however, ''accepts as valid and lawful the actions of a state regulatory board unless that action is overturned by a state court . . . pursuant to state law.'' *Kamal Tiwari,* 76 FR 71604, 71607 (2011) (quoting *George S. Heath,* 51 FR 26610 (1986)). Rather, Respondent's challenge to the lawfulness of the Texas Board's Suspension Order must be raised in the forums provided by the State. *Id.* (quoting 51 FR at 26610). *See also Calvin Ramsey,* 76 FR 20034, 20036 (2011) (quoting *Hicham K. Riba,* 73 FR 75773, 75774 (2008) (''DEA has repeatedly held that a registrant cannot collaterally attack the results of a state criminal or administrative proceeding in a proceeding brought under section 304 [21 U.S.C. 824] of the CSA.'')).

Here, there is no dispute over the material fact that Respondent is no longer currently authorized to dispense controlled substances in Texas, the State in which he is registered. Accordingly, he is not entitled to maintain his registrations. I will therefore adopt the CALJ's recommendation that I revoke Respondent's registrations and deny any pending applications to renew his registrations. R.D. 6.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(3) and 28 CFR 0.100(b), I order that DEA Certificates of Registration Nos. BS3909718 and FS3571660 be, and they hereby are, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f), I order that any applications to renew the above registrations be, and they hereby are, denied. This Order is effective immediately.[4]

Dated: May 1, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–09284 Filed 5–5–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–24]

Roberto Zayas, M.D., Decision and Order

On May 18, 2015, the Deputy Assistant Administrator, of the then-Office of Diversion Control, issued an Order to Show Cause to Roberto Zayas, M.D. (hereinafter, Respondent), of Houston, Texas and Dover, Florida. ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's Certificates of Registration Nos. FZ2249743 and FZ2418401, the denial of any pending applications to renew or modify these registrations, and the denial of any applications for new registrations, on the ground that his ''continued registration is inconsistent with the public interest.'' *Id.* at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is the holder of Registration No. FZ2249743, pursuant to which he is authorized to dispense schedule II through V controlled substances as a practitioner, at the registered address of 12121 Jones Road, Houston, Texas; the Order alleged that this registration was due to expire on May 31, 2016. *Id.* The Show Cause Order also alleged that Respondent is the holder of Registration No. FZ22418401, pursuant to which he is authorized to dispense schedule II through V controlled substances as a practitioner, at the registered address of 14222 Melouga Preserve Trail, Dover, Florida; the Order alleged that this registration is due to expire on May 31, 2017. *Id.*

As grounds for the proposed actions, the Show Cause Order alleged that on September 20, 2010, Respondent ''signed a Memorandum of Agreement'' (MOA) which ''imposed requirements . . . regarding [the] operation, management and supervision of seven different clinics'' he ''own[s] and/or manage[s] and control[s]'' which are located in various Texas cities. *Id.* at 1–2. The Show Cause Order alleged that ''pursuant to paragraph 8 of the MOA, [Respondent] agreed that '[i]f controlled substances in Schedules II through V are purchased for any clinic, to be administered and/or dispensed to the clinic patient, [he] shall cause to be made and maintained all DEA required documents and information including records, reports, and inventories' '' and that ''[a]ll required documentation shall be maintained as required by federal and Texas laws and regulations.'' *Id.* at 2. The Show Cause Order then alleged that pursuant to another part of paragraph 8, Respondent ''agreed . . . that '[i]f any controlled substance is administered or dispensed at any clinic including the [seven clinics he owns or controls], the health care provider doing the administering and/or dispensing to the patient shall be registered at the clinic as required by 21 U.S.C. 822(a)(2) and 21 CFR 1301.12.'' *Id.* And with respect to paragraph 9 of the MOA, the Order alleged that Respondent was required to submit to the DEA Houston Division Office ''on a quarterly basis, the total number of controlled substances dispensed, to include the date dispensed, full name of patient, address of patient, name of controlled substance dispensed, quantity dispensed and [the] dispenser's initials.'' *Id.*

The Show Cause Order alleged that ''[b]etween August 28 and September 13[,] 2013,'' DEA conducted inspections of each of the clinics and ''determined that [Respondent] repeatedly violated the terms of paragraphs 8 and 9 of the MOA.'' *Id.* The Show Cause Order then alleged that ''controlled substances were dispensed and/or administered at four of the [clinics] during periods when the individual doing the dispensing and/or administering was not registered . . . at the'' clinic. *Id.* at 2.

The Show Cause Order also alleged that Respondent failed to make and maintain complete and accurate controlled substance inventories at six of the clinics; that he failed to make and maintain complete and accurate dispensing records at five of the clinics; and that he failed to make and maintain complete and accurate receipt records at several of the clinics. *Id.* at 3 (citing 21 CFR 1304.11(e)(3); *id.* § 1304(c);[1] *id.* § 1304.22(c); and *id.* § 1304.22(a)(2)). The Show Cause Order further alleged that Respondent failed to timely submit 10 of the required quarterly dispensing reports, that 10 of the reports that were submitted ''on July 20, 2013, were back-dated and hence, failed to indicate the true date they were prepared,'' and that ''[a]ll of these reports'' falsely represented that ''neither [Respondent] nor any of the . . . clinics . . . have dispensed any controlled substances to their patients for their medical needs.'' *Id.*

Finally, the Show Cause Order alleged that Respondent ''violated 21 CFR 1306.04(b) by issuing prescriptions 'in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.' '' *Id.* The Order then identified two instances in which Respondent allegedly issued prescriptions for testosterone products which listed him (and in one instance, a clinic) as the patient. *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. The matter was placed on the docket of the Office of

[4] For the same reasons which led the Texas Board to order the temporary suspension of Respondent's medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

[1] While there is no such provision, this appears to be a mistaken citation to 21 CFR 1304.22(c), which sets forth the records required to be maintained by dispensers.

Administrative Law Judges and following the departure from the Agency of the ALJ to whom the case was initially assigned, the matter was re-assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). Following pre-hearing procedures, the CALJ conducted an evidentiary hearing on October 27–28, 2015, in Houston, Texas. At the hearing, the Government elicited testimony from multiple witnesses and introduced numerous exhibits into evidence; Respondent testified on his own behalf and introduced a single exhibit.

On February 19, 2016, the CALJ issued his Recommended Decision. Therein, the CALJ found proved the allegations that Respondent: (1) Issued prescriptions to obtain controlled substances for office use in violation of 21 CFR 1306.04, *see* R.D. at 54; (2) violated 21 CFR 1304.11 and/or the MOA at six clinics by failing to cause to be made and maintained compliant inventories, *see* R.D. at 57–58, 68; (3) violated 21 CFR 1304.22(c) and/or the MOA by failing to cause to be made and maintained compliant dispensing records at the six clinics, *see* R.D. at 59–60, 70; (4) violated 21 CFR 1304.22(c) and/or the MOA by failing to cause to be made and maintained compliant receipt records at the six clinics, *see* R.D. at 61, 72; (5) violated 21 U.S.C. 822(a)(2) and 21 CFR 1301.12(a), as well as the MOA, on multiple occasions when employees of four of the clinics administered testosterone to patients and there was no practitioner registered at the clinic's location, *see* R.D. at 66; and (6) violated the MOA on eight occasions when he failed to timely submit the quarterly dispensing reports. *Id.* at 75. Based on these conclusions, the CALJ found that Respondent has committed such '' 'acts as would render his registration under [21 U.S.C. 823(f)] inconsistent with the public interest,' '' and that the Government had ''ma[d]e out a *prima facie* case that maintaining [his registrations] would be contrary'' to the requirements of 21 U.S.C. 823(f) and 824.'' *Id.* at 76 (quoting 21 U.S.C. 824(a)(4)).

Turning to whether Respondent had produced sufficient evidence to rebut the Government's *prima facie* case, the CALJ found that while Respondent ''begrudgingly accepted responsibility when his counsel led him to do so, . . . when left to his own devices, in response to questions by Government counsel, he approached the topic with a tenor that bordered on hostile sarcasm.'' *Id.* at 77. The CALJ thus concluded that ''[t]his record simply does not support a finding that the Respondent has accepted responsibility in any meaningful way.'' *Id.* While the CALJ noted that Respondent's evidence of subsequent remedial measures was ''rendered irrelevant in light of his refusal to accept responsibility,'' he further concluded that his ''purported evidence of corrective measures as it exists in the . . . record does not advance his position.'' *Id.* After noting Respondent's testimony that his clinics had stopped administering controlled substances as well as that they had stopped providing their patients with the option of having their prescriptions shipped to the clinic for pickup, the CALJ explained that ''[n]one of these practice modifications reflect efforts to improve compliance with DEA regulations, adhere to terms of present or future . . . MOAs, or better guard against controlled substance diversion.'' *Id.* at 78. Continuing, the CALJ characterized Respondent's testimony as ''essentially lecturing the Agency that its pesky regulations and the DEA MOA have proven so bothersome that he will gratuitously punish his patients because of them, and it is all the fault of the DEA.'' *Id.* The CALJ further explained that ''[i]t would be difficult to divine an enhanced commitment to DEA regulation compliance from a man who freely admits that he still has not read them.'' *Id.* (citing Tr. 473–74).

The CALJ further found that Agency's interests in both specific and general deterrence ''provide significant support for'' revoking his registration. *Id.* With respect to the former, the CALJ found that ''there is little in the record that lends support to the proposition that the Respondent's future behavior will deviate in any positive respect from his past behavior,'' noting that ''Respondent blatantly disregarded his obligations under both the DEA regulations and the DEA MOA.'' *Id.* at 78–79. And as for the Agency's interest in general deterrence, the CALJ found that ''[a] sanction less than revocation in this case would send a message to the regulated community that diligence in recordkeeping is not truly required and that agreements entered into with the Agency may be freely disregarded without consequence.'' *Id.* at 80. Finally, the CALJ rejected Respondent's contention that his conduct involved only ''recordkeeping violations'' which did not warrant revocation, explaining that this case did not present the situation ''where a small number of modest recordkeeping errors are acknowledged and remedied promptly,'' and that ''[i]n this case, the anomalies were plentiful and dangerous'' and ''include instances where *no* records were kept.'' *Id.* The CALJ thus recommended that Respondent's registrations be revoked and that any pending renewal applications be denied. *Id.* at 81.

Respondent filed Exceptions to the Recommended Decision. Thereafter, the record was forwarded to my Office for final agency action.

Having considered the record in its entirety, as well as Respondent's Exceptions, I agree with the CALJ's findings and legal conclusions as enumerated above. However, I further conclude that by failing to ensure that all six clinics made and maintained compliant inventory, dispensing and receipt records, Respondent not only violated the MOA, he also violated the CSA and DEA regulations. Moreover, while I agree with the CALJ's legal conclusion that Respondent violated the MOA by failing to timely submit eight of the required quarterly reports, I reject the Government's contention that the ''reports contained false representations'' because ''each report states that 'neither [Respondent] nor any of the IMC clinics . . . have dispensed any controlled substances to their patients for their medical needs.' '' ALJ Ex. 1, at 3, ¶ 5(c).

I also agree with the CALJ's conclusion that Respondent has committed such '' 'acts as would render his registration under [21 U.S.C. 823(f)] inconsistent with the public interest,' '' and that the Government had ''ma[d]e out a *prima facie* case that maintaining [his registrations] would be contrary'' to the requirements of 21 U.S.C. 823(f) and 824.'' R.D. at 76 (quoting 21 U.S.C. 824(a)(4)). I further agree with the CALJ's conclusions that the ''record simply does not support a finding that the Respondent has accepted responsibility in any meaningful way,'' *id.* at 77, that the Agency's interests in both specific and general deterrence ''provide significant support for'' revoking his registration, *id.* at 78–79, and that the egregiousness of Respondent's misconduct supports the revocation of his registration. *Id.* at 80–81. Accordingly, I will adopt the CALJ's recommended order that his registration be revoked and that any pending application be denied. I make the following findings.

Findings of Fact

Respondent is a physician licensed in Texas and Florida. He is also the holder of DEA Certificate of Registration No. FZ2418401, pursuant to which he is authorized to dispense controlled substances in schedules II through V, at the registered address of 14222 Melouga Preserve Trail, Dover, Florida. R.D. at 4. This registration does not expire until May 31, 2017. *Id.* Respondent was also

the holder of DEA Certificate of Registration No. FZ2249743, pursuant to which he was authorized to dispense controlled substances in schedules II through V, at the registered address of 12121 Jones Road, Houston, Texas; this registration was due to expire on May 31, 2016. *Id.* However, because as of May 31, 2016, Respondent was under an Order to Show Cause, and did not submit a renewal application until June 27, 2016, this application was untimely and did not keep his registration in effect pending the issuance of this Decision and Order. *See* 5 U.S.C. 558; 21 CFR 1301.36(i). I therefore find that Certificate of Registration No. FZ2249743 expired on May 31, 2016. I further find, however, that Respondent's June 27, 2016 application remains pending before the Agency.

At the time of the events at issue here, Respondent owned indirectly and controlled seven different clinics through a limited partnership known as Z Healthcare Management; 99 percent of this entity is owned by the Zayas Family Trust with the remaining one percent owned by Z Healthcare Systems, Inc., the latter being 100 percent owned by Respondent; as of the date of this proceeding, he still owned and controlled five of these clinics.[2] RX 1, Tr. 59, 371. These clinics included: (1) IMC Cy-Fair, which was located at 12121 Jones Road, Houston, Texas during the relevant time period, *see* GX 6; (2) IMC FM 1960, which was located at 3648 FM 1960, Houston, Texas, but has since closed, *see* GX 16, Tr. 365; (3) IMC Southwest, which was located at 7447 Harwin, Suite 100, Houston, Texas, *see* GX 22; (4) IMC Oak Hills, which was located at 4805 Fredericksburgh Road, San Antonio, Texas, *see* GX 12; (5) IMC Woodlands, which was located at 25329 I–45 North Suite B, The Woodlands, but which moved to 314 Sawdust Road, Spring, Texas during February/March 2013, GX 19; (6) IMC Victoria, which was located at 3804 John Stockbauer Drive, Suite E, Victoria, Texas, but has since closed,[3] GX 25, Tr. 365; and: (7) IMC Corpus Christi, which was located at 4646 Corona Drive, #280, Corpus Christi, Texas. GXs 33, 34.

The MOA

On September 8, 2010, Z Healthcare Systems entered into a Settlement Agreement with the Office of the United States Attorney for the Southern District of Texas. GX 4, at 6. According to the agreement, the Government alleged that between August 2005 and June 2006, three IMC clinics dispensed controlled substances, in particular phentermine, ''without a valid DEA registration.'' *Id.* at 8.

While Z Healthcare Systems was not required to admit liability, it did agree to pay $25,000 to the United States. *Id.* at 9. It also agreed that ''each health care provider of each of its facilities including the [seven clinics] must have a separate DEA registration to administer, dispense, and prescribe a controlled substance for a legitimate medical purpose at each facility.'' *Id.* at 10. It further agreed that ''[i]f any controlled substance is purchased in order to be administered or dispensed, each facility is required to comply with the record-keeping and security requirements under 21 U.S.C. 801 to End and 21 CFR 1300 to End.'' *Id.* at 10–11. Respondent signed the Agreement as the President of Z Healthcare Systems. *Id.* at 13.

Thereafter, on September 20, 2010, Respondent entered into a Memorandum of Agreement (MOA) with the Agency, which imposed various conditions which give rise to the allegations at issue in this proceeding. GX 4, at 5. After noting the investigation that led to the Settlement Agreement, the MOA stated that it ''establishes the terms and conditions under which DEA will continue to permit [Respondent] to administer, dispense and prescribe any [s]chedules II though V controlled substance'' and for granting his February 2009 application for registration at the IMC—Woodlands clinic. *Id.* at 2. Of relevance here are the terms and conditions imposed under paragraph 8. It provides that:

> If controlled substances in Schedules II through V are purchased for any clinic, to be administered and/or dispensed to the clinic patients, [Respondent] shall cause to be made and maintained all DEA required documents and information including records, reports, and inventories. All required documentation shall be maintained as required by federal and Texas laws and regulations, pertaining to the administering, dispensing, and prescribing of controlled substances. If any controlled substance is administered or dispensed at any clinic included the [seven clinics], the health care provider doing the administering and/or dispensing to the patient shall be registered at the clinic as required by 21 U.S.C. 822(a)(2) and 21 CFR 1301.12(a) and any administering and/or dispensing of a controlled substance shall be documented in the patient chart and made available for inspections as set forth in paragraph . . . 12 of this MOA.

