Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties. The Commission intends to prepare only a public report in this investigation. The report that the Commission makes available to the public will not contain confidential business information. Any confidential business information received by the Commission in this investigation and used in preparing the report will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: September 14, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–23112 Filed 9–18–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[Docket No. ATF 48N]

Granting of Relief; Federal Firearms Privileges (2011R–13T)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice.

ACTION: Notice of granting of restoration of Federal firearms privileges.

SUMMARY: Northrop Grumman Guidance and Electronics Company, Inc. (NGGECI) (formerly Litton Systems, Inc.), a subsidiary of Northrop Grumman Corporation (NGC), has been granted relief from the disabilities imposed by Federal laws by the Director of ATF with respect to the acquisition, transfer, receipt, shipment, or possession of firearms.

FOR FURTHER INFORMATION CONTACT: John D. Aiken, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue NE., Washington, DC 20226, telephone (202) 648–8499.

SUPPLEMENTARY INFORMATION: The Attorney General is responsible for enforcing the provisions of the Gun Control Act of 1968 (GCA), 18 U.S.C. Chapter 44. He has delegated that responsibility to the Director of ATF, subject to the direction of the Attorney General and the Deputy Attorney General. 28 CFR 0.130(a). ATF has promulgated regulations that implement the provisions of the GCA in 27 CFR Part 478.

Section 922(g) of the GCA prohibits certain persons from shipping or transporting any firearm in interstate or foreign commerce, or receiving any firearm which has been shipped or transported in interstate or foreign commerce, or possessing any firearm in or affecting commerce. These prohibitions apply to any person who—

(1) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;

(2) Is a fugitive from justice;

(3) Is an unlawful user of or addicted to any controlled substance;

(4) Has been adjudicated as a mental defective or committed to a mental institution;

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been discharged from the Armed Forces under dishonorable conditions;

(7) Having been a citizen of the United States, has renounced U.S. citizenship;

(8) Is subject to a court order that restrains the person from harassing, stalking, or threatening an intimate partner or child of such intimate partner; or

(9) Has been convicted in any court of a misdemeanor crime of domestic violence.

The term ''person'' is defined in section 921(a)(1) as including ''any individual, corporation, company, association, firm, partnership, society, or joint stock company.''

Section 925(c) of the GCA provides that a person who is prohibited from possessing, shipping, transporting, or receiving firearms or ammunition may make application to the Attorney General to lift the firearms disability imposed under section 922(g) ''if it is established to his satisfaction that the circumstances regarding the disability, and the applicant's record and reputation, are such that the applicant will not be likely to act in a manner dangerous to public safety and that the granting of the relief would not be contrary to the public interest.'' The Attorney General has delegated the authority to grant relief from firearms disabilities to the Director of ATF.

Section 925(c) further provides that ''[w]henever the Attorney General grants relief to any person pursuant to this section he shall promptly publish in the **Federal Register** notice of such action, together with the reasons therefor.'' Regulations implementing the provisions of section 925(c) are set forth in 27 CFR 478.144.

Since 1992, Congress has eliminated funding for ATF to investigate or act upon applications for relief from federal firearms disabilities. However, since 1993 Congress has authorized funding for ATF to investigate and act upon applications filed by corporations for relief from Federal firearms disabilities.

An application to ATF for relief from Federal firearms disabilities under 18 U.S.C. 925(c) was submitted for NGGECI. In the matter under review, NGGECI, a subsidiary of NGC, had been convicted in United States District Court for violations of 18 U.S.C. 2, 287, 1001, and 1341 in 1986 and, in 1994, for violations of 18 U.S.C. 2, 371, 641, and 1343.

Pursuant to 18 U.S.C. 925(c), NGGECI, a wholly-owned subsidiary of Northrop Grumman Systems Corporation (NGSC) (which is a wholly-owned subsidiary of NGC), is granted relief from the disabilities imposed by Federal laws with respect to the acquisition, transfer, receipt, shipment, or possession of firearms as a result of these convictions. It has been established to my satisfaction that the circumstances regarding NGGECI's disabilities and its record and reputation are such that the NGGECI will not be likely to act in a manner dangerous to public safety, and that the granting of the relief would not be contrary to the public interest.

B. Todd Jones,

Acting Director.

[FR Doc. 2012–22858 Filed 9–18–12; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–28]

Rene Casanova, M.D.; Decision and Order

On September 29, 2011, Administrative Law Judge Timothy D. Wing issued the attached recommended decision.[1] Neither party filed exceptions to the decision.[2]

[1] All citations to the ALJ's decision are to the slip opinion as originally issued.

[2] On October 21, 2011, Respondent moved for a ten-day extension of the deadline for filing his exceptions, stating that he had ''been in trial in a state court proceeding this week and has not had sufficient time to properly draft exceptions to the Recommended Order''; the Government consented to the motion. Consent Mot. to Extend Deadline for Filing Exceptions to Recommended Order, at 1.

Having considered the entire record, I have decided to adopt the ALJ's findings of fact and conclusions of law except as discussed below.[3] While I agree with the ALJ that substantial evidence supports the conclusion that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing controlled substance prescriptions to three undercover officers, ALJ 62–64, I find some of his reasoning unsupported by substantial evidence.

