[57]

DEA regulations require a registrant to dispose of controlled substances consistent with procedures outlined in 21 CFR § 1307.21. There are no provisions in the regulations to allow a non-registrant to return a controlled substance to a registrant. There is no factual dispute in this case, and the Respondent readily admitted in testimony, that on occasion controlled substances were returned and destroyed. An undated ''narcotic log'' introduced at hearing reflects the return of ''various'' medications during the month of December, although no year is indicated. (Gov't Ex. 10, at 1.)

The Respondent testified in substance that her office policy was that if a patient did not like the medication, or had a bad reaction to the medication, the patient could return it; ''we would count it, document it, destroy it'' and it ''didn't happen very often.'' (Tr. 248.) There is no indication that this practice as described by Respondent was a frequent occurrence, and there is no evidence of any diversion of the controlled substances returned. In fact, the un-rebutted testimony of the Respondent is that they were destroyed.

The testimony of Respondent and DI Chalmers provides evidence that Respondent did not properly secure all Schedule II–V controlled substances in a securely locked, substantially constructed cabinet. Although there is no evidence regarding the exact quantities of controlled substances maintained at Respondent's Mesa office, there is sufficient evidence in the form of Respondent's testimony, and that of DI Chalmers, to determine that Respondent did maintain possession of some controlled substances, including at least fentanyl and Suboxone. Additionally, given the credible testimony of both Respondent and DI Chalmers that some controlled substances were found in unlocked cabinets, it is apparent that Respondent did not store all Schedule II–V controlled substances in a securely locked, substantially constructed cabinet as required by applicable regulations. The fact that Respondent did not maintain control over the key to access her medication safe and was unfamiliar with the necessary procedure for opening the safe further indicates that Respondent also did not maintain an adequate key control system.

Although the evidence indicates that Respondent did not follow adequate security procedures, the question remains as to whether that information can be considered in determining if Respondent's continued registration is consistent with the public interest. In order to comport with due process requirements, the DEA must ''provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'' *CBS Wholesale Distributors,* 74 FR 36,746 (DEA 2009) (citing *NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990)). The DEA has previously held that an issue cannot be the basis for a sanction when the Government has failed to ''disclose 'in its prehearing statements or indicate at any time prior to the hearing' that an issue will be litigated.'' *Id.* at 36,750 (citing *Darrell Risner, D.M.D.,* 61 FR 728 (DEA 1996)). The DEA has also previously found, however, that a respondent may waive his objection to admission of evidence not noticed by the Government prior to the hearing when a respondent does not timely object and when the respondent also raises the issue himself. *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755 (DEA 2009).

In the instant matter, the Government did not raise the issue of security controls in the OSC or in its Prehearing Statement. In fact, the Government first raised the issue of Respondent's security controls during the direct examination of DI Chalmers. The Government asked DI Chalmers whether Respondent's storage cabinets were locked and if they were capable of being locked. (Tr. 94.) While it is true that Respondent did not object to the line of questioning, and offered some testimony on direct examination with regard to controlled substances kept locked in safes, Respondent's primary testimony regarding the issue was raised during the Government's cross-examination of Respondent.

I therefore find that the Government did not provide Respondent with adequate notice regarding Respondent's security control measures and that the issue cannot serve as a basis for determining whether Respondent's continued registration would be inconsistent with the public interest.[58]

The Government also alleges that Respondent failed to effectively monitor the receipt and distribution of controlled substances because Respondent did not maintain an effective recordkeeping system in accordance with 21 CFR §§ 1304.03(b), 1304.04, 1304.11, 1304.21 and 1304.22(c). This substantive issue was noticed in the OSC/IS and in subsequent Prehearing Statements.

Pursuant to 21 CFR §§ 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c) and 1304.22(a)(2)(iv), a registered individual practitioner is required to maintain records of controlled substances in Schedules II–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 fail to make, keep or furnish required records.[59]

One mandatory recordkeeping vehicle is DEA Form 222, the ''official triplicate order form[] used by physicians to order scheduled narcotics'' and other controlled substances.[60] 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.[61] In addition, 21 CFR § 1305.03 requires that a DEA Form 222 be used for each distribution of a controlled substance listed in Schedule I or II, and Section § 1305.13 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.''

Failing to comply with recordkeeping laws and regulations relating to controlled substances can justify revocation. ''[A] blatant disregard for statutory provisions implemented to maintain a record of the flow of controlled substances and to prevent the diversion of controlled substances to unauthorized individuals[] would justify revocation'' of a certificate of registration.'' [62]

[53] Gov't PHS, at 4.

[54] 21 CFR 1301.71 (2010).

[55] *Id.* 1301.71(b).

[56] *Id.* 1301.75(b).

[57] *Id.* 1301.76(b).