Id. at 2–3. Also of relevance are the terms and conditions included in paragraph 9. It provides that Respondent:

> shall submit to the DEA Diversion Group Supervisor, DEA Houston Division Office . . . on a quarterly basis, the total number of controlled substances dispensed, to include the date dispensed, full name of patient, address of patient, name of controlled substance dispensed, quantity dispensed and dispenser's initials.

Id. at 3. Respondent further ''agree[d] that any violation of this MOA may result in the initiation of proceedings to immediately suspend or revoke his . . . Certificate of Registration. *Id.* at 4.

The 2013 Investigation

In April 2013, Respondent submitted an application to renew his registration, which ''was due to expire at the end of May.'' Tr. 86. On the application, Respondent was required to answer several questions including one which asked if his state medical license had been suspended. *Id.* at 91. Because Respondent provided a ''yes'' answer to this question, *id.,* his application was not approved and was flagged for further review by a Diversion Investigator (DI). *Id.* at 84–85. The DI visited the Texas Medical Board's Web site and printed out the suspension order that Respondent referenced on his application. *Id.* at 88; *see also* GX 2, at 1–11. However, the DI also found that the Board's Web site listed another order which was not mentioned on Respondent's application and printed it out.[4] Tr. 88; GX 2 at 12–20. The DI also queried DEA's databases and determined that Respondent ''was under an MOA,'' and that the MOA's terms required ''that he had to report quarterly his dispensing in all [of] his clinics.'' Tr. 88. However, upon searching the Agency's case file for the previous investigation, the DI could only find one report, which she believed was dated April 24, 2011. Tr. 107.

While the DI's initial attempts to contact Respondent were unsuccessful, on May 23, 2013, she spoke with Respondent and told him that she ''need[ed] a written statement regarding the board order that [he] reported.'' *Id.* at 97. According to the DI, Respondent ''basically was like, you can go find it yourself. And at some point, he hung up the phone.'' *Id.* at 98.

Subsequently, on June 3, 2013, the DI sent Respondent an email which raised

[2] The clinics were themselves incorporated, with two held by limited liability corporations and the others held by c-corporations. RX 1.

[3] According to Respondent, the IMC 1960 and Victoria clinics were probably closed in 2014. Tr. 366.

[4] While the DI testified that this was an order, it was actually a complaint, which was filed by the Board on September 5, 2012. GX 2, at 19. However, the Board and Respondent settled the matter, and on February 12, 2014, the complaint was dismissed. *Id.* at 21.

three issues; Respondent replied to the email the next day. GX 36, at 1–2. First, the DI asked Respondent to ''[p]lease provide a detailed explanation relating to the suspension of [his] Texas Medical License in 2008'' and to ''be specific as to the details as to why [his] medical clinics were deemed a 'danger to the public good.' '' *Id.* at 2. Respondent replied that ''[t]his is irrelevant to the renewal of my DEA certificate. You are welcome to get the one sides [sic] version of the story on the [TMB] Web site.'' *Id.*

Second, the DI wrote that ''[r]ecords indicate that you are currently under a Memorandum of Understanding (MOU) . . . signed on September 2010, however, there is [a] record of only one (1) required quarterly reporting [sic] from you. If you have [a] record that you previously sent the required quarterly reporting [sic] please forward copies from April 2011 to the present . . . . '' *Id.* Respondent replied: ''As I said to you on the phone, you are mistaken. I am not, nor have I ever been under and [sic] MOU.'' *Id.*

Finally, the DI asked Respondent to ''[p]lease describe your current medical practice[,] please include all locations and the names and numbers of any Physician Assistants . . . or Nurse Practitioners . . . that you currently supervise. Please indicate what changes you have made in your current medical practice that differentiates it from your current practice.'' *Id.* Respondent wrote back: ''Again this is irrelevant to the renewal of my DEA certificate.'' *Id.*

However, on June 19, 2013, Respondent wrote to the DEA Houston Office to ''sincerely apologize for the misunderstanding that I was under with respect to the agreement we struck in 2010.'' GX 35, at 1. Respondent offered to answer the DI's questions either by email or in person. *Id.* He also enclosed 10 of the quarterly reports which the DI had previously requested and represented that ''I haven't practiced much in Texas since 2010, and I certainly haven't dispensed any medication to patients.'' *Id.*

Each of these reports was a one-page letter, which was dated on an approximately quarterly basis beginning with January 29, 2011 and ending on April 24, 2013. GX 3, at 1–10. Each report contained the following statement:

> This letter is being sent to you as required by the DEA Memorandum of Agreement which was executed by me and your office. I am submitting the letter to indicate that since the signing of the Agreement neither I nor any of the IMC clinics, located in the State of Texas, have dispensed any controlled substances to their patients for their medical needs.

GX 3, at 1–10. Subsequently, Respondent submitted two more reports (dated July 20 and September 25, 2013), which contained the same statement. Tr. 113; GX 3, at 11–12.

Thereafter, the DI decided to investigate whether Respondent's clinics were in compliance with both the MOA's recordkeeping and registration conditions. Tr. 114. The DI proceeded to issue a subpoena to Respondent requesting the names of the practitioners at each clinic. *Id.* at 115. She also decided to conduct inspections of each clinic.[5] *Id.*

The IMC Cy-Fair Inspection

On August 28, 2013, the DI, accompanied by another DI, went to the IMC Cy-Fair clinic where they presented their credentials to Respondent and issued a notice of inspection. Tr. 116. The DI asked Respondent if there were any controlled substances on hand; Respondent answered that he didn't know because he had just flown in that morning. *Id.* at 117. The DI asked the office manager, who told her that clinic did have controlled substances on hand. *Id.* The DI then asked Respondent if the controlled substances were ordered using his registration; he answered that he had ''no idea.'' *Id.* The DI also asked Respondent if someone else had used his registration to order the drugs; Respondent again answered that he had ''no idea.'' *Id.* The DI further asked to see the clinic's receiving records, and after being ''shown the bottle of testosterone that was in the cabinet in the back area . . . asked to see the dispensing log,'' which was provided by the office manager. *Id.* at 119.

During the inspection, the office manager ''could not produce any [receiving] records,'' regardless of whether the purchases had been made before or after he commenced his employment at the clinic. *Id.* at 119–20. Nor did the clinic have either an initial or biennial inventory. *Id.* at 119, 127. While the office manager said he would ''go to [the] storage area'' and look for the records, he produced no records other than a dispensing log for testosterone during the inspection, which lasted two to three hours. *Id.* at 120, 125. According to the DI, two days later, she received an email from the office manager which included a spreadsheet of the clinic's purchases. *Id.* at 121.

The DI further testified that there was ''[a] vial of testosterone'' on hand, which according to the clinic's employees, was ''used for administering to patients.'' *Id.* at 121–22. According to the DI, the vial of testosterone did not bear a patient's name on its label.[6] *Id.* at 124.

With respect to the dispensing log, the DI testified that the entries were not compliant because they did not list the dosage form of the testosterone, the patient's address, and in some instances, did not list the amount.[7] *Id.* at 130. There was also an entry which was missing the initials of the dispenser, and multiple entries appeared to have the patient's signature or initials but not those of the dispenser. *See id.* at 130–31; *see also* GX 8, at 2, 5.

As for the clinic's receipt records, *see* GX 9, they were comprised of a single sheet which contained 9 line items for purchases occurring between November 1, 2012 and August 6, 2013. Each entry stated: ''10 Testosterone Cypionate 200MG/ML'' followed by the date and initials. GX 9, at 1. According to the DI, these records were missing multiple items of required information including the name, address and registration number of the seller, the date it was shipped and date it was received. Tr. 132–33. On further questioning, the DI explained that the record did not list how much of the solution had been received as ''you don't know if'' the notation of ''10'' is for ''ten vials'' or ''if it's ten what.'' *Id.* at 133. Upon review of the receiving record, the DI emailed the office manager and asked him to clarify whether the initials were of the person ordering or receiving the drugs and whether the date was for the date the drugs were ordered or received; the office manager replied that he assumed that the initials were of the employee who ordered the drugs and that the date was the date of ordering. *Id.* at 134–36; GX 38, at 2.

Based on information provided by Respondent in response to the previously issued subpoena, as well as information obtained during interviews she conducted of the clinic employees, the DI determined the names of the practitioners who had worked at the clinic. Tr. 138. She also conducted a query of the DEA Registration database to determine if the clinic had a practitioner who was registered at the clinic from the date the MOA was signed (Sept. 20, 2010) through September 20, 2013. *Id.* at 139. According to the DI, ''between March 2,

[5] However, several other Investigators were involved in the inspections.

[6] According to the inventory conducted by the DIs and witnessed by Respondent, the vial contained 5 milliliters of the drug. GX 7.

[7] While a number of the entries included the notation of ''.5,'' they did not list the unit of measure. GX 8, at 5.

2011 and September 26, 2011, there was no practitioner or mid-level practitioner [who was] registered at'' the clinic. GX 6; Tr. 139–40. According to the dispensing log, on September 13, 2011, testosterone was administered to patient C.F. Tr. 145; GX 8, at 5. Moreover, the dispensing log contains numerous entries showing that controlled substances were being dispensed at the clinic during the period covered by the MOA. Tr. 148.

The IMC Woodlands Inspection

On September 11, 2013, the DI, accompanied by two DIs and an Intelligence Research Specialist, went to the IMC Woodlands clinic and presented their credentials and a notice of inspection to Nurse Practitioner Penny Norman. *Id.* at 150. The DI ''requested inventories, receiving records, [and] dispensing logs.'' *Id.* at 150–51. However, the clinic did not have any inventories or receipt records and was able to provide only its testosterone shot log, which was a single page, and which showed that the clinic had administered testosterone on 25 occasions between November 20, 2012 and September 10, 2013. GX 20, at 1; Tr. 155–56. The DI inventoried the controlled substances then on hand and found that ''[t]here was one bottle of testosterone on site,'' which did not bear a patient's name.[8] Tr. 152. According to N.P. Norman, while some patients would obtain prescriptions for testosterone, the clinic's medical assistants (MAs) would administer testosterone to patients who ''had trouble giving it to themselves.'' [9] *Id.* at 274. The MAs could not, however, ''give an injection unless [there was] an order from a provider.'' *Id.* at 279–80.

According to the DI, sometime in either February or March 2013, this clinic moved from the address of 25329 I–45 North, Suite B, The Woodlands, to 314 Sawdust Road, Suite 119, Spring, Texas. GX 19. While two practitioners were registered at the clinic's Woodlands location prior to the move, neither practitioner changed his/her registration to reflect the clinic's new location until September 13, 2013. *Id.* Thus, no practitioner was registered at the clinic from the date it moved until September 13, 2013. *Id.* However, the testosterone shot log shows that testosterone was administered on at least 14 occasions [10] after the clinic had moved to its new location and neither practitioner was registered there. GX 20.

The IMC Victoria Inspection

On September 12, 2013, the DI, accompanied by another DI, went to the IMC Victoria clinic, and presented their credentials and a notice of inspection to Nurse Practitioner Ginger Carver. Tr. 160–61. The DIs asked for the clinic's ''inventories, receiving records, and administration . . . or dispensing logs.'' *Id.* at 161. The DIs also took a closing inventory and found that the clinic had both testosterone and phentermine on hand. GX 31. According to the DI, N.P. Carver told her that some of the testosterone was for ''office use.'' Tr. 161–63; 169 (testimony that the N.P. referred to the office use testosterone ''as the house bottle''). Moreover, at the bottom of the cabinet was a crate containing phentermine and testosterone in bags prepared by a pharmacy located in Houston (Empower Pharmacy) to which were attached receipts listing the names of patients. Tr. 164–65, 169–70. According to the DI, the drugs were shipped to the clinic and were to be picked up by the patients. *Id.* at 163, 170. However, some of the testosterone was stored at the clinic for patients who were ''not comfortable with administering to themselves,'' and the clinic staff would administer the drugs when these patients ''came in for their appointment[s].'' *Id.* at 170.

While Ms. Carver provided the DI with the clinic's testosterone injection log and its receiving records, she did not provide an inventory. *Id.* at 172, 185. The DI further testified that no practitioner was registered at the clinic between from May 22, 2013 and August 29, 2013. *Id.* at 176. The testosterone injection log shows, however, that the clinic administered testosterone at least 117 times during this period.[11] *See* GX 26, at 1–5, 7, 12–14, 16. According to the DI, there were instances in which the name of the person administering the drugs was not identified. Tr. 179; *see* GX 26, at 3 (Patient L.P.); *id.* at 4 (multiple patients). There were also entries that were not dated. Tr. 181; *see* GX 26, at 2–5, 15.

As for the receiving records, the DI testified that they did not comply with the Agency's regulations because they did not have the supplier's name, address, and DEA number. Tr. 185; *see also* GX 32. Nor did the records include the ordering registrant's name, address, and DEA number. Tr. 185; *see also* GX 32. Of note, GX 32 is a list of both controlled and non-controlled prescriptions filled by Empower Pharmacy on various dates between October 1, 2012 and May 31, 2013, which list a prescription number, the patient's name, the dates on which the prescriptions were written and filled, the quantity, drug name and strength, the ''doctor,'' the pharmacist's initials and price. GX 32. Some of the pages list a total number of prescriptions and a ''Total Price.'' *See id.* at 2, 6–7, 10. According to the DI, this document was a list of ''every prescription that was shipped to [the] clinic where the patient paid the clinic, picked up the prescription, and then the clinic . . . would pay the pharmacy whatever the total was at the end of the month.'' Tr. 186. The DI further testified that ''[w]ithin these records, there are purchases of testosterone in the clinic name.'' *Id.; see, e.g.* GX 32, at 1(RX# C177831 dispensed on 10/22/12 and listing patient as ''Victoria Clinic'').

The IMC Corpus Christi Inspection

On September 13, 2013, the DI, accompanied by another DI, went to the IMC Corpus Christi clinic where they presented their credentials and a notice of inspection to Nurse Practitioner Allen Ford. Tr. 189. The DIs ''asked to see what controlled substances they had on hand,'' and after finding that the clinic had testosterone, ''asked for [the clinic's] inventories, records of receipt, and their dispensing log.'' *Id.* As the clinic's copier was not working, the clinic emailed various records to the DIs including its dispensing records and receiving records. *Id.* at 190, 196; GX 28. While the DIs along with NP Ford took an inventory of the controlled substances then on hand, the clinic did not have a prior inventory. GX 33.

Of note, the clinic had 18 milliliters of testosterone 200 mg/ml on hand for ''office use,'' as well as 60 phentermine 45mg and 140 testosterone 200 mg/ml that it was storing for patients. *Id.* According to the DI, the latter drugs were in sealed bags which had a patient name on them. Tr. 191.

The DIs testified, however, that some of the dispensing records did not identify the drug, *id.* at 197, and even when the records identified that

[8] While the DI testified that the results of the closing inventory were documented on GX 29, this document includes the notation of ''10 ml'' in the column for ''Bottle Count/ML'' and list ''18 ml'' as the ''Quantity.'' GX 29. While this suggests that the clinic had more than one bottle of testosterone (as testified to by the DI), the inventory was signed by N.P. Norman and it is undisputed that the clinic had some testosterone on the premises on the date of the inspection.

[9] Ms. Norman also testified that the clinic ''would do . . . lab work'' on the patients ''to make sure'' they needed testosterone. Tr. 276.

[10] As the evidence does not establish the date on which the clinic moved, the precise number of administrations cannot be ascertained. However, from April 1, 2013 through the date of the inspection, the clinic administered testosterone 14 times. GX 20.

[11] In some instances, the administration log lists an administration but does not include the date on which it occurred.

testosterone was the drug being dispensed, the record did not state the ''dosage form'' and the patient's address. *Id.* at 198. As for its receipt records, the clinic provided a single page with the title ''Log of Scripts'' and which was apparently created by Empower Pharmacy and lists ''[p]rescriptions filled between 8/29/2011 and 8/29/2013'' and the patient as ''CLINIC CORPUS CHRISTI.'' GX 28. The document shows that Empower filled 14 prescriptions for testosterone 200 mg/ml and one prescription for a drug called ''Scream Cream,'' [12] which also contains testosterone, for the Corpus Christi clinic. *Id.; see also* Tr. 410. According to the DI, this record did not comply with DEA's regulations for receiving records because it did not contain the clinic's address and registration number, the package size or form, ''and you don't know how many was shipped, when it was shipped, and how it was shipped [sic].'' Tr. 199.