More specifically, with respect to the undercover officer who posed as patient J.S., the ALJ, citing the evidence that she had a negative drug screen, used slang to refer to oxycodone and admitted that ''she had not seen a doctor for the controlled substances she admitted taking,'' concluded that J.S.'s '' 'risk for medication misuse or diversion' was patent.'' ALJ at 56. The ALJ then concluded that because ''Respondent conceded that he did not refer [J.S.] to a specialist,'' and did not ''otherwise display[] 'special attention' to her heightened risk of diversion,'' his conduct was ''inconsistent with'' Fla. Admin. Code Ann. r. 64B8–9.013(e). *Id.* at 56–57. According to this provision, which has since been superceded:

> the physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Fla. Admin. Code Ann. r. 64B8–9.013(e).

Of significance, no authority (*i.e.,* such as a decision of either the Florida Board of Medicine or Florida courts), is cited to establish that this provision has been interpreted as imposing a mandatory obligation of consultation or referral. Moreover, at no point did the Government's Expert testify that given the presentation of J.S. as a patient, the accepted standard of medical practice required that Respondent refer her to another physician.

It is true that the Government's expert criticized Respondent ''for failing to inquire whether the patient had a substance abuse history or history of addiction.'' ALJ at 61. While this appears to be a violation of the standard governing the ''evaluation of the patient,'' and the Government's Expert testified as to the importance of determining whether a patient has a substance abuse and addiction history, Tr. 372–73, it is not clear why the failure to do so establishes that his conduct was inconsistent with the then-existing referral standard. *See* ALJ at 61.

There is, however, substantial evidence to support the finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to J.S. (as well as the two other undercover officers). With respect to all three patients, the Government's Expert testified that Respondent did not take an appropriate history or perform an appropriate physical examination. Tr. 335. While each of the undercovers provided an MRI, the Government Expert explained that an MRI is ''simply a diagnostic tool'' and that ''finding [a] pathology on an MRI does not entitle any practitioner to prescribe controlled substances,'' *id.* at 336, because a ''pathology of an MRI in no way indicates that there is any painful condition'' and must be correlated with the patient's history and physical examination findings. *Id.* at 365. The Government further testified that Respondent's documentation was ''substandard'' and ''very sketchy,'' *id.* at 337, and that he did not ''support the need for the controlled substances with appropriate documentation establishing a valid medical need and treatment plan.''[4] *Id.* at 339. Finally, the Government's Expert testified that ''[i]n all of the cases, the [Respondent] prescribed controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose.'' *Id.*

Under Agency precedent, these findings establish a *prima facie* case that Respondent ''has committed such as acts as would render his registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further agree with the ALJ's conclusion that Respondent has failed to accept responsibility for his misconduct in prescribing controlled substances to the undercover officers and that he has also failed ''to demonstrate that he will not engage in future misconduct.'' *Id.* at 72. Accordingly, I will adopt the ALJ's recommendation that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BC8677746, issued to Rene Casanova, M.D., be, and it hereby is, revoked. I further order that

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Noting that the exceptions were due the same day that Respondent filed his motion, the ALJ denied the motion finding that he had not demonstrated good cause for the extension. Ruling on Consent Mot., at 1. As the First Circuit has explained, the claim that one's ''attorney was preoccupied with other matters * * * has been tried before, and regularly has been found wanting.'' *De la Torre v. Continental Ins. Co.,* 15 F.3d 12, 15 (1st Cir. 1994) (citing *Mendez* v. *Banco Popular de Puerto Rico,* 900 F.2d 4, 7 (1st Cir. 1990)). *See also De la Torre,* 15 F.3d at 15 (quoting *Pinero Schroeder* v. *FNMA,* 574 F.2d 1117, 1118 (1st Cir. 1978)) (' 'Most attorneys are busy most of the time and they must organize their work so as to be able to meet the time requirements of matters they are handling or suffer the consequences.' '); *McLaughlin* v. *City of LaGrange,* 662 F.2d 1385, 1387 (11th Cir. 1981) (''[t]he fact that counsel has a busy practice does not establish 'excusable neglect' ''); *see also Kamir Garces-Mejias,* 72 FR 54931, 54932 (2007).

[3] I do not adopt the ALJ's conclusion ''that the reference in 21 U.S.C. 823(f)(5) to 'other conduct which may threaten the public health and safety' would as a matter of statutory interpretation logically encompass the factors listed in § 824(a).'' ALJ at 32–33 & n 62. *See Kwan Bo Jin,* 77 FR 35021, 35021 n.2 (2012).

Nor do I adopt the ALJ's finding that ''Respondent's biennial inventory did not go back a full two years from the date of the audit.'' ALJ at 36 (citing Tr. 200). Whether a biennial inventory has been timely completed is based on either the date that a ''registrant first engages in the manufacture, distribution, or dispensing of controlled substances,'' or on the date of a subsequent biennial inventory. 21 U.S.C. 827(a); *see also* 21 CFR 1304.11(c) (''After the initial inventory is taken, the registrant shall take a new inventory of all stocks of control substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.''). In short, a registrant's compliance with this requirement is not measured from the date of an audit.

The ALJ also made various factual findings related to the manner in which the clinic administered urine tests. *See* ALJ at 42–44 (crediting testimony of Agent that no one monitored his urine test, that one patient had said that he had simply scooped urine and water from the toilet and used that as his sample, and one patient had another person provide his urine sample for him); *see also* ALJ at 50 (''there was no supervision while [a second S/A] provided a urine specimen''). Based on this evidence, the ALJ concluded that ''[t]he emerging image