[58] In this case, even assuming, *arguendo,* that I were to consider this additional evidence of security control measures with regard to an appropriate sanction, I would not find the additional facts to warrant revocation.

[59] 21 U.S.C. 842(a)(5).

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

[61] *See, e.g.,* 21 CFR 1305.15–.19.

[62] *Robert L. Dougherty, Jr., M.D.,* 60 FR 55,047, 55,050 (DEA 1995) (citing *George D. Osafo, M.D.,* 58 Fed. Reg 37,508, 37,509 (1993) (revoking practitioner's registration where ''[r]espondent failed to comply with numerous recordkeeping requirements[, explaining that] . . . it is a registrant's responsibility to be familiar with the

Continued

DEA regulations state that a registered individual practitioner is required to keep records of controlled substances in Schedules II, III, IV and V which are dispensed.[63] As a general matter, records are required to be kept by the registrant and must be available for at least two years.[64]

The evidence at hearing on this issue included the testimony of DI Dunn and DI Chalmers. DI Dunn testified that he reviewed the records seized by the FBI during search warrants executed at the Respondent's registered and unregistered office locations, as well as her home. DI Chalmers testified that she was present at the search of Respondent's unregistered office on Mesa Drive in April 2009, participating in a search of the medication room and a location at the back of the medication room that may have been the Respondent's office. DI Chalmers further testified that drug logs were among the items seized. (Tr. 92.) DI Dunn explained that from his review of the records seized he found records for the dispensing of Demerol, but not the receipt of that drug. He further explained that because Demerol is a Schedule II controlled substance, it can only be transferred between registrants pursuant to a DEA Form 222. A review of the seized documents by DI Dunn revealed no copies of DEA Form 222.

DI Dunn further testified that ''there were other drugs there or an indication of other drugs there'' to include the controlled substances Demerol, Ambien, Balacet and Provigil. (Tr. 34, 36.) DI Dunn indicated that dispensing logs existed for Demerol but no invoices were found reflecting purchases of Demerol. DI Dunn also found no dispensing logs or inventories for Provigil and Ambien.

The evidence at hearing further included a narcotic log seized from Respondent during the April 2009 FBI search, reflecting the administration of Demerol on numerous occasions from August 26, 2008, to March 25, 2009. (Gov't Exs. 9, 10 at 2.)

The Respondent testified that she was never asked for any copies of DEA Form 222 and was unaware of any of the audits. With regard to whether she possessed copies of DEA Form 222, as required, her testimony was equivocal. The Respondent testified on direct examination that she ''did not recall having DEA Form 222's for Demerol at the time of the April 2009 search'' but ''guessed'' that ''we did.'' The Respondent was less equivocal in her testimony regarding having copies of DEA Form 222 at the Collier street temporary office, stating ''I didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' (Tr. 197.) Respondent also introduced records that Respondent obtained from a pharmacy supplier that include three references to Demerol purchases by Respondent. The shipping dates were August 26, September 24, and October 30, 2008. (Resp't Ex. 9, at 5–7.) None of the documents appear relevant to the presence of copies of DEA Form 222 at Respondent's unregistered Mesa office as of April 2009, because Respondent testified that no controlled substances were moved from her registered office in Denton, Texas to the temporary Collier Street office, as they were destroyed prior to Respondent's being evicted. (Tr. 197–98.)

The absence of any copies of DEA Form 222 found by DI Dunn during his review of the seized documents related to the search of Respondent's office, along with Respondent's lack of certainty that any were present, supports a finding that Respondent did not keep proper records for controlled substances that were ordered and maintained under her registration. DI Dunn's testimony is consistent with the testimony of DI Chalmers regarding the seizure of documents during the April 2009 search warrant, including the seizure of Government exhibits nine and ten. While the testimony offered with regard to the specifics of the FBI search was limited, the evidence as a whole reflects that a considerable quantity of documents was seized from Respondent's office. The fact that no copies of DEA Form 222 were found, independent of whether Respondent was asked to produce them, is persuasive proof of non-compliance.

The Respondent's testimony on the topic is equivocal at best, and is fully consistent with a finding that few if any copies of DEA Form 222 were maintained at the Respondent's unregistered Mesa office during 2009. ''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against diversion of controlled substances.'' *Paul H. Volkman, M.D.,* 73 FR 30,630, 30,643 (DEA 2008). The evidence of record, including the Respondent's own testimony, reflects that at least during the time period from in or about November or December 2008 until April 2009, Respondent did not properly maintain copies of DEA Form 222 for Demerol, a Schedule II controlled substance. Similarly, the Respondent's acceptance and documentation of returned controlled substances was not in compliance with applicable regulations. Nor did the Respondent maintain other documentation related to the controlled substances Ambien Balacet and Provigil.