The DI also testified that when she asked how the clinic obtained the drugs for office use, ''the office manager indicated that Mr. Ford would issue a prescription . . . to actually say[] office use.'' *Id.* at 193; *id.* at 194. The Government submitted copies of six prescriptions which the clinic issued to obtain testosterone ''for clinic use.'' GX 34. Asked why she deemed these documents to be prescriptions rather than order forms, the DI explained that ''the document says, prescription, in multiple places''; she also testified that when she asked the clinic's office manager: ''[h]ow do you obtain the testosterone for your office use . . . she said, Mr. Ford issues a prescription.'' Tr. 205. The DI added that when she asked the office manager if she had ''copies of those prescriptions . . . this is what she presented.'' *Id.* The DI also observed that the forms list ''a date of birth'' for the clinic although she was ''not sure why.'' *Id.* Of further note, next to the word ''ALLERGIES'' the forms include the abbreviation ''NKDA'' (no known drug allergies). *See* GX 34. The forms also included the notation: ''This prescription may be filled with a generically equivalent drug product unless the words ''BRAND MEDICALLY NECESSARY'' are written in the practitioner's own handwriting on this prescription form.'' *Id.* Finally, each of the prescriptions was signed by a practitioner. GX 34.

[12] According to Respondent, scream cream was compounded by a pharmacy and Super Scream Cream contained testosterone. *Id.* at 411–12. Based on the prescription number for the scream cream, which is prefaced with a ''C'' for controlled, *see* GX 28, at 62; I find that this formulation was controlled.

The IMC FM 1960 West Inspection

On September 11, 2013, two other DIs went to the IMC FM 1960 West clinic and conducted an inspection. Tr. 287; GX 14. During the inspection, the DIs determined that the clinic had controlled substances ''on hand'' and asked for the clinic's dispensing records, invoices, and an inventory. Tr. 288. On taking inventory of the controlled substance on hand, the DIs found that there was one vial of testosterone that did not bear a patient name. *Id.* A DI testified that she was told by clinic employees that the vial ''was used to administer testosterone [to] the[] male patients that would come in and get testosterone injections.'' *Id.* The DIs also found ''several bags of controlled substances that were . . . like from a pharmacy, that were already bagged up in patient names,'' *id.,* and ''had a prescription number.'' *Id.* at 291. These drugs included progesterone/testosterone cream and phentermine capsules. GX 14.

As for its records, the clinic did not have either an initial or biennial inventory. Tr. 288, 304–05. The clinic also did not have receipt records on hand but had Empower Pharmacy fax a two-page document bearing the caption: ''PATIENT Rx HISTORY REPORT'' and which also listed the clinic as the patient. *Id.* at 296, 305; GX 15. As submitted for the record, the document lists by prescription number and date various drugs distributed by Empower Pharmacy to the clinic including such controlled substances as testosterone and Scream Cream beginning on September 24, 2011 and ending on March 25, 2013. GX 15. The DI explained that the document did not comply with DEA regulations for receipt records because it does not contain the dates the drugs were received by the clinic. Tr. 296.

As for the clinic's dispensing records, the clinic provided a one page ''Testosterone Shot Log.'' GX 17. The log listed 20 different instances of testosterone administrations by the patient's name and date beginning on September 27, 2011 through August 30, 2013. *Id.* While the log also listed the initials of a medical assistant, it contained no information as to the patient's address, the drug strength and the amount administered. *Id.*

The DI testified that during the inspection she asked ''who is registered here?'' Tr. 298. Subsequently, she determined no one was ''registered at the clinic at the time.'' *Id.* Moreover, the testosterone shot log and the receipt records show that testosterone was obtained on May 18, 2012 and administered the next day, and the lead DI found that ''between April 4, 2012 and July 22, 2012, there was no practitioner or mid-level practitioner registered at the clinic.'' GX 16. The lead DI also found that there was no practitioner or mid-level practitioner registered at the clinic between October 5, 2012 and September 11, 2013. *Id.* Yet the receipt records show that the clinic obtained Scream Cream containing testosterone on or about October 20, 2012 and testosterone 200mg/ml on January 28, 2013, and the testosterone shot log shows that the drug was administered to patients on November 9 and 29, and December 28, 2012, as well as on January 28, July 29, and August 30, 2013. *See* GX 15, at 2; GX 17. Because no practitioner was registered at the clinic at the time of the inspection, the DIs seized the clinic's controlled substances. Tr. 298.

The IMC Oak Hills Inspection

On August 28, 2013, several DIs from the San Antonio District Office conducted an inspection of the IMC Oak Hills clinic. *Id.* at 308–09, 314. During the inspection, one of the DIs interviewed N.P. Norman, who explained that clinic was ''a hormone and weight-loss clinic'' which ''used testosterone and ketamine.'' *Id.* at 309. According to the DI, she was told by both N.P. Norman and the clinic's ''chief financial manager'' that the clinic ordered testosterone ''for office use.'' *Id.* at 310–11. Ms. Norman further explained that a prescription would be sent to Empower Pharmacy and that the testosterone would be ''mailed to the clinic for dispensation, administration to the patients.'' *Id.* at 310. Ms. Norman also told the DI that she was a floater who ''cover[ed] various clinics'' and that ''the same practice is [used] at all clinics.'' *Id.* at 311.

According to another DI who participated in the inspection, an inventory was taken of the controlled substances on hand. GX 11. According to the document memorializing the results, apparently one bottle of testosterone 200 mg/ml was on hand; the document, however, lists the quantity as ''30 mg.'' [13] *Id.*

One of the DIs also ''asked for the inventory records of the dispensations of the testosterone.'' Tr. 319. Among the records submitted into evidence is a testosterone log, which like other such logs, lists various administrations by date, patient name, dose, lot number of the drug, and the medical assistant's

[13] Given that the testosterone was in liquid form, it is not clear why the quantity was listed in milligrams rather than milliliters.

initials. GX 13, at 1–3. The log, however, includes only the administrations between April 3 and August 24, 2013. *See id.* The clinic also provided the DIs with a document bearing the caption: ''Testosterone Daily Drug Inventory Log.'' *Id.* at 4–28. The document shows the quantity of testosterone on hand on a daily basis beginning with January 1, 2011 but ending on March 30, 2013 in both the ''AM'' and ''PM,'' as well as the amounts dispensed, added to inventory, and wasted.[14] *Id.*

The IMC Southwest Inspection

On September 11, 2013, DIs went to the IMC Southwest clinic in Houston, Texas, and conducted an inspection. Tr. 324. The DIs requested the clinic's inventories, receiving records, . . . transfer records, any records related to the controlled substances that [were] on hand,'' including dispensing records. *Id.* at 326. While the clinic provided dispensing records, it did not provide any inventories or receiving records. *Id.*

The DIs took an inventory of the controlled substances on hand and found that the clinic had testosterone in the 200 mg/ml strength. GX 30, at 1. As for the quantity of testosterone, the closing inventory simply notes the number ''13''; however, according to the DI, this represented 13 vials. *See id.;* Tr. 327 A separate inventory sheet documents that the clinic had on hand 630 tablets of phentermine 37.5 mg, 90 tablets of phentermine 30 mg, and 90 tablets of phendimetrazine 35 mg. GX 30, *Id.* at 2. According to the DI, none of the testosterone vials was labeled with the name of a specific patient. Tr. 327. However, there were specific patient names on some of the drugs lists on second page of the inventory. *Id.* at 327–28.

The clinic did provide the DIs with a ''Testosterone Log,'' showing the date, the patient's name, the amount administered, and the medical assistant's initials. GX 23. The log's first entry is dated September 4, 2012; the last is dated September 7, 2013. *See* id. at 1, 4. However, none of the entries list the strength of the testosterone or the patient's address. Tr. 329–30. A DI testified that one of the clinic's staff members had told him that another clinic had closed and that its controlled substances were transferred to the Southwest clinic. *Id.* at 330–31. However, the Southwest clinic did not have any records documenting the transfer of the controlled substances.[15] *Id.* at 331.

Evidence Related to Respondent's Quarterly Reports

In addition to her testimony to the effect that Respondent failed to comply with the MOA because he did not timely file the required quarterly reports, the lead DI testified that the statements made in the reports were untrue. Tr. 213. As to why, the DI explained that ''[b]ased upon the records received at each clinic, there was dispensing at the clinics during the periods covered in these quarterly statements.'' *Id.* The DI further testified that during her interactions with Respondent, whether in person, by phone or by email, there was no ''discussion about what was meant by dispensing controlled substances.'' *Id.* She also testified that there was no ''discussion about whether the dates'' of the ''reports were accurate.'' *Id.* at 214.

Later, on cross-examination, the lead DI testified that her understanding of the term ''dispense'' as used in the MOA ''goes back to'' the definition in 21 U.S.C. 802, which ''includes administering and actually physically . . . taking of the medication.'' *Id.* at 244. She also testified on cross-examination that Respondent violated the MOA because there were recordkeeping violations and because ''he was required to submit quarterly reports'' which he failed to do until ''he was basically pushed at some level to finally submit them.'' *Id.* at 249.

Respondent's Evidence

Respondent's case was comprised solely of his testimony and a single demonstrative exhibit which showed how his various businesses (including the clinics) were held. Respondent testified that he graduated with honors from Harvard and attended medical school at Johns Hopkins. Tr. 346. Thereafter, he ''did a transitional residency'' which involved rotating through various specialties. *Id.* at 349. After his residency, Respondent worked in a private practice for several doctors in the Cy-Fair section of Houston, Texas on a part-time basis; he also worked on a *locum tenens* basis and treated workers compensation patients. *Id.* at 349–51. According to Respondent, he has practiced family medicine throughout the entirety of his medical practice and considers himself to be a general practitioner. *Id.* at 350. Respondent eventually started his own practice and purchased another practice in the Cy-Fair section from a physician who was retiring. *Id.* at 353. While Respondent moved this practice to a new office, it is now known as the IMC Cy-Fair clinic. *Id.* Respondent also acquired a third practice from another physician who was retiring. *Id.* at 354.

According to Respondent, in late 2004/early 2005, Respondent sold the practices and moved to Miami, Florida, where he was also licensed, intending to open some clinics, only to find that the barriers to entry were greater than in Texas. *Id.* at 356. Respondent then decided to concentrate on developing software for electronic medical records and moved to Washington State. *Id.* However, ''at the end of 2010,'' Respondent bought back the Texas practices. *Id.* at 358, 360.

Regarding the MOA, Respondent testified that ''in 2006 . . . everything went down . . . [but] since I already sold the practices . . . it didn't matter to me whether I had a registration, because I wasn't working. I wasn't living in Texas or working in Texas.'' *Id.* at 359. However, after he knew that he ''was going to . . . buy the practices back . . . [he] started the process to finally get these matters resolved.'' *Id.* According to Respondent, he was advised by his counsel at the time that ''the easiest and best way'' to resolve the matters was to sign the MOA ''because otherwise [he was] going to have this protracted fight'' and the Agency had ''sat on the paperwork'' from 2006 to 2009.[16] *Id.* Respondent further explained that he had to have his DEA number to get on insurance plans as well as Medicare and Medicaid. *Id.* at 360. However, Respondent testified that

[14] The Government also submitted an Exhibit showing the various practitioners who worked at the Oak Hills Clinic and the locations at which they were registered and the dates on which they were registered at the various locations. GX 12. According to the table, Oak Hills did not have a Practitioner or Mid-Level Practitioner registered at it between December 11 and 20, 2010. *Id.* The Government did not, however, produce any evidence the clinic had controlled substances on hand or that it dispensed any controlled substances during this period.

[15] In an exhibit showing the registered addresses of various IMC Southwest practitioners and the dates they were registered at the particular addresses, the following statements were made: ''The Dispensing/Administration Log provided during the NOI showed 127 testosterone injections administered to 15 patients by Medical Assistants (Non-DEA Registrants),'' and that ''[b]etween November 7, 2013 and May 6, 2014[,] there was no Practitioner or Mid-Level Practitioner registered at IMC Southwest.'' GX 22.

However, the Government produced no evidence showing that this clinic either possessed or dispensed controlled substances during the November 7, 2013 through the May 6, 2014 period.

[16] Respondent was, however, allowed to continue to dispense controlled substances under his old registration and was provided with a letter to this effect. *Id.* at 361. While Respondent asserted that insurance companies and some pharmacies would not accept this letter, DEA does not control the actions of these entities. Moreover, given Respondent's testimony that he had moved to Washington State to concentrate on software development, it is unclear the extent to which he was even practicing medicine during this period.

during the period when he did not own the clinics, he was ''involved as a consultant and [would] occasionally substitute'' for a practitioner. *Id.* at 373.

Turning to the period after he entered the MOA and repurchased the clinics (specifically, from late 2010 to 2013), Respondent testified that ''[e]veryone in the clinics [was] at least a medical assistant,'' and that ''[m]ost of the time, there was a midlevel provider, a physician assistant or a nurse practitioner, a supervising or collaborating physician, and myself.'' *Id.* at 381. Respondent added that ''[s]ometimes [he] was the collaborating physician or the supervising doctor,'' and ''[s]ometimes [he] wasn't.'' *Id.* Asked by the CALJ whether he was ''involved in the day-to-day operations of these clinics,'' Respondent explained that he ''wasn't every day, but [that he] was involved in . . . administration [and] management.'' *Id.* Respondent further testified that ''[s]ometimes [he] was involved in the hiring,'' that he was ''certainly . . . involved in training of the midlevels and the doctors, because many of the things that [the clinics] do . . . including bioidentical hormone replacement, are not taught in medical school or residency.'' *Id.*

During this time period, Respondent ''was actually living in Washington State and coming to Texas when [he] had to'' because he was able to review the patients' electronic medical records from a remote location through a virtual private network (VPN). *Id.* at 382, 385. Respondent stated that on his visits to Texas he would generally visit each clinic and stay ''[f]rom several hours to days . . . depend[ing] on the clinic needs'' and ''whether the staff was performing well and what have you.'' *Id.* at 384.

Respondent admitted that through the VPN, he could determine what services the clinics were providing. *Id.* at 385. While Respondent asserted that he ''couldn't see the invoices or the ordering'' because the drugs were ordered ''by fax or . . . calling in,'' through the electronic medical records he ''could see . . . if somebody . . . had ordered the administration of testosterone.'' *Id.* at 386–87. Continuing, Respondent explained that he ''couldn't see—like the office manager would call or send a prescription over to the pharmacy to get filled, so I couldn't see . . . if it was for general office use.'' *Id.* at 387.

Respondent asserted that ''this is a common practice,'' maintaining that ''hospitals don't order anesthesia medications for every individual patient'' and that ''[t]hey order . . . stock bottles, and the anesthesiologist will use whatever is appropriate for a particular patient, because they don't know how long the surgery's going to go.'' *Id.* at 388. He then added: ''[t]hat happens every single day in every single hospital in this state, you know. You know, this is not something that's unique to these practices. And we're not even talking about that much medicine, for God's sake.'' *Id.; see also id.* at 450–52 (analogizing the clinics' practice of using office stock to dispense to the use of standing orders at hospitals).

Respondent maintained that the testosterone shots were administered pursuant to a standing order in the patients' charts, and that ''just because [the practitioner] isn't physically on site doesn't mean that order is not valid.'' *Id.* at 452; *see also id.* at 483. Respondent further testified that under the rules or policy of the Texas State Board, a standing order can last for ''three months.'' *Id.* at 453.

Asked by his counsel what he did when he was physically at the clinics, Respondent testified that he would interview the staff and ''maybe pull some patients aside and ask them . . . if they had a good experience or whether the staff was taking good care of them and things like that.'' *Id.* at 389. He would also do a ''physical inspection and make sure that everything was the way it should be in each practice,'' by which he meant that he ''would make sure that everything was neat and clean and in order'' and that ''everyone was just doing their [sic] job.'' *Id.* at 389–90.

Respondent was then asked by his counsel, ''what, if anything, [he] did . . . with respect to ensuring compliance with . . . the controlled substance issues in this case?'' *Id.* at 390. Respondent answered: ''first of all . . . we didn't do that many . . . of these injections . . . . And this is relevant, because . . . we're not talking about that much. Every clinic had one bottle of testosterone they would use, one.'' *Id.* After the CALJ told Respondent that he had not answered his counsel's question, Respondent testified: ''And, you know, so I would go, and I would make sure that . . . that everyone's being documented. Now, we have two forms of records here. One is the electronic records, and the other one was the physical log. Okay?'' *Id.* at 390–91.

The CALJ then asked Respondent ''to tell us what steps you were taking to make sure that your clinics were . . . in compliance with the'' MOA? *Id.* at 391. Respondent answered:

> Okay. You know, all I did would [sic] glance at the logs. I would glance at them and make sure that they're being recorded with the name and the date and the amount that was—of medicine that was given. I would glance at them. That's just—you know, as part of my inspection, I would just glance. Like, you know, I wasn't scrutinizing them and measuring, you know, how much was left and things like that. I would just, you know—
>
> I think the staff is very honest, in general honest, and—

Id. Finding the answer to ''still [be] going far afield,'' the CALJ summarized Respondent's testimony to the effect that he would interview staff members and ''some patients about their care,'' ''do a physical inspection,'' and ''glance at the logs.'' *Id.* at 392. The CALJ then asked Respondent if this was ''the sum total of what [he] did?'' *Id.* Respondent answered ''yes,'' and added that he would also train the ''new personnel'' on the protocols and make sure ''that all their equipment was working,'' such as the fax machines and computers; he also stated that he would give the staff ''feedback on any comments'' from the patients. *Id.*

With respect to the testosterone injections, Respondent explained that he ''would just look through [the physical log] and make sure they were keeping a log.'' *Id.* at 394–95. Asked what records the clinics maintained on ''the ordering side,'' Respondent asserted that ''most everybody maintained the invoices that, you know—because, you know, the clinic has to pay their [sic] bills every month and everything like that. So they maintained invoices. They would file it or scan it and put it onto . . . one of the servers.'' *Id.* at 395. Asked whether he had any information that the invoices from the pharmacy were being maintained, Respondent testified:

> I believe for the most part. I mean, most of the managers are fairly experienced, and they know that . . . part of their job is to scan the invoices, and to keep them on servers . . . as a record of the bills paid and things like that.
>
> They may not keep a physical copy always, but they're supposed to scan. Now, did I check every single time in all seven clinics? No. Of course, I mean, that's an incredible amount of work. I can't be in seven places at once. So I just would occasionally check, and I would ask, and I trusted my staff.

Id. at 396.

Respondent further asserted that he would ask his office managers: ''Are you making sure you're scanning this? Are you making sure you're recording that? Are you making sure the medical assistants are doing—. I would ask the managers . . . and make sure that everything was being done . . . correctly.'' *Id.* Respondent then testified that he ''absolutely'' did not ''physically check every single time,'' and asserted that ''[t]here's no way one person can do

all that work'' but that he was ''trying [his] best'' and ''trusting [his] staff . . . to do their job.'' *Id.* Asked by the CALJ if he thought this was a valid defense to the allegations that he failed to comply with the MOA, Respondent testified that he did not ''think it's a defense'' but that he had ''explanations on . . . things.'' *Id.* at 397.

The CALJ then asked Respondent if he thought that ''say[ing] that it's too much work'' was a valid excuse for failing to comply with the MOA. *Id.* at 398. Respondent answered: ''Unfortunately, Judge, medicine is not as good of a business as it used to be.'' *Id.* Instructed by the CALJ to ''[s]tick with my question,'' Respondent answered: ''Yes. So it's not about making money. It's about patient care. You know, the difference in revenue that doctors make now versus back in the past is night and day.'' *Id.* After noting Respondent's testimony to the effect ''that patient care had very little to do with the things that you were looking at'' and that ''it's too much work to do more than what you're doing,'' the CALJ asked: ''What if the terms of the MOA required that?'' *Id.* at 398–99. Respondent answered:

> Yes, sir. The MOA required that, as I understood it, to send in reports for patients who are—that were dispensed medication. And because were [sic] not dispensing medication, I agreed to the MOA. So with respect to, you know, having logs, because the State didn't want the clinics to dispense, no one was going to dispense anymore, you know.

Id. at 399. Respondent then insisted that ''[c]omplying with the MOA wasn't too much work'' and that ''[w]hat [he] meant was . . . checking all the deposits and all the invoices and all the payments and reconciling them with the—it wasn't having anything to do with the MOA.'' *Id.* After asserting that he was ''involved in patient care as well,'' Respondent added that he ''didn't mean it was too much to comply with the MO[A] . . . but I just meant like . . . micromanaging and checking every single little thing, that was—that's too much work. I didn't say that, you know—.'' *Id.* at 400–01.

Subsequently, Respondent's counsel referred to paragraph 5 of the MOA and its ''reference to administer, dispense and prescribe'' [17] and asked Respondent what he understood the term ''administer to mean?'' *Id.* at 406. Respondent answered: ''Administering means that I order myself or I physically give a patient a medication in the office'' by ''[d]irect application, orally or through injection or IV or what have you.'' *Id.* Then asked what he understood the term ''dispense'' to mean, Respondent testified: ''Dispense means to give a patient, physically give a patient medication for self-administration outside of the office.'' *Id.* at 407.[18]

Turning to paragraph 8 of the MOA, Respondent testified that the clinics never used any schedule II controlled substances and that the drugs they used were appetite suppressants (phentermine, phendimetrazine, and diethylpropion [19]) and ''bioidentical hormones,'' *i.e.,* testosterone. *Id.* at 407–09. Respondent also testified that the clinics always administered ''the same concentration'' of testosterone, 200 mg/ml, and did so ''by injection.'' *Id.* at 409–10.

Respondent was then asked to explain his understanding of his obligations under paragraph 8. *Id.* at 412. As found above, this provision stated that ''[i]f controlled substances in [s]chedules II through V are purchased for any clinic, to be administered and/or dispensed to the clinic patients, [Respondent] shall cause to be made and maintained all DEA required documents and information including records, reports, and inventories.'' GX 4, at 2–3.[20] Respondent answered: ''That for the patients that I saw and the patients that were under my care, that I made sure that there were appropriate records being kept.'' Tr. 413. Asked by the CALJ if this applied to ''all the patients in all these clinics,'' Respondent answered: ''No, sir. I wasn't the caregiver for most of these patients. I was the supervising doctor, but every midlevel has their credentials. Every single doctor also has their credentials.'' *Id.*

Upon further questioning by his counsel as to his understanding of his recordkeeping obligations under the MOA, Respondent testified that ''there was no dispensing done in any of the practices at all. Administering, making sure that the medical assistants recorded the administration in the . . . electronic medical record and making sure they maintained the log that was consistent with the medical record.'' *Id.* at 418. Respondent also explained that ''every single prescription is recorded, because when you save the note, it saves the prescriptions that you wrote as part of the note.'' *Id.*

Subsequently, Respondent was asked if he fully complied with the documentation requirements of paragraph 8. *Id.* at 431. Respondent answered: ''I feel as though I have, because there were logs kept, both electronically and written, and there was no diversion.'' *Id.* at 431–32. Then asked if he knew ''whether opening inventories were taken . . . at these clinics,'' Respondent answered: ''There was hardly any testosterone ordered for any of the practices, and—.'' *Id.* at 432. After directing Respondent to answer the question, the CALJ asked: ''Was there [an] opening inventory taken? And what is the answer to that question?'' *Id.* Respondent testified: ''My answer to the question is I don't know what opening inventory means. What does that mean?'' *Id.*

Respondent was then asked by his counsel what was his ''understanding of the inventory requirements . . . if any, under the MOA?'' *Id.* at 433. Respondent answered: ''Whenever medication is—controlled medication is administered to a patient, that their name be recorded, the amount of the medication be recorded, the site, the date, you know, probably the lot number of the medication, the lot number.'' *Id.*

Moreover, when asked on cross-examination if he ''acknowledge[d] that none of [the] clinics were [sic] able to produce an initial inventory,'' Respondent testified: ''No. It's not correct.'' *Id.* at 471. Asked ''[w]hy is it not correct,'' Respondent answered: ''when you have people coming in, flashing badges and individually interviewing staff members, they're scared . . . they're worried, they're like, Oh, my God, am I going to get fired? . . . It is an incredible intrusion onto the practice. The staff doesn't even know . . . what an inventory is.'' *Id.* at 471–72. When then asked if there were inventories at the clinics that were not provided to the DIs, Respondent replied: ''Define inventory. There were logs kept of—.'' *Id.*

Respondent subsequently admitted that he had neither read the Code of Federal Regulation's definition of the term inventory, nor the regulations requiring the keeping of inventories. *Id.*

[17] This provision states: ''This Memorandum of Agreement (''MOA'') is between [Respondent] and DEA and establishes the terms and conditions under which DEA will continue to permit [Respondent] to administer, dispense and prescribe any Schedules II through V controlled substances. Respondent and DEA agree to the following[.]'' GX 4, at 2. The subsequent terms are, however, in separately numbered paragraphs. *See id.* at 2–5.

[18] As for the term ''prescribe,'' Respondent testified that it ''means you're writing prescriptions, sending it to a pharmacy, and the patient's filling it at a pharmacy.'' Tr. 407.

[19] While Respondent testified that each of these three drugs is in schedule III, this is true only of phendimetrazine, as both phentermine and diethylpropion are in schedule IV. *See* 21 CFR 1308.13(b); *see also id.* § 1308.14(f).

[20] This paragraph also provided that ''[a]ll required documentation shall be maintained as required by federal and Texas laws and regulations, pertaining to the administering, dispensing, and prescribing of controlled substances.'' GX 4, at 2–3.

at 473. The Government then asked: ''you don't even know what those regulations are, do you?'' *Id.* Respondent testified: ''I assumed that the logs were the inventory. Okay? I assumed that, foolishly. Admittedly, if that was my mistake, it's my mistake. I did not go through the Code and read it, nor did my attorneys or consultant tell me that that was what was necessary.'' *Id.* Respondent nonetheless continued to maintain that ''the way'' he saw it, ''the log served as the inventory.'' *Id.* Respondent subsequently maintained that he had not read the regulations since being served with the Show Cause Order because ''we're not administering anymore'' and ''there is no controlled substance at all on the premises,'' and thus, in his view, ''it's not even relevant for me to read [the regulations] anymore.'' *Id.* at 474.

Respondent was also asked by his counsel if he agreed ''that at least on some of the . . . [testosterone] logs, there was some missing information?'' *Id.* at 433. Respondent agreed, and he also agreed that he was not in compliance with these sections of paragraph 8. *Id.* at 433–34. Respondent further testified that he accepted responsibility for not complying with paragraph 8. *Id.* at 434.

Paragraph 8 also required, in relevant part, that ''[i]f any controlled substance is administered or dispensed at any [of the] clinic[s] . . . the health care provider doing the administering and/or dispensing to the patient shall be registered at the clinic as required by 21 U.S.C. 822(a)(2) and 21 CFR 1301.12(a).'' GX 4, at 3. Respondent explained that he understood his obligation under this provision as to ''[m]ake sure that . . . the provider seeing the patient, unless it was . . . a temporary or a sub or something, that they changed their [sic] address on their [sic] DEA certificate to the practice, so they could administer. You don't have to have your address changed to prescribe, because you can go anywhere just to prescribe. But to administer . . . that would be the case.'' Tr. 419.

Later, on cross-examination, Respondent maintained that the instances in which no practitioner was registered at a clinic and yet controlled substances were administered to patients ''was an oversight,'' and that ''[t]here may have been some mid levels who didn't . . . change their address.'' *Id.* at 464, 491. However, when pressed by the Government as to whether he was going to admit that this had occurred, Respondent answered: ''I don't know whether it's true or not.'' *Id.* at 465; *see also id.* at 490. Respondent nonetheless insisted that he was accepting responsibility for this misconduct. *Id.* at 465. Respondent also testified to the effect that even if there was no DEA-registered person registered at a specific clinic, there were ''either mid-levels or doctors . . . and everybody was properly credentialed.'' *Id.* at 495.

Turning to paragraph 9 of the MOA, as found above, it required the submission of a quarterly report to the DEA Field Division of ''the total number of controlled substances dispensed, to include the date dispensed, full name of patient, address of patient, name of controlled substance dispensed, quantity dispensed and dispenser's initials.'' GX 4, at 3; Tr. 419–20. On questioning by his counsel, Respondent admitted that 10 of the reports were not timely submitted and that he violated paragraph 9. *Id.* at 420. As for why he backdated the reports when he did not submit them until June 19, 2013, Respondent testified he did so ''[b]ecause they were required to be filed on a quarterly basis, so I just dated the correspondence to reflect . . . every particular quarter.'' Tr. 421–22.

As for why he denied that he was subject to the MOA in his June 4, 2013 email to the DI, *see* GX 36, Respondent testified that he did so ''[b]ecause all of this was such an unpleasant experience, [so] I blocked it out of my mind.'' *Id.* at 426. Continuing, Respondent maintained:

> It was such an unpleasant experience, I literally blocked it out of my mind, so that I didn't, you know, remember, you know, having these sorts of things, and I relied on someone to remind me, and that didn't happen.
>
> And so I just, you know, blocked it out, I mean, because it was so unpleasant, and it was so humiliating, and it was so degrading, and it's—not to mention, you know, costing a fortune. And I literally just blocked it out. I mean, that's the—you know, athletes do this when they have a bad play. They block out the bad play, and they move on.
>
> And so that's—you know, that was my mindset. And so once I realized that, hey, I was wrong and [the DI] was right, I immediately sent a letter of apology and I sent in the reports.

Id. at 426–27. Respondent further maintained that he ''had buried'' the events surrounding his entering the MOA ''so deep in my psyche, just so I could stay sane and stay working and productive, just like an athlete would do, like after a bad play.'' *Id.* at 427. Respondent then noted that ''[p]eople who are victims of crimes, people who are—they block out the bad experience, you know, and that's exactly what I did, because this was an ordeal, Judge. This was a harrowing, awful, horrible experience to go through.'' *Id.* at 428.

Asked by his counsel ''what if any efforts'' he had made to prevent the recurrence of the issues raised regarding his compliance with the MOA, Respondent testified that ''there was obviously no dispensing.'' *Id.* at 436. Continuing, he testified that:

> since [the DI's] inspections are so unpleasant and so invasive that I told everybody that we were not going to administer any medication to any patient anymore, despite the fact that many patients appreciated it because they don't feel comfortable self-injecting. It's actually a lot of work for the clinics to do that . . . It's very tedious. And we did it as a courtesy to the patients.

Id. at 436–37. Later, Respondent maintained that the clinics have not ''administered anything for over a year.'' *Id.* at 448.

As found above, during several of the inspections, the DIs found controlled substances that the Empower Pharmacy had shipped to the clinics which bore labels indicating that they had been dispensed for specific patients. Respondent testified that the clinics engaged in this practice ''[a]s a convenience to the patients,'' and ''they would act essentially as a delivery service for some of the patients that couldn't afford to have the medicines mail-ordered to . . . their homes,'' because ''it was an extra $15'' to have the prescription shipped to the patient's home *Id.* at 438. However, Respondent acknowledged that the clinics offered this service without regard to ''a patient's financial status.'' *Id.* at 439. Respondent subsequently testified that the clinics ''don't do it anymore'' and that ''we're going to just send it to your home.'' *Id.* at 446. He also disputed the Government's suggestion that the clinics ''had to have a registered person at that clinic'' when the clinics accepted delivery and stored the prescriptions that were dispensed for specific patients. *Id.* at 479–80; *see also id.* at 481 (testifying that in his view, it is ''absolutely'' legal for a clinic to accept prescriptions for patients when no practitioner is registered at the clinic).[21]

Respondent testified that ''[a]t this point,'' the clinics have ''zero'' physical contact with controlled substances, and that their controlled substance activity is limited to prescribing. *Id.* at 448. He also represented that that he does not intend for the clinics to have any physical contact with controlled substances ''at least for the duration of [his] license.'' *Id.* at 449.

Respondent testified that it is permissible to use a prescription to

[21] Notwithstanding that it elicited extensive testimony about this practice, the Government made no argument that it is illegal.

obtain a stock bottle, but maintained that he had never done so. *Id.* at 454. Asked whether the clinic employees had ever done so, Respondent asserted that ''they didn't write it but they would order it under the DEA number of the person who was registered at that address.'' *Id.; see also id.* at 455 (testifying ''no' to CALJ's questions: ''Have staff members in your clinics, have they written prescriptions[?]''). However, on follow-up questioning by the CALJ, Respondent admitted that the ''mid levels'' had done so. *Id.* He also asserted that ''[i]t's absolutely proper'' for a mid-level practitioner to use a prescription to order controlled substances for office use because ''[t]hey have their own DEA certificate, and they have their own medical licenses.'' *Id.* at 456–57.