(f) Respondent's Testimony

In mitigation, the Respondent testified that she had never had a prior DEA complaint or investigation, and has been in medical practice for twenty-five years, practicing in Texas since 1991. (Tr. 110, 113 & 225.) Respondent further testified that in January 2008 she became aware of a theft of fentanyl and reported the theft to DEA and other law enforcement agencies. DI Dunn also testified that he investigated the reported theft issues in May 2008, and found Respondent's reporting of theft to be proper but the theft and loss reports submitted by Respondent were incomplete. (Tr. 55.) Respondent also testified at hearing to the theft of a safe from her office in late 2008, which possibly included Suboxone and other scheduled medications, as well as ''all my triplicates.'' (Tr. 119, 196.) The Respondent also testified that in late 2008 she was evicted from her then-registered location and had to move to a temporary office (Collier office) for a short period of time, before moving to her permanent office location (Mesa office). During late 2008 and 2009, Respondent also experienced employee issues, to include alleged misuse of prescription pads, theft and related financial matters. (Tr. 209–10.) At Respondent's Mesa office she has five active examination rooms, and relies on her staff to maintain logs and inventory. (Tr. 205.) Respondent has approximately thirty (30) patient visits per day and described herself as a ''workaholic'' working non-stop without a lunch break. (Tr. 116.)

I find the Respondent's testimony at hearing to be generally credible. The Respondent's manner throughout her testimony was serious and deliberate. Respondent's education, experience and training, which included regular continuing medical education in pain management, reasonably supported her opinion testimony with regard to patients [JF], [HM], [TR] and [MM]. This opinion testimony was also fully consistent with Dr. Babuji's testimony. The Respondent testified throughout a four hour period without reference to notes or other written material, unless specifically directed by counsel, and was accurately able to recall events with a reasonable level of certainty. The Respondent did not display hostility during testimony or other visible mannerisms that adversely impacted her credibility.

On balance, however, the Respondent's record-keeping violations, handling of returned controlled substances and failure to properly change her registered address weigh significantly in favor of revocation.

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

As to factor five, there is no other substantial evidence of record demonstrating conduct by Respondent which may threaten the public health or safety, other than the risk of diversion inherent in the failure to maintain effective controls and procedures to guard against theft and diversion of controlled substances, which has been evaluated under factors two and four.

VI. CONCLUSION AND RECOMMENDATION

I find that a balancing of the foregoing public interest factors supports a finding that the Government has established a prima facie case in support of revocation of Respondent's registration, or denial of an application for registration. Once DEA has made its prima facie case for revocation, the burden then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *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).

A ''Respondent's failure to maintain accurate records . . . is sufficient by itself. . .'' in some cases, to conclude that granting a registration would be inconsistent with the public interest. *Volkman,* 73 FR at 30644.

Federal regulations applicable to controlled substances''); *see also Hugh I. Schade, M.D.,* 60 FR 56,354, 56,356 (DEA 1995) (noting the inventory procedures required by Sections §§ 1304.11 to 1304.13, and 1305.06).

[63] 21 CFR 1304.03(b) (2010).

[64] *Id.* § 1304.04

The facts in *Volkman* pertaining to record keeping violations involved a doctor who ''rapidly became the largest practitioner-purchaser in the nation of oxycodone'' which included ordering ''hundreds of thousands of dosage units of these drugs'' over time periods as short as several months. *Id.* at 30,643. The facts in *Volkman* further reflected that no dispensing logs were maintained, at times exceeding an entire year. *Id.* at 30,645.

Additionally, where a registrant has committed acts inconsistent with the public interest, a 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 (DEA 2009). Also, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio,* 74 FR 10,083, 10,094 (DEA 2009).

The Respondent testified in substance that she updated her new registration address with Texas authorities, made various efforts to do so with DEA including receiving correspondence, and therefore thought she had satisfied her obligation. (Tr. 161–63; ALJ Ex. 2.) Respondent's explanation for record keeping violations is less specific. The Respondent's testimony as a whole demonstrated that she understood the seriousness and importance of record keeping requirements, and testified that while at the temporary Collier street location ''I didn't have those little DEA 222s, so I really didn't purchase any scheduled medications during that brief period of time.'' (Tr. 197.) The Respondent also testified that she believed she ''had very effective oversight'' of controlled substances.'' (Tr. 248.) This belief is contradicted by Respondent's own testimony. Respondent also testified that she relied heavily on her staff with regard to inventory and maintenance of controlled substances, and that Respondent did very little herself. (Tr. 205.) The evidence of record does demonstrate, however, that Respondent's errors were often due to lack of knowledge, omission or neglect, rather than a deliberate violation of the record keeping requirements.