Subsequently, Respondent's counsel asked him if there is ''anything relative to the nature of the investigation that you feel is important for the Judge to hear about?'' *Id.* at 457. Respondent replied:

> I do have a lot to say. Okay. The only reason we're here, Judge, the only reason why a senior attorney from the DEA's office flew down here on taxpayer money over some logs, okay, that may not have been kept correctly is because when—you mentioned yesterday why did it take 12 months between the time that you—you know, that you approved the registration, renewal registration. Right? Remember you asked that? And the time it happened.
>
> I'll tell you exactly why. I have a friend of mine who's a federal agent. He told me that I can make a congressional complaint. Okay.

Id. at 458. Following an objection by the Government which was overruled, Respondent added:

> That I can make a congressional complaint against a federal agent who I feel has harassed me. And [the DI] has. Not only has she been ridiculously invasive in all my practices but she has attempted to vandalize and sabotage my relations with my vendors. Okay. And tried to ruin my business.
>
> She left me alone for months and months and months and months. As soon as I made the congressional complaint . . . [m]agically two months later I'm here with you taking up your time over this nonsense.

Id. at 459. Respondent then asserted that the proceeding was ''pure retaliation'' for the ''congressional complaints'' and that ''[w]e made all the changes.'' *Id.* He maintained that ''[t]he only reason'' he had been subjected to this proceeding was because he had ''made the congressional complaint.'' *Id.* at 460. And he asserted:

> [w]hat is a senior attorney of the DEA flying all the way down here arguing over logs? Are you kidding? Why wasn't he here in 2006? Why wasn't he here in in 2008? Why wasn't he here in 2010? Because it was such a tiny matter; like don't they have better things to do than this.
>
> I mean literally the reason they're doing it, it's a CYA, Judge. Okay? It's a CYA, because it's like, oh, my career's on the line, I might get fired over this, and so now we have to go full steam against this doctor.

Id. Respondent subsequently testified that he had filed his complaints to members of Congress in the spring of 2015. *Id.* at 488. However, on rebuttal, the Government recalled the lead DI who testified that she had submitted the documentation requesting the issuance of an Order to Show Cause to DEA Headquarters in February 2014, well before Respondent complained to his representatives. *Id.* at 497, 499.

Respondent further disputed that his clinics had engaged in any unlawful practices, testifying that ''[t]here's never anything unlawful being done. I've never been accused of doing anything unlawful.'' *Id.* at 476.

Discussion

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

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to suspend or revoke an existing registration or deny an application. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[22]

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, I conclude that the Government's evidence with respect to Factors Two, Four, and Five[23] supports

[22] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant/applicant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[23] As to factor one, the Government introduced into evidence the Texas Medical Board's 2008 Order Granting Temporary Suspension of his Texas medical license and the Board's subsequent Termination of Temporary Suspension and Entry of Agreed Order. GX 2, at 1–11. Moreover, in September 2012, the Board filed a complaint alleging various violations with respect to the prescribing of drugs including progesterone, testosterone, and phentermine by Respondent and mid-level practitioners he supervised. *Id.* at 13–16. However, the complaint was eventually dismissed on the Board's motion after the parties resolved the matter. *Id.* at 21. Thus, Respondent currently possesses authority under Texas law to dispense controlled substances. Moreover, there is no evidence that the Texas Medical Board has made a recommendation to the Agency with respect to Respondent. *See* 21 U.S.C. 823(f)(1). While Respondent is also registered in Florida, there is no evidence as to the status of his Florida medical license and the Florida Board has likewise made no recommendation to the Agency with respect to Respondent.

In any event, the Government does not rely on factor one at all. *See* Gov. Proposed Findings of Fact, Conclusions of Law, and Argument 20–29. However, even assuming that Respondent currently possesses authority to dispense controlled substances under Texas law and thus meets a prerequisite for maintaining his registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the revocation of Respondent's

the conclusion that Respondent and the entities he controlled violated both provisions of the CSA and DEA regulations, as well as provisions of the MOA, which although they do not constitute violations of law or regulation, nonetheless constitute actionable misconduct which render his continued ''registration inconsistent with the public interest.'' 21 U.S.C. 823(f), 824(a)(4). Because I further agree with the ALJ's finding that Respondent has not accepted responsibility for his misconduct, I also agree with the ALJ that he has not rebutted the Government's *prima facie* showing. Because I find that Respondent's misconduct is egregious, I will order that Respondent's registration be revoked and that any pending application be denied.

Factor Two—Respondent's Experience in Dispensing Controlled Substances

The evidence shows that Respondent was previously the subject of an agency investigation of several IMC clinics which were allegedly ''dispensing controlled substances to their patients without a valid registration.'' GX 4, at 1. While Respondent was not required to admit to liability for any violation of federal law, the Agency agreed to grant his renewal application subject to his entering the MOA. The MOA specifically states that it ''establishes the terms and conditions under which DEA . . . continues to permit [him] to administer, dispense and prescribe any [s]chedules II through V controlled substance.'' *Id.* at 2. The MOA also states that Respondent's ''new registration will remain subject to applicable law *and the terms and condition of this Memorandum of Agreement.*'' *Id.* (emphasis added).

The CALJ acknowledged that a registrant's conduct that violates the terms imposed by an MOA can constitute acts rendering a registration ''inconsistent with the public interest,'' even when the violations do not amount to a violation of the CSA or its implementing regulations. R.D. at 45 (citing, *inter alia, Fredal Pharmacy,* 55 FR 53592, 53593 (1990)). The CALJ, however, asserted that ''[a]gency precedent has been less sure-footed about where among the public interest factors an MOA violation should be considered.'' *Id.* The CALJ then discussed several agency decisions that considered MOA violations under Factor Two and asserted that ''the analyses employed by the Agency in'' these cases—which he characterized as ''lumping together activities which have no direct bearing on dispensing into Factor [Two]'' and as ''analytically infirm''—''should be abandoned.'' *Id.* at 46 (discussing *Mark De La Lama,* 76 FR 20011, 20018 (2011); *Erwin E. Feldman,* 76 FR 16835, 16838 (2011); *Michael J. Septer,* 61 FR 53762, 53765 (1996)).

I disagree that Factor Two requires that an activity have a ''direct bearing on dispensing.'' Here, as in previous cases, the MOA ''established the terms and conditions under which [the Agency] will continue to permit [Respondent] to administer, dispense and prescribe and [s]chedules II through V controlled substances'' and his new registration is subject to the MOA's ''terms and conditions.'' Because that registration provides the authority by which Respondent may dispense controlled substances, any violation of it is properly considered as relevant in assessing his ''experience in dispensing . . . controlled substances.'' Indeed, even the various MOA violations discussed in other cases, which, in the CALJ's view, do not have a ''direct bearing on dispensing,'' were indisputably relevant in assessing the registrant's experience in dispensing controlled substances.

Discussing *Septer,* the CALJ asserts that the registrant's violation of an MOA provision requiring ''daily audits . . . clearly involve[d] no 'experience in dispensing.' '' R.D. 46. Quite the contrary, the MOA provision at issue in *Septer* was imposed after both DEA and state-level investigators conducted an accountability audit at the practitioner's office and found ''a shortage of approximately 190,000 to 203,000 dosage units of [s]chedule III and IV controlled substances.'' 61 FR at 53762. Whether these drugs were ordered by Dr. Septer or one of his employees, the drugs were ordered under his practitioner's registration, pursuant to which he was authorized to dispense controlled substances, and thus, his inability to account for the drugs was part of his ''experience in dispensing.'' As the MOA's provision was clearly intended to prevent a recurrence of this experience, and the Agency had an obviously compelling interest in ensuring that his more recent experience did not repeat his earlier experience, the MOA violation was clearly relevant under Factor Two.[24]

The CALJ suggests that in *Mark De La Lama,* 76 FR 20011, the Agency improperly considered MOA violations under Factor Two that included the respondent's failure to maintain a prescription log and failure to notify the local DEA office that he was transferring his registration to another address, asserting that ''neither activity involves 'experience in dispensing.' '' [25] R.D. 46. While the MOA's condition that the respondent maintain a prescription log exceeded the requirements of the CSA and DEA regulations, the respondent's failure to comply was clearly relevant in assessing his experience in dispensing controlled substances. As for his failure to notify the local DEA office when he changed his practice location, the whole point of the MOA was to ensure that the Agency ''would be able to monitor Respondent's handling [which includes the dispensing] of controlled substances.'' 76 FR 20014. As during the period following the issuance of the registration which was conditioned on his entering the MOA, the respondent would accrue experience in dispensing controlled substances—which the Agency had a heightened interest in monitoring given his history of controlled substance offenses—Respondent's violations of both MOA conditions clearly involved conduct relevant in assessing his experience in dispensing controlled substances.

The CALJ also suggests that in *Erwin E. Feldman,* 76 FR 16835 (2011), the Agency improperly considered certain violations under Factor Two even though they did not involve prescribing. According to the CALJ, such violations as failing to maintain a prescription log, failing to ''maintain[] specified patient charts for specified periods of time,'' failing to ''maintain[ ] state prescription monitoring program reports for a specified period of time,'' and not ''notifying the DEA about the initiation of any state administrative proceedings'' do not involve prescribing and thus ''have no direct bearing on dispensing'' under Factor Two. R.D. 46.

registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[24] DEA has long interpreted Factor Two to encompass not only those activities that are included in the statutory definition of dispensing but also those that are ancillary to those activities such as handling or possessing controlled substances.

[25] These conditions were imposed based on the respondent's conviction for drug distribution offenses. 76 FR at 20018.

However, a careful reading of the Agency's findings in *Feldman* shows that the Agency did not even find that the physician violated the MOA by failing to maintain patient charts or prescription monitoring reports. *See* 76 FR at 16837–88. However, even if it had, each of the MOA's provisions was a condition placed on the physician's authority to dispense controlled substances, and thus, subsequent allegations that he violated the MOA were clearly relevant in assessing his experience in dispensing controlled substances. Moreover, while in general terms the MOA's requirement that he notify DEA about the initiation of any state administrative proceedings may not have necessarily involved the dispensing of controlled substances, the physician was accused by the State of both ''prescribing drugs without a lawful diagnostic or therapeutic purpose'' and ''prescribing Suboxone to treat opioid dependence without having obtained the necessary certification.'' *Id.* at 16837 (int. quotations and citations omitted). Thus, even aside from the fact that it was a condition on his registration, the physician's violation of this provision was clearly relevant in assessing his experience in dispensing controlled substances.

In any event, misconduct is misconduct whether it is relevant under Factor Two, Factor Four,[26] or Factor Five, or multiple factors. And although the CALJ asserts that ''[a]s agency precedent now stands, the distinction between the considerations of Factor [Two] are nearly imperceptible in this case from those considered under Factor [Four]'' and that ''[t]he risk of this approach is that evidence offered against the Respondent is considered and weighted twice,'' R.D. 43, the Agency has repeatedly explained that it does not mechanically count up the factors and determine how many favor the Government versus how many favor the respondent. *See Krishna-Iyer,* 74 FR at 459, 462. Rather, the inquiry focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct.[27] *Id.*

The Show Cause Order also alleged that Respondent violated various provisions of the MOA which do not themselves rise to the level of violations of the CSA or DEA regulations. These include the allegation that Respondent violated paragraph 8 of the MOA because controlled substances ''were dispensed and/or administered'' to patients at various clinics when the clinics did not have a practitioner who was registered at the clinic. ALJ Ex. 1, at 2. They also include the allegation that Respondent violated paragraph 9 of the MOA by failing to submit quarterly reports of his controlled substance dispensings to the DEA Houston Office.

Failure To Ensure That if Controlled Substances Were Administered or Dispensed at a Clinic, the Provider Doing the Administration or Dispensing Was Registered at the Clinic

Under the CSA's registration provisions, ''[a] separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.'' 21 U.S.C. 822(e). *See also* 21 CFR 1301.12(a) (''A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are . . . dispensed by a person.''). While by regulation DEA has exempted from the separate registration provision ''[a]n office used by a practitioner (who is registered at another location in the State . . .) where controlled substances *are prescribed but neither administered nor otherwise dispensed* as a regular part of the professional practice of the practitioner at such office and *where no supplies of controlled substances are maintained,*'' *id.* 1301.12(b)(2) (emphasis added), this provision makes plain that if controlled substances are administered at a clinic, the practitioner must be registered at that location.

As found above, in paragraph 8 of the MOA, Respondent agreed that ''[i]f any controlled substance is administered or dispensed at any clinic . . . the health care provider doing the administering and/or dispensing to the patient shall be registered at the clinic as required by 21 U.S.C. 822(a)(2)[28] and 21 CFR 1301.12(a).'' While the Government does not argue that Respondent personally violated the CSA's separate registration provision, the evidence is clear that several of the clinics administered testosterone to patients during various time periods when there was no practitioner registered at the particular clinic.

With respect to the Cy-Fair clinic, the evidence shows that one testosterone shot was administered when no practitioner was registered at the clinic. GX 6, at 1; GX 8, at 5. As for the FM 1960 clinic, the evidence shows that one testosterone shot was administered on May 19, 2012, on which date no practitioner was registered at the clinic and five testosterone shots were administered between October 5, 2012 and September 11, 2013, during which

[26] The CALJ opines that ''several of the violations in *Feldman* were also likely violations of applicable state, federal, and/or local laws, but there was no mention of Factor 4, even though in an earlier case, *OTC Distribution Co.,* 68 FR 70538, 70542 (2003), the Agency considered the respondent's failure to comply with the terms of the MOA as a failure to comply with applicable law, despite the fact that the conduct was not unlawful, but merely a violation of the MOA in that case.'' R.D. 46 (footnotes omitted). With respect to *Feldman,* the CALJ speculated that the respondent's ''multiple-refills scrips most likely violated'' 21 CFR 1306.12, which allows practitioners to issue multiple prescriptions to provide up to a 90-day supply of a schedule II controlled substance. *Id.* n.106. However, in *Feldman,* the Government made no such allegation and the Agency made no such finding. Indeed, with respect to the physician's violation of the MOA's condition which limited him to authorizing only one refill, the refills were for only schedule III and IV controlled substances. 76 FR at 16836–37. Indeed, none of the Decision's findings involved schedule II drugs. *See id.*

As for the CALJ's discussion of *OTC Distribution,* I agree that the mere failure to comply with the term of an MOA does not necessarily establish a violation of an ''applicable . . . law[ ] related to controlled substances.'' 21 U.S.C. 823(f). While this factor has long been interpreted as encompassing both laws and duly enacted regulations, most MOA terms are the product of negotiation between the Agency and an applicant/registrant and do not arise from either the legislative or rulemaking process. Even where an MOA term imposes the same requirements as a law or regulation, a violation of that term falls under Factor Four because it is also a violation of a duly enacted law or regulation.

[27] The CALJ also opines that under Agency precedent, ''where the Government produces no evidence of other misconduct over the course of a lengthy career as a registrant, it will assume it to be benign and not consider under Factor [Two] (as Congress intended), but rather, as a matter of sanction discretion.'' R.D. 43. However, while the Agency's decisions typically set forth the specific public interest factors in discussing the evidence offered by the Government in support of its *prima facie* case, this does not mean that a respondent's evidence of a lengthy history of compliance is given no weight in the public interest determination. In a revocation proceeding, the statute specifically directs the Agency to determine whether the registrant ''has committed *such acts* as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4) (emphasis added). The public interest factors of section 823(f) simply shape the scope of the relevant evidence in the proceeding, and given the nature of this inquiry, the Agency properly considers a respondent's evidence of a lengthy history of compliance after the Government makes out its *prima facie* case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions.

As for the CALJ's discussion of *Krishna-Iyer* v. *DEA,* 249 Fed. App'x 159 (11th Cir. 2007), in which he asserts that this Agency failed to follow the Eleventh Circuit's order on remand, as well as his assertion that while the Tenth Circuit in *MacKay* v. *DEA* ''upheld an Agency final order that included the *Krishna-Iyer* analysis, but the Agency's view of Factor [Two] was not a focus of the Court's decision,'' R.D. 41, these mistaken contentions have been thoroughly addressed and rejected. *See Wesley Pope, M.D.,* 82 FR 14944, 14981–82 (2017). I therefore decline to re-address the CALJ's discussion.

[28] Under this provision, ''[e]very person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.'' 21 U.S.C. 822(a)(2).

period no practitioner was registered at the clinic. GXs 16, 17.

With respect to the Woodlands clinic, the evidence shows that no practitioner was registered at the clinic from the date it moved (in either February or March 2013) to its new location until two days after the inspection and that during this period, testosterone was administered to patients at least 14 times. GXs 19 & 20. Yet the evidence also shows that the two practitioners who worked at the clinic had been registered at its previous location, and thus the evidence suggests that the practitioners simply forgot to change their registered address.

While these are relatively minor violations, the evidence with respect to the Victoria clinic is of considerably greater concern. There, testosterone was administered at least 117 times during a more than three-month period when no practitioner was registered at the clinic.[29] *See* GX 26, at 1–5, 7, 12–14, 16; GX 25. Given the scope of the controlled substance activities being engaged in by the Victoria clinic, Respondent failure to ensure that clinic was in compliance with the CSA is an egregious violation of the MOA.

Failure To Timely File Accurate Quarterly Dispensing Reports

As found above, in the MOA, Respondent also agreed to submit to the Houston DEA Field Division Office a report, ''on a quarterly basis, [of] the total number of controlled substances dispensed, to include the date dispensed, full name of patient, address of patient, name of controlled substance dispensed, quantity dispensed and dispenser's initials.'' The Government alleged that Respondent violated this provision for two reasons: (1) He submitted untimely reports, and (2) the reports he submitted contained ''false statements'' because he denied ''that controlled substances had been dispensed from his clinics.'' Govt. Post-Hrng. Br. 23.

Neither the Act nor the Agency's regulations require a practitioner to file quarterly reports of their dispensings. Nonetheless, the Agency has held that a violation of an MOA provision constitutes actionable misconduct under the public interest standard even if does not amount to a violation of the Act or an agency regulation. *See Erwin E. Feldman,* 76 FR 16835, 16838 (2011) (citing *Fredal Pharmacy,* 55 FR 53592, 53593 (1990)).

Here, Respondent admitted that he did not timely file 10 of the reports and that he violated paragraph 9 of the MOA by failing to timely file the reports. Tr. 4209. While the CALJ found that the evidence only supports a finding that Respondent did not timely file eight of the reports, either way, the evidence supports the conclusion that Respondent repeatedly violated the MOA by failing to timely file the reports.

I reject, however, the Government's contention that Respondent also violated the MOA because the reports falsely stated that the clinics had dispensed no controlled substances during the various quarterly periods when the clinics were administering testosterone injections to various patients. ALJ Ex. 1, at 3, ¶ 5(c); Gov. Post-Hrng. Br. 21. In support of its contention, the Government invokes the CSA's definitions of the terms ''dispense'' and ''dispenser.'' Gov. Post-Hrng. Br. 23 (citing 21 U.S.C. 802(10)). Notably, the CSA defines the term ''dispense'' to ''mean[ ] to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance,'' and it defines ''[t]he term 'dispenser' [to] mean[ ] a practitioner who so delivers a controlled substance to an ultimate user.'' 21 U.S.C. 802(10).

The argument is nonetheless unavailing because the Government ignores that numerous provisions of the MOA differentiate the terms ''dispense'' (and ''dispensing'') from the terms ''administer'' (and ''administering'') and ''prescribe'' (and ''prescribing''). For example, paragraph two states that ''DEA continued to allow [Respondent] to *administer, dispense, and prescribe* controlled substances,'' GX 4, at 1, ¶ 2 (emphasis added); and paragraph five states that ''[t]his Memorandum of Agreement . . . is between [Respondent] and DEA and establishes the terms and conditions under which DEA will continue to permit [Respondent] to *administer, dispense and prescribe* any Schedules II through V controlled substance.'' *Id.* at 2, ¶ 5 (emphasis added).

So too, in paragraph seven, Respondent ''agree[d] to abide by all federal and Texas laws and regulations including statutes and regulations related to the *administering, dispensing and prescribing* of controlled substances.'' *Id.* at 2, ¶ 7 (emphasis added). Likewise, paragraph 8 provides that:

> If controlled substances in Schedules II though V are purchased for any clinic, to be *administered and/or dispensed* to clinic patients, [Respondent] shall cause to be made and maintained all DEA required documents and information including records, reports, and inventories. . . . . If any controlled substance is *administered or dispensed* at any clinic . . . the health care provider doing the *administering and/or dispensing* to the patient shall be registered at the clinic as required by 21 U.S.C. 822 (a)(2) and 21 CFR 1301.12(a) and any *administering and/or dispensing* of a controlled substance shall be documented in the patient chart . . . .

Id. at 2–3, ¶ 8 (emphasis added). And finally, paragraph 11 states that Respondent ''will not *administer, dispense, or prescribe* a controlled substance to any individual without a doctor-patient relationship and a treatment plan outlining the purpose for *administering, dispensing or prescribing* a controlled substance for a legitimate medical purpose.'' *Id.* at 3, ¶ 11 (emphasis added).

By contrast, the reporting obligation of paragraph 9 makes reference only to ''the total number of controlled substances *dispensed,* to include the date *dispensed* . . . name of controlled substances *dispensed,* quantity *dispensed* and *dispenser's* initials.'' *Id.* at 3, ¶ 9 (emphasis added). While the Government points to the statutory definition of the term ''dispense,'' the argument fails because the MOA contains no provision which explicitly defines the term ''dispense'' as encompassing the administration of a controlled substance or which incorporates by reference the CSA's definition of term.[30] Thus, given the

[29] In some instances, the log entry was missing the date of the administration. *See, e.g.,* GX 26, at 4. However, where the entries before and after such an entry were dated and those dates were within the period in which no practitioner was registered at the clinic, those administrations are deemed to have occurred on or between the entries which were dated and within the period. Moreover, even if I ignored entirely the undated entries, the evidence would still support a finding that there were 110 administrations which occurred during the period in which a practitioner was not registered at the clinic.

[30] In its post-hearing brief, the Government notes Respondent's testimony to the effect that ''[t]he state and the federal definition[s] of . . . administering [ ] and dispensing are different.'' Gov. Post-Hrng. Br. 17. Correctly noting that the Texas Health and Safety Code defines the term ''dispense'' to '' 'include[ ] the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery,' '' the Government argues that Respondent's claim that he relied on the state definition is without merit. *Id.* at 24 (quoting Tex. Health & Safety code § 481.001(12)).

The Government ignores, however, that the Rules of the Texas Medical Board define the term ''[d]ispense'' as only the ''[p]repairing, packing, compounding, or labeling for delivery a prescription drug . . . in the course of professional practice to an ultimate user . . . by or pursuant to the lawful order of a physician,'' as well as the term ''[a]dminister'' as only ''[t]he direct application of a drug by injection, inhalation, ingestion, or any other means to the body of a physician's patient.'' Tex. Admin Code § 169.2(2) & (4). Other provisions of the Board's rules distinguish between the

Continued

numerous instances, both before and after paragraph 9, in which the MOA differentiates between the terms ''dispense'' and ''administer'' (even though the latter is expressly included in the CSA's definition of the former), the Government cannot persuasively argue that the MOA clearly imposed on Respondent the obligation to file a quarterly report of the clinic's administrations.

At most, the Government's reliance on the CSA's definition creates an ambiguity as to the meaning of the term as used in the MOA.[31] Even so, ambiguities in contracts are generally resolved against the drafter. Here, while there is no direct evidence as to which party drafted the MOA or this particular term, the MOA does contain a provision pursuant to which Respondent ''waive[d] all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of'' the MOA, thus suggesting that the Government wrote the MOA. *Id.* at 4. *See Restatement (Second) of Contracts* § 206, at 105 cmt. a (1981) (''Where one party chooses the terms of a contract, he is likely to provide more carefully for the protection of his own interests than for those of the other party.''). Moreover, while there may be some negotiation over the specific wording of MOA provisions, MOAs are customarily drafted by the Government and the Government has produced no evidence that Respondent drafted paragraph nine.

Thus, I conclude that the Government created the ambiguity as to whether the term ''dispense'' as used in paragraph nine was intended to include the full scope of the statutory definition which also encompasses administering and prescribing or the narrower meaning which encompasses only the physical delivery of a controlled substance to an ultimate user. Because paragraph 9 does not effectuate compliance with any provision of the CSA or DEA regulations, I apply settled principles of contract law and resolve the ambiguity against the Government.[32] *See Restatement (Second) of Contracts* § 206, at 105 (''In choosing among the reasonable meanings of a promise or agreement or a term thereof, that meaning is generally preferred which operates against the party who supplies the words or from whom a writing otherwise proceeds.'').

Factor Four—Respondent's Compliance With Applicable Laws Related to Controlled Substances

In the Show Cause Order, the Government alleged that with respect to various clinics, Respondent violated both paragraph 8 of the MOA and DEA recordkeeping regulations, including the requirements to: (1) Make and maintain inventories as required by 21 CFR 1304.11(e)(3); (2) make and maintain complete and accurate dispensings records as required by 21 CFR 1304.22(c); and (3) make and maintain complete and accurate records of the receipts of the controlled substances as required by 21 CFR 1304.22(c) and 1304.22(a)(2). ALJ Ex. 1, at 3. The Show Cause Order also alleged that Respondent violated 21 CFR 1306.04(b), by authorizing prescriptions to obtained controlled substances ''for the purpose of general dispensing to patients.'' *Id.*

The Alleged Violations at Cy-Fair

The evidence clearly establishes that Respondent was registered at the Cy-Fair clinic and that the clinic was in possession of testosterone and engaged in the administration of the drug to patients. The evidence also shows that the clinic did not have either an initial or biennial inventory at the time of the inspection. Respondent thus violated the CSA and DEA regulations. *See* 21 U.S.C. 827(a) (1) (''every registrant under this subchapter shall . . . as soon . . . as such registrant first engaged in the . . . dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand''). *See also* 21 CFR 1304.11(b) (''every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engaged in the . . . dispensing of controlled substances''); *id.* § 1304.11(c) (requiring that ''[a]fter the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years'').

The evidence also shows that while the Cy Fair office manager provided the DIs with a log showing its administrations of testosterone, the log was missing required information including the address of the patient and the name of the finished form dispensed (*i.e.,* the strength of the testosterone per ml). This too was a violation of the CSA and DEA regulations. *See* 21 U.S.C. 827(a)(3) (''every registrant under this subchapter . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him''); *see also* 21 CFR 1304.22(c) (''records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of the dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser'').[33]

As for Cy Fair's receipt records, the clinic provided but a single page listing nine instances in which it had acquired ''10 Testosterone Cypionate 200 mg/ml'' by date. GX 9, at 1. However, this document was not ''a complete and accurate record of each such substance . . . received . . . by'' the clinic. 21 U.S.C. 827(a)(3). Specifically, while the document included the number ''10'' before the drug name, it does not indicate whether this number refers to the quantity of the drug in the vials or the number of vials. *See* 21 CFR 1304.22(c) (incorporating by reference 21 CFR 1304.22(a)(2)(ii) & (iv) (requiring that records list ''each finished form'' and ''the number of units of finished forms . . . acquired from other persons''). Moreover, the record does not include ''the name, address, and registration number of the person from whom the units were acquired.'' 21 CFR 1304.22(a)(2)(iv). Thus, Respondent

''[a]dministration of [d]rugs,'' *id.* § 169.3, and ''[p]roviding, [d]ispensing, or [d]istributing [d]rugs.'' *Id.* § 169.4. As to the former provision, it states, in part, that ''[a] physician may personally administer those drugs to his or her patients, which are, in the physician's medical judgment, therapeutically beneficial or necessary for the patient's treatment.'' *Id.* § 169.3. As to the latter, it states, in part, that ''a physician may provide, dispense, or distribute drugs for use or consumption by the patient away from the physician's office or after the conclusion of the physician-patient encounter.'' *Id.* § 169.4. Thus, the Board's rules provide some support to Respondent's contention.

[31] Indeed, under the Government's broader interpretation, Respondent was also required to include each controlled substance prescription he wrote. Yet the Government never took issue with Respondent's failure to include on the reports the prescriptions that were issued at the various clinics.

[32] The Government also alleged that the ''reports submitted . . . on July 20, 2012, were back-dated and hence, failed to indicate the true date they were prepared.'' ALJ Ex. 1, at 3 ¶ 5(c). However, the Government was well aware of the fact that the reports had not been timely submitted, and the Government has offered no evidence explaining why Respondent's back dating of the reports was capable of influencing the outcome of its investigation given that Respondent never represented that he had previously submitted the reports. *See Roy S. Schwartz,* 79 FR 34360, 34363 n.6 (2014).

[33] *See also id.* (requiring dispensers to ''maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section.'' As relevant to the administration log, this information includes, ''the name of the substance'' and ''[e]ach finished form (*e.g.,* . . . 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (*e.g.,* . . . 3 milliliter vial'').

violated 21 U.S.C. 827(a)(3) for this reason as well.

The Government further alleged Respondent violated 21 CFR 1306.04(b), which prohibits the use of ''[a] prescription . . . in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.'' ALJ Ex. 1, at 3, ¶ 6. As support for the allegation that Respondent used prescriptions to order the testosterone from the Empower Pharmacy, the Government produced a document created by the pharmacy which lists testosterone ''[p]rescriptions filled between 8/29/2011 and 8/29/2013'' and the patient as ''CLINIC, CYFAIR.'' GX 37, at 2. The document includes an Rx Number for each dispensing, the date of the dispensing and the date written, the number of refills, and lists both Respondent and several nurse practitioners as the ''Doctor.'' *Id.* The Government also submitted copies of six testosterone prescriptions, several of which included Respondent's name on the signature line as well as that of one of the mid-level practitioners. *See id.* at 74–79.

The DI who obtained these documents from the Empower Pharmacy testified, however, that the prescription documents were ''generated by the pharmacy'' and not the clinic. She further characterized one of the documents as ''on a blank—what is commonly used as a call-in prescription form.'' Tr. 226. While these documents were created by the pharmacy, and standing alone would not have been sufficient to sustain the allegation, on direct examination, Respondent admitted that ''the office managers would call or send a prescription over to the pharmacy to get filled'' for general office use and asserted that ''this is a common practice'' in hospitals. *Id.* at 387–88. *See also id.* at 311 (testimony of DI that nurse practitioner who floated between various clinics told him that ''the same practice'' was used ''at all clinics'').

Moreover, in his testimony, Respondent never asserted that his employees were simply ordering the drugs without issuing prescriptions and that it was actually Empower Pharmacy's decision to use a call-in prescription form to document the transaction. *Id.* at 455–56. Indeed, he repeatedly defended the practice, asserting that it was ''absolutely proper'' for his office staff to use a prescription to obtain a controlled substance for office use. *Id.* at 456–57. Thus, Respondent was clearly aware that his various office managers engaged in this practice including those at Cy-Fair.

In his post-hearing brief, Respondent asserts that ''there is no evidence that he wrote the prescriptions, knew about them, or 'authorized' them as the term is commonly understood.'' Resp. Closing Argument, at 6. The argument is counterfactual. Respondent clearly knew that his clinics (and in particular, the Cy-Fair clinic) were administering testosterone to patients and he also knew how his clinics were obtaining the drug. Moreover, even if Respondent did not personally authorize the Cy-Fair prescriptions, the mid-level practitioners who authorized the prescriptions were only able to do so because Respondent delegated prescribing authority to them. *See* Tex. Occupations Code § 157.0511 (authorizing a physician to delegate prescribing authority for schedule III through V controlled substances); *id.* § 157.0512 (requiring a prescriptive authority agreement by which a physician delegates prescribing authority to advance practice registered nurses and physician assistants and setting rules for such agreements). Thus, with respect to the prescriptions issued by Cy-Fair to obtain testosterone, I conclude that Respondent violated 21 CFR 1306.04(b).[34]

Nor were Respondent's violations of 21 CFR 1306.04(b) confined to the Cy-Fair clinic as the Government produced two other testosterone prescriptions which were authorized under his registration which were for the use of the Oak Hills and FM—1960 clinics. *See* GX 37, at 70, 85. Specifically, the Government produced a prescription dated October 19, 2012 for Scream Cream[35] ''#5 ml'' which lists Respondent as the prescriber and the patient as ''1960—R Zayas.'' GX 37, at 85. The Government also produced a prescription dated February 6, 2013 for one 10 ml bottle of testosterone which again lists Respondent as the prescriber and the patient as ''Oak Hills—Dr. R. Zayas.'' *Id.* at 70. Also, each of these prescriptions bears Respondent's registration number for his Houston registered address. Thus, the evidence is clear that prescriptions were authorized pursuant to Respondent's registration, and even if he did not personally call in the prescriptions, he is strictly liable for the misuse of his registration by any person to whom he entrusted his registration. *See Rosemary Jacinta Lewis,* 72 FR 4035, 4041 (2007).

Alleged Violations at the Other Clinics

As discussed above, Respondent was registered only at the Cy-Fair clinic at the time of the inspection. Thus, with respect to the recordkeeping allegations, Respondent argues that he was ''the DEA registered supervising physician at [only] one of'' the clinics (*i.e.,* Cy Fair), and that ''the Government is attempting to turn a contractual violation into a violation of a statute or regulation which is unjustified, unsupported by existing case law, or might be beyond the DEA's statutory authority.'' Resp.'s Closing Argument, at 5. Respondent further maintains that:

> The case against him is based on [the] unstated (and as yet unsupported) assumption that the DEA has authority to sanction a registrant for a breach of contract where the contract seeks to impose the obligations of a . . . registrant for which [he] was not the . . . registrant, on the theory that because he owns the entity which has a controlling interest in the operating company which owns and manages the clinics, that somehow establishes a violation of federal law.
>
> *Id.*

The CALJ found Respondent's argument persuasive to the extent it involved his contention that he cannot be held liable for violating the CSA and Agency regulations pertaining to recordkeeping at the clinics where he was not registered. *See* R.D. 62. The CALJ explained that:

> Although each dispensing registrant is required to maintain a [registration] at the place[s] where administering/dispensing occurs, these alleged (and established) administering/dispensing events pertained to other individuals, not to the Respondent. The same can be said of those portions of the [Show Cause Order] ¶5(b) allegations pertaining to dispensing, receiving, and inventory records at the non-Cy-Fair clinics that dispensers are required to create and maintain . . . . Evaluated in a world without the DEA MOA, these allegations do not raise evidence within the purview of the public interest factors in relation to the Respondent.

Id. The CALJ did, however, consider the evidence as to the recordkeeping violations by the non-Cy Fair clinics as constituting ''such other conduct which

[34] As for Respondent's assertion that it is common practice that hospitals do not order anesthesia medications for every patient and order stock bottles, undoubtedly that is true. While there is no evidence in the record as to how hospitals order the drugs they administer or dispense to patients, what a hospital cannot do is use a prescription to order the drugs for general dispensing. Indeed, hospitals typically order the stock from a registered distributor, and with respect to the schedule II drugs which are invariably used for anesthesia, they must use an Order Form as required under 21 U.S.C. 828(a) & (c)(2). *See also* 21 CFR Pt. 1305.

[35] Notwithstanding that there was a non-controlled version of Scream Cream, the pharmacy assigned a prescription number for this dispensing which begins with a C, thus evidencing that this was for a product which contained testosterone.

may threaten public health and safety.'' *See id.* at 66–72.[36]

I reject Respondent's and the CALJ's conclusion that Respondent is not liable for violating the CSA's recordkeeping provisions because he was not the registrant at the six other clinics.[37] Indeed, this Agency has previously noted that liability can be imposed on a non-registrant for failing to keep required records even though that conduct is also properly chargeable to a registered practitioner. *See Moore Clinic Trials, L.L.C.,* 79 FR 40145, 40156 (2014) (holding non-registrant clinic owner liable for failure of physician to maintain required records). Indeed, in *Moore,* the Agency explained that under the CSA, if controlled substances are dispensed at a clinic, both the clinic's owner and the physician it employs or contracts with to perform services on the clinic's behalf are responsible for maintaining complete and accurate records. *See* 79 FR at 40156 (citing *United States* v. *Clinical Leasing Serv., Inc.,* 759 F. Supp. 310, 313 (E.D. La. 1990), *aff'd* 925 F.2d 120, 123 (5th Cir. 1991)). As the court explained in *Clinical Leasing Services:*

> The clinic is charged with failure to maintain proper records. The law clearly requires every ''person'' (including a corporation) to maintain proper records if that person dispenses controlled substances. By employing physicians to dispense drugs in connection with its operation, the clinic is a dispenser of controlled substances. Therefore, *the clinic, as well as the physicians it employs, must maintain the proper records required by law.*

759 F. Supp. at 312 (emphasis added).

The court expressly rejected the clinic's contention that ''it was not required to maintain records,'' because ''the record keeping requirements pertain only to 'registrants,''' noting that 21 U.S.C. 842(a)(5) ''does not require that one who refuses or fails to make, keep, or furnish records be a 'registrant,''' but applies to ''any person,'' including '''an individual, corporation . . . business trust, partnership, association, or other legal entity.''' *Id.* at 313 (quoting 21 CFR 1301.02(j)).

Multiple federal courts have likewise rejected the contention that the CSA's recordkeeping requirements do not apply to non-registrant owners of clinics that dispense controlled substances. *See United States* v. *Robinson,* 2012 WL 3984786, *6–7 (S.D. Fla., Sept. 11, 2012) (holding non-registrant owner of cosmetic surgery clinic liable for recordkeeping violations under section 842(a)(5); statute ''includes the broader term of 'any person' and does not limit application of the subsection to registrants''); *id.* at * 7 (''Where corporate officers have been in a position to prevent or correct the violations at issue, courts have found that there is individual liability under the subsection, which plainly applies to all 'persons.'''). *See also United States* v. *Stidham,* 938 F.Supp. 808, 813–15 (S.D. Ala. 1996) (holding non-registrant owner of methadone clinic liable for recordkeeping violations); *United States* v. *Poulin,* 926 F.Supp. 246, 250–51 (D. Mass. 1996) (''The recordkeeping provisions of the [CSA] apply to all persons who dispense drugs, even if they have not registered as required under the Act'' and holding both pharmacy's owner/proprietor and corporate entity liable for recordkeeping violations); *see also* 21 U.S.C. 842(a)(5).

Notwithstanding the various arrangements and entities used by Respondent to hold the clinics, the record clearly establishes that Respondent was the real owner and operator of the clinics. *See* GX 4, at 13 (settlement agreement with United States Attorney signed by Respondent as President of Z Healthcare Systems, Inc.); *see also* Tr. 381–82, 384–87, 392, 394–96 (Respondent's testimony discussing his role in overseeing the clinics). Thus, with respect to the six other clinics, he is also a ''person'' within the meaning of 21 U.S.C. 842(a)(5) and 21 CFR 1301.02(j), and as such, he is liable for any recordkeeping violations committed by the other clinics even if those clinics had a practitioner who was registered at the clinic.[38]

As for the other six clinics, the evidence shows that each of these clinics was either entirely missing certain records or failed to maintain complete and accurate records as required by the CSA and DEA regulations. With respect to the Woodlands clinic, the clinic did not have any inventories and receipt records. Tr. 155–56. Thus, Respondent is liable for violating 21 U.S.C. 827(a)(1) (requiring inventories) and § 827(a)(3) (requiring records of receipts) with respect to this clinic. Moreover, while the clinic presented the DI with its Testosterone Shot Log, the log was missing various items of required information including the patients' addresses, the finished form of the substance (*e.g.,* the concentration per milliliter), and the volume administered to the patient. Thus, Respondent is liable for failing to ''maintain a complete and accurate record'' of its testosterone administrations at this clinic. *See* 21 U.S.C. 827(a)(3) and 21 CFR 1304.22(c).

As for the Victoria clinic, it did not have an initial or biennial inventory. Thus, Respondent is liable for violating 21 U.S.C. 827(a)(1). While the clinic provided its testosterone injection log to the DIs, none of the entries included the patient's address and a number of entries were not dated. *See* GX 26. And while the entries on some pages of the log did include both the concentration of the finished form (''200 mg'') and the dose, nearly all of the other entries were missing the drug's concentration. *Compare* GX 26, at 2–5, 15, *with id.* at 1, 6–14, 16. Thus, Respondent is liable for failing to ''maintain a complete and accurate record'' of the Victoria clinic's testosterone administrations. *See* 21 U.S.C. 827(a)(3) and 21 CFR 1304.22(c).

While the Victoria clinic provided receipt records, which appears to be a printout from a pharmacy, the records are illegible with respect to the name of the supplier, its address, and its DEA registration. GX 32; *see* 21 CFR 1304.22(c) (incorporating by reference 21 CFR 1304.22(a)(2)(iv)). Thus, Respondent is also liable for the clinic's failure to ''maintain a complete and accurate record'' of its testosterone receipts. 21 U.S.C. 827(a)(3).

The Corpus Christi clinic also did not have an initial or biennial inventory. Tr. 194. Thus, Respondent is liable for violating 21 U.S.C. 827(a)(1). And while the clinic produced records of its administrations, with a separate log sheet for each patient, none of the records included the patient's address

[36] While I agree with the CALJ that violating a provision of an MOA does not necessarily establish a violation of an applicable law related to controlled substances which is actionable under factor four (''[c]ompliance applicable . . . States, Federal or local laws related to controlled substances''), *see* R.D. 46 (citing *OTC Distribution Co.,* 68 FR 70538, 70542 (2003)), for reasons explained above, under federal law, Respondent is also liable for failing to maintain complete and accurate records at the non Cy-Fair clinics. Thus, this conduct is clearly actionable under Factor Four.

[37] While the Government does not appear to have relied on the theory that Respondent, as the owner of the clinics, is liable for the recordkeeping violations committed at the non-Cy Fair clinics, I conclude that Respondent has raised the issue. *See* Resp. Closing Argument, at 5. And even if I concluded that Respondent did not raise the issue of whether he is personally liable under the CSA for the record-keeping violations committed at the clinics where he was not registered, this would not change the outcome of this matter because he still violated the MOA by failing to ''cause to be made and maintained all DEA required documents and information including records, reports, and inventories.'' GX 4, at 2.

[38] As found above, nearly every clinic had a substantial period in which it did not have a practitioner who was registered at it. Respondent does not explain who, but him, was responsible for the respective clinic's recordkeeping violations in these periods.

and most of the records did not even list the name of the controlled substance. *See* GX 28; 21 CFR 1304.22(c); *id.* § 1304.22(a)(2)(ii). Moreover, while some of the log sheets bore the heading of ''TESTOSTERONE,'' the sheets did not list the drug concentration. *See id.* (incorporating by reference 21 CFR 1304.22(a)(2)(ii)). Thus, Respondent is liable for the clinic's failure to ''maintain a complete and accurate record'' of the controlled substances it dispensed. 21 U.S.C. 827(a)(3).

As for the Corpus Christi clinic's receipt records, these consisted of a ''Log of Scripts'' which appears to have been created and provided by the Empower Pharmacy. GX 28, at 62. This record was also missing required information in that while it listed the drug and finished form (200 mg/ml injectable), as well as a quantity, it did not list the volume of the finished form and the record does not specify whether the quantity figure referred to the number of vials or the number of milliliters shipped by the pharmacy. *Id.;* 21 CFR 1304.22(c) (incorporating by reference 21 CFR 1304.22(a)(2)(ii) & (iv)). Moreover, while the Log indicates the date the drugs were ''dispensed'' by Empower, the clinic did not record on the document ''the date on which the controlled substances are actually received.'' 21 CFR 1304.21(d).[39] Thus, Respondent is liable for the clinic's failure to ''maintain a complete and accurate record'' of the controlled substances it dispensed. 21 U.S.C. 827(a)(3).

Similarly, the FM 1960 West clinic also did not have either an initial or biennial inventory. Tr. 288, 305. Thus, Respondent is liable for the clinic's failure to comply with 21 U.S.C. 827(a)(1). The clinic also did not have receipt records on hand; instead, it had Empower Pharmacy fax a report which listed the clinic as the patient and the ''dispensings'' to it. GX 15. As before, the report was not ''a complete and accurate record'' because it did not list the number of units or volume of the testosterone products (both injectables and the Scream Cream) the clinic received and did not document the date the drugs were received. 21 CFR 1304.21(d); 1304.22(c). Moreover, given that the clinic did not have the receipt records on hand, it clearly violated 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(a) by failing to maintain these ''on a current basis.'' Respondent is thus liable for these violations.

As for the testosterone shot log, each entry was missing the patient's address, the dosage form, and the volume administered. GX 17. Thus, this record was not ''a complete and accurate record'' as required under 21 U.S.C. 827(a)(3). *See* 21 CFR 1304.22(c); *see also id.* § 1304.22(a)(2)(ii). Respondent is therefore liable for these violations as well.

The Oak Hills clinic provided the Investigators with its ''Testosterone Daily Drug Inventory Log.'' This document did include the required information including the dosage form (on some but not all of the log's pages) and quantity on hand; the log also included counts that had been taken within the last two years. GX 13, at 4–28. Thus, this record largely complied with 21 U.S.C. 827(a)(1).

The clinic also provided a testosterone log, which listed administrations. The log did not, however, include the patients' addresses or the dosage form (concentration) of the testosterone. *Id.* at 1–3. Moreover, the administration log only included administrations between April 3, 2013 and August 24, 2013, *id.,* even though the daily drug inventory shows that testosterone was dispensed on numerous occasions within the two-year period preceding the inspection. *Id.* at 12–22. Thus, Respondent is liable for the clinic's failure to maintain ''a complete and accurate record'' of the administrations. 21 U.S.C. 827(a)(3); *see also* 21 CFR 1304.22(c); *id.* § 1304.22(a)(2)(ii); 21 U.S.C. 827(b) (''Every . . . record required under this section . . . shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States . . . .'').

Upon the request of the Investigators, the Southwest Clinic did not provide either inventory records or receipt records. Tr. 326. Moreover, while a clinic employee told an Investigator that controlled substances had been transferred to the clinic from another clinic that had closed, Southwest had no record documenting the transfer. *Id.* at 331. Thus, Respondent is liable for the clinic's failure to take initial or biennial inventories, *see* 21 U.S.C. 827(a)(1), as well as the clinic's failure to ''maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . received . . . by'' it. *Id.* § 827(a)(3).

As for the testosterone log, it was also missing the patients' addresses and the dosage form (concentration) of the testosterone. *See* 21 CFR 1304.22(c); *id.* 1304.22(a)(2)(ii). Moreover, the earliest dispensing record in the testosterone log was dated September 4, 2012. GX 23, at 4. Yet a prescription report obtained from Empower Pharmacy shows that injectable testosterone was ''dispensed'' to the clinic (as the ''patient'') on April 24, 2012, June 5, 2012, July 19, 2012, August 18, 2012 and September 1, 2012, thus supporting the inference that the clinic was regularly administering testosterone prior to the first entry in its testosterone log without documenting the administrations. *See* GX 37, at 3. I therefore conclude that Respondent is liable for the clinic's failure to ''maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . delivered by'' it. 21 U.S.C. 827(a)(3); 21 CFR 1304.22(c).

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

The Government also argues that Respondent has engaged in other conduct which is actionable under Factor Five.[40] Of specific relevance here, the Government argues that ''Respondent's false statement and obstructionist behavior towards [the DI] are also applicable under Factor Five insofar as they constitute the failure to maintain effective controls against diversion.'' *Id.* (citing *Island Wholesale, Inc.,* 68 FR 17406, 17407 (2003)[41] and *Leonel Tano,* 62 FR 22968, 22971 (1997)).

Here, the evidence shows that Respondent made a false statement and obstructed the DI who was assigned to review his renewal application. Specifically, when asked by the DI in an email to forward to her copies of the quarterly reports of his dispensings which were required under the MOA, Respondent denied that he was even under an MOA. Respondent's statement was clearly false and while the DI

[39] Indeed, the record states that it was ''[p]rinted'' on August 29, 2013, three weeks after the date on which the last prescription listed was dispensed by Empower Pharmacy, and lists 15 prescriptions going back February 14, 2012. GX 28, at 62. However, both the CSA and DEA regulations require that receiving records be maintained ''on a current basis.'' 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a). This record clearly did not comply with this requirement.

[40] The Government also argues that ''[t]o the extent Respondent's multiple failures to comply with the . . . MOA is [sic] not actionable under Factor Four, it would be actionable under Factor Five.'' Gov. Post-Hrng. Br. at 25. It then points to the allegations regarding the quarterly dispensing reports, the failure to ensure that the clinic practitioners were properly registered, and that the clinics were not maintaining proper records. *Id.* at 26. As each of these allegations has been addressed under either Factor Two or Factor Four, they do not constitute ''other conduct.''

[41] This case did not, however, involve a practitioner, but rather a list I chemical distributor. *See* 68 FR 17407. The ''catch-all'' factor for list I distributor only requires a showing that the factor is ''relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(5). This is a considerably lower bar than ''such other conduct which may threaten the public health and safety.'' *Id.* § 823(f)(5).

obviously knew that the statement was false, the statement nonetheless had the capacity to influence the Agency's decision as to whether to grant his renewal application and was made with fraudulent intent as Respondent obviously knew that his registration was subject to the MOA and that he had failed to comply with the requirement that he submit the quarterly reports. *See United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985) (''It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.''); *United States* v. *Norris,* 749 F.2d 1116, 1121 (4th Cir. 1984) (''There is no requirement that the false statement influence or effect the decisionmaking process of a department of the United States Government.''). This is actionable misconduct under Factor Five. *See Shannon L. Gallentine,* 76 FR 45864, 45866 (2011); *see also Hoxie* v. *DEA,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician and his forthrightness in assisting in the investigation . . . important factors in determining whether the physician's registration should be revoked.'').

So too, in response to the DI's request to ''describe [his] current medical practice'' and to ''please include all locations and the names and DEA numbers of any Physician Assistants . . . or Nurse Practitioners that [he] currently supervise[d],'' he replied that ''this is irrelevant to the renewal of my DEA certificate.'' GX 36, at 2. The information requested by the DI was, however, relevant to the renewal of his registration because it was fully within the Government's authority to investigate whether Respondent had complied with the MOA. *See Hoxie,* 419 F.3d at 483.

Moreover, at the hearing, Respondent offered the excuse that he had ''blocked'' the events surrounding his entering into the MOA out of his mind because it was such an ''unpleasant'' and ''humiliating'' experience. Tr. 426–27. The CALJ did not find his testimony credible, characterizing his testimony as a ''dubious account of a variety of amnesia that deprived him of any memory of even the existence of the highly-detailed . . . MOA'' that ''was simply implausible.'' R.D. 33. The CALJ further noted that Respondent's ''memory lapse commenced and ended at points that were conveniently tailored to his narrative and [was] entirely unsupported by any medical diagnosis.'' *Id.* As the CALJ concluded, ''it is clear that he made it up.'' R.D. 33. I agree with the CALJ's assessment that Respondent's testimony regarding his failure to comply with the MOA was false; his provision of false testimony also constitutes actionable misconduct under Factor Five. Thus, I conclude that an adverse finding is warranted under Factor Five.

Summary of the Government's *Prima Facie* Case

As found above, the Government's evidence with respect to Factors Two and Four establishes that Respondent has committed multiple violations of the CSA and DEA regulations, as well as the MOA. The Government's evidence shows that Respondent repeatedly failed to comply with the MOA's provision which required that any clinic that either administered or dispensed controlled substances have a practitioner who was registered at the clinic, as well as the provision that he timely file quarterly reports of the clinics' dispensings.

The Government's evidence further shows that Respondent violated various recordkeeping requirements under the CSA and DEA regulations, including the requirements that he: (1) Make and maintain initial and biennial inventories, (2) make and maintain complete and accurate dispensing records, and (3) make and maintain completed and accurate records of receipts of controlled substances. *See, e.g.,* 21 U.S.C. 827(a) & (c). Moreover, as the real owner of the clinics, Respondent is liable for these violations of the CSA and DEA regulations, notwithstanding that he was registered at only the Cy-Fair clinic. Also, the evidence shows that Respondent violated 21 CFR 1304.22(c), by authorizing prescriptions to obtain controlled substances for ''general dispensing to patients.''

The evidence further shows that Respondent made a materially false statement to the DI and attempted to obstruct her investigation. And finally, the evidence shows that Respondent gave false testimony in the proceeding.

I therefore conclude that the Government has satisfied its *prima facie* burden of showing that Respondent ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4), and which support the revocation of his Florida registration and the denial of his pending application for his Texas registration. *See id.* § 823(f).

Sanction

Where, as here, the Government has established grounds to revoke a registration or deny an application, a respondent must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (citing *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Cuong Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).

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

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

The CALJ found that Respondent's acceptance of responsibility ''was

equivocal, at best, and was entirely self-serving.'' R.D. 77. The CALJ further found that ''[h]e begrudgingly accepted responsibility when his counsel led him to do so, but . . . in response to questions by Government's counsel, he approached the topic with a tenor that bordered on hostile sarcasm.'' *Id.* The CALJ specifically noted Respondent's testimony that the proceeding was ''nonsense,'' that it was ''arguing over logs,'' and that this ''we're not even talking about that much medicine.'' *Id.* Moreover, Respondent continued to insist that it is ''absolutely proper'' for his employees to use prescriptions to order controlled substances for office use. Tr. 456. And when asked whether he was going to admit to violating the MOA provision which required that if any clinic dispensed or administered a controlled substance, the dispensing/administering was to be done by a practitioner who was registered at the clinic, he asserted that he did not ''know whether it's true or not'' while nonetheless insisting that he was accepting responsibility for this misconduct. *Id.* at 465.

In his Exceptions, Respondent points to his testimony that he ''changed the business of his clinics such that they no longer handled controlled substances, thus avoiding the recordkeeping and inventory problems which led to the MOA violations.'' Resp. Exceptions, at 5. He argues that ''there is DEA precedent that in some conditions, acceptance of responsibility is not absolutely required.'' *Id.* (citing *Rosalind A. Cropper,* 66 FR 41040 (2001)). He correctly notes that in *Cropper,* the Agency granted the respondent's application notwithstanding her failure to admit to any of the proven misconduct, which involved treating patients for opiate addiction with methadone for more than three days without being registered as a narcotic treatment program. 66 FR at 41048. Respondent argues ''[t]he Cropper case appears [to] show[ ] that there are exceptions to the acceptance of responsibility requirement in cases like this one where the Respondent has changed his circumstance and business to avoid a recurrence of the problems which are the subject of the DEA action.'' Exceptions, at 5–6.

Relying on *Cropper,* Respondent argues that even if I agree with the CALJ that ''there was not complete acceptance of responsibility by the Respondent . . . revocation is not required because of the changed circumstance.'' *Id.* Addressing the CALJ's statement that ''[t]he tenor of the Respondent's declaration that his clinics will no longer directly handle controlled substances strikes less as a remedial step than it does as a tantrum,.'' R.D. 77 n.197, he argues that the CALJ ''is reading . . . an intentionality element which does not exist in the case law'' and that ''[a]ll that is required is that a registrant take actions to ensure that the violative conduct does not recur.'' *Id.* at 6. He further argues that ''[t]he important point'' to be taken from *Cropper* ''was that [Dr. Cropper's] job didn't put her near the drug [methadone] and that was enough . . . to conclude that remedial efforts were adequate.'' *Id.* And Respondent argues that regardless of what the CALJ ''feels is his motivation for the change'' in his practice, ''it should be enough that [he] had made sure that the recordkeeping and inventory problems/violations which are at the heart of this case will not recur.'' *Id.* at 6–7. Finally, he maintains that his change in the clinics' practices ''can be viewed as a manifestation of his acceptance; for even in an acceptance of responsibility analysis, actions should speak louder than words.'' *Id.* at 7.

I reject Respondent's contentions. While it true that there are some cases besides *Cropper* in which the Agency imposed a sanction less than revocation or outright denial notwithstanding the respondent's less than unequivocal acceptance of responsibility, those cases have generally involved less egregious misconduct than that engaged in by Respondent. For example, in *Gregory Owens,* 74 FR 36751 (2009), the Agency imposed a three-month suspension, notwithstanding the respondent's equivocal evidence as to his acceptance of responsibility. *Id.* at 36757–78. However, the proven misconduct was limited to failing to report a state board disciplinary order and failing to submit a quarterly drug activity log during a four-month period.[42] *Id.* at 36757.

To be sure, in *Jeffrey Martin Ford,* 68 FR 10750 (2003), the Agency granted a new registration to a dentist who had been convicted of four felony counts of violating the Controlled Substances Act including conspiracy to possess with intent to distribute cocaine, possession with intent to distribute cocaine and marijuana, and the use of the mail to facilitate a narcotics transaction. *Id.* at 10751. Moreover, the Agency granted the respondent a new registration, notwithstanding that it found perplexing ''the [r]espondent's apparent willingness to accept responsibility for past actions on the one hand . . . and his seeming refusal to acknowledge wrong doing in other respects,'' as well as its concern ''that the [r]espondent has apparently failed to learn from the negative experiences surrounding his drug use.'' 68 FR at 10753. While the decision apparently excused the respondent's failure to unequivocally accept responsibility based on his having attended drug rehabilitation and remained sober for more than 10 years, as well his having satisfied the conditions for reinstatement of his state license, the decision does not even address whether he accepted responsibility for his criminal conduct. Because I find the reasoning of this case unpersuasive, were a case with similarly egregious misconduct presented to me, I would not grant a registration absent a clear and unequivocal acceptance of responsibility for all of misconduct that was proven on the record.

In sum, while there may be some instances in which the proven misconduct is not so egregious as to warrant revocation or a lengthy suspension (*see, e.g., Owens*), and a respondent, while offering a less than unequivocal acceptance of responsibility nonetheless offers sufficient evidence of adequate remedial measures to rebut the Government's proposed sanction, this is not such a case. Here, Respondent agreed to abide by all federal laws and regulations related to the administering, dispensing and prescribing of controlled substances, as well as that he ''shall cause to be made and maintained all DEA required . . . records, reports, and inventories'' at any clinic that administered or dispensed controlled substances''; he also agreed to ''abide by [the MOA's] contents in good faith.''

The evidence, however, suggests that Respondent had no intention of abiding by the MOA in good faith but rather entered the agreement simply to get the Government off his back. Tr. 359 (Respondent's testimony that he entered the MOA because it was ''the easiest and best way'' to keep his registration'' and avoid a ''protracted fight''). For example, notwithstanding that he promised to ensure that his clinics would maintain proper inventories (which he was legally obligated to do even in the absence of the MOA), Respondent testified that he had not even read the applicable regulations which require the keeping of inventories. Tr. 473. Indeed, even as of the hearing, he still had not read the

[42] To be sure, there are also cases predating the Agency's decision in *Jayam Krishna-Iyer,* 74 FR 459, 464 (2009), in which even a respondent who knowingly diverted controlled substances and who failed to accept responsibility for his misconduct was granted a new registration. *See, e.g., Anant N. Mauskar,* 63 FR 13687, 13689 (1998). However, in *Krishna-Iyer,* the Agency explicitly overruled any case which suggests that a physician who has engaged in knowing diversion is entitled to remain registered absence a credible acceptance of responsibility. *See Krishna-Iyer,* 74 FR at 464 n.9.

regulations. *Id.* at 474. While he attempted to shift the blame to his attorneys and consultant for failing to tell him what was required under the MOA, Respondent offered no testimony that he asked either his attorneys or consultant to explain what was required. *Id.* at 473–74. So too, while Respondent submitted the first two quarterly reports in a timely fashion, thereafter, he blew off this requirement until he was confronted by the DI.

So too, even acknowledging that the absolute amounts of the testosterone being handled by the various clinics were not especially large, it is notable that six of the clinics had recordkeeping violations including missing inventories, missing receipt records, and missing required information related to the clinics' administration of the drug. And notwithstanding his legally erroneous contention that he cannot be held to have violated the CSA's recordkeeping requirements at the non-Cy Fair clinics because he was not the registrant at those clinics, there were recordkeeping violations even at the Cy-Fair clinic, where he was registered.

Likewise, while he agreed that if his clinics engaged in administration or dispensing, the provider would be registered at the clinic, here again, Respondent breached the agreement. Particularly egregious is his failure to ensure that there was a registered provider at the Victoria clinic, where testosterone was administered at least 117 times during a three-month period when no practitioner was registered at the clinic.

I thus conclude that Respondent's misconduct was egregious (a conclusion which is buttressed by my findings with respect to Factor Five), and given his failure to offer a credible and meaningful acceptance of responsibility, I hold that he has not refuted the conclusion that his continued registration ''is inconsistent with the public interest'' and that both the revocation of his Florida registration and the denial of his Texas renewal application are warranted.[43]

I further agree with the CALJ that the Agency's interests in both specific and general deterrence support the revocation of his Florida registration and the denial of his Texas application. As for the Agency's interest in specific deterrence, Respondent is not barred from reapplying in the future, and were Respondent to do so and offer a credible acknowledgement of his misconduct (to go along with his remedial measures) and be granted a new registration, the sanctions I impose in this Decision and Order would hopefully deter him from engaging in future misconduct. As for the Agency's interest in general deterrence, not only does the Agency have an obvious and manifest interest in deterring violations of the CSA and regulations by members of the regulated community, the Agency also has a manifest interest in ensuring that those members to whom it extends the forbearance of an MOA will comply with the terms of those agreements.

I therefore conclude that Respondent has not refuted the Government's *prima facie* showing that his registrations are not consistent with the public interest. 21 U.S.C. 823(f), 824(a) (4). Accordingly, I will order that Respondent's Florida registration be revoked and that his application to renew his expired Texas registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FZ2418401 issued to Roberto Zayas, M.D., be, and it hereby is, revoked. I also order that any pending application of Roberto Zayas, M.D., to renew or modify this registration, be, and it hereby is, denied.

I further order that that the pending application of Roberto Zayas, M.D., to renew DEA Certificate of Registration FZ2249743, be, and it hereby is, denied. I further order that any other pending application of Roberto Zayas, M.D., for a DEA Certificate of Registration, be, and it hereby is, denied. This Order is effective June 7, 2017.

Dated: April 28, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–09285 Filed 5–5–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Workforce Innovation Fund Grants Reporting and Recordkeeping Requirements

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Workforce Innovation Fund Grants Reporting and Recordkeeping Requirements,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 7, 2017.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201702-1205-004* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–

---

[43] I have also considered Respondent's argument that ''[r]evocation is too severe and [is] not required.'' Resp. Exceptions, at 7. Therein, Respondent maintains that ''it seems clear that recordkeeping violations of the type found in this case are rarely if ever a reasons [sic] to revoke a provider's DEA registration.'' *Id.* He also contends ''that the conduct proven in this case seems far less egregious than any of the 2015 cases including the two (*Corbett* and *Zina*), which did not result in . . . revocation.'' *Id.* at 7–8.

Contrary to Respondent's understanding, recordkeeping violations alone can support the revocation of a registration or the denial of an application, and in this case, there were violations of multiple requirements at nearly every one of the clinics. *See Keith Ky Ly,* 80 FR 29025, 29035 (2015) (citing *Paul H. Volkman,* 73 FR 30630, 30644 (2008)). Nor is the evidence in this matter confined to the recordkeeping violations, as it also includes his failure to file the required quarterly reports, his failure to ensure that there was a provider who was registered at the clinics which were dispensing or administering controlled substances, his use of prescriptions to obtain controlled substances for general dispensing to patients, his false statement in denying that he was subject to the MOA, his obstructionist behavior when the DI requested certain information, and his giving false testimony as to the reason why he denied to the DI that he was under the MOA.

As for Respondent's reference to the ''*Corbett*'' case, Respondent did not provide a citation and I am unaware of any case involving a respondent with this name. As for his reference to the ''*Zina*'' case, even assuming that this was typographical error and that Respondent was referring to *Abbas E. Sina,* 80 FR 53191 (2015), a self-abuse case, the case provides no comfort to Respondent because Dr. Sina fully admitted to his misconduct. *Id.* at 53201. (Dr. Sina also offered credible evidence of his rehabilitation, including four years of compliance with his monitoring contract with no failed drug tests, as well as the testimony of two physicians who attested to his commitment to his recovery and compliance with his monitoring contract. *See id.* at 53201–202). I thus reject's Respondent's contention.

Finally, while Respondent also invokes *Morall* v. *DEA,* he ignores that, in that case, there were findings that the respondent's recordkeeping violations ''occurred over a fairly short period of time'' and that the respondent ''appeared to regret'' her misconduct. 412 F.2d at 166; *see also id.* at 183. Here, by contrast, Respondent's recordkeeping violations are not confined to a fairly short period and involve multiple clinics, and as the CALJ concluded, Respondent has not offered a credible acceptance of responsibility.