The alleged conduct supported by substantial evidence in this case centers on Respondent's record keeping violations, which have been documented to be deficient over a relatively short period of time, as well as a failure to update her registered address, and improper acceptance and disposal of returned controlled substances from patients. The Government argues in its post-hearing brief that revocation is the appropriate remedy in this case. An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. *See Morall* v. *DEA,* 412 F.3d 165, 181 (D.C. Cir. 2005) (sanction will be upheld unless unwarranted in law or without justification in fact).

In support of its recommendation for revocation, the Government cites *Paul H. Volkman,* 73 FR 30,630, 30,644 (DEA 2008), which is significantly distinguishable from the facts of this case. Respondent's conduct in this case occurred over a comparatively short period of time, with substantially fewer controlled substances, and with no evidence of actual diversion of any controlled substances. The Government cites no other precedent to support a revocation sanction on facts similar to Respondent's, nor does there appear to be any. The Respondent's errors and conduct clearly were neglectful and serious during the relevant time period, and likely due in part to ongoing issues including eviction from her registered office, employee problems, and an office break-in and theft, among other factors. That said, a revocation penalty is simply not rationally related to the evidence of record established by substantial evidence or proportionate to Respondent's misconduct.

I find that Respondent's testimony as a whole demonstrates that she has sufficiently accepted responsibility for her actions and omissions with regard to a revocation penalty, but Respondent's explanation of past errors and demonstrated plan to avoid future violations is insufficient to support an unconditional registration. Accordingly, I recommend that Respondent's COR BC0181999 as a practitioner not be revoked or a pending application denied, on the condition that Respondent: a) within a reasonable period of time as set forth in the agency's final order in this matter, satisfy the appropriate DEA designee that Respondent has state authority to handle controlled substances in Texas, the state in which she is registered with DEA; [65] b) submit to the nearest Field Division Office of DEA no later than one (1) year after issuance of a DEA COR, documentation reflecting successful completion of accredited training at Respondent's expense, in the proper maintenance, inventory, and record-keeping requirements for controlled substances, with such training to take place after the Agency issues a final order in this matter; and c) for one (1) year after the issuance of a COR, Respondent shall submit to the nearest Field Division Office of DEA, on a quarterly basis, a log of all controlled substances in Schedules II, III, IV and V received, maintained and dispensed by Respondent.

Dated: October 26, 2010

s/ Timothy D. Wing,
Administrative Law Judge

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–24]

Trenton F. Horst, D.O.; Decision and Order

On March 25, 2014, Administrative Law Judge Gail A. Randall (ALJ) issued the attached Recommended Decision.[1] The Government filed Exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I have decided to adopt the ALJ's findings of fact and conclusions of law.[2] However, for reasons explained below, I respectfully amend the ALJ's recommended sanction because it is contrary to precedent and, in my opinion, gives insufficient weight to the Agency's interest in deterring intentional diversion, both on the part of Respondent and the community of registrants. *See David A. Ruben,* 78 FR 38363, 38386 (2013). A discussion of the Government's Exceptions follows.

The Government's Exceptions

The Government raises two exceptions to the ALJ's recommended decision: First, it takes exception to the ALJ's finding that Respondent '' 'has sufficiently accepted responsibility for his actions and instituted remedial measures to ensure that the misconduct will not reoccur.' '' Exceptions, at 2 (quoting R.D. 36). Second, it argues that the ALJ's recommended sanction is inconsistent with agency precedent. Exceptions, at 5–6.

As for the first exception, the Government urges that I reject this finding, contending that Respondent ''continues to[] minimize the nature of his misconduct.'' *Id.* at 4–5. As support for its contention, the Government cites Respondent's testimony regarding his treatment at a rehabilitation center which it maintains was inconsistent with his conduct during his stay. More specifically, the Government notes Respondent's testimony that:

> it was a little bit difficult to acclimate myself for the first few weeks, probably six weeks. It took me a while to kind of get into the flow of things. Thereafter, I'd like to think I became a model participant. I spent seven months there.

Tr. 210. The Government then notes that Respondent was subject to a ''no female contract'' during the initial four months of his treatment, and that he breached the contract when he had contact with another patient and engaged in sexual relations with her

[65] 21 U.S.C. 824(a)(3).

[1] All citations to the Recommended Decision (R.D.) are to the ALJ's slip opinion as originally issued.

[2] As ultimate factfinder, I am familiar with my obligations under the Administrative Procedure Act and the role of the ALJ's recommended decision. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The 'substantial evidence' standard is not modified in any way when the Board and its examiner disagree . . . . The findings of the examiner are to be considered along *with the consistency and inherent probability of testimony.* The significance of his report, of course, depends largely on the importance of credibility in the particular case.'') (emphasis added). So too, the courts are quite familiar with the standard of review of an Agency decision. Accordingly, I decline to publish the ALJ's discussion of the substantial evidence test and the standard of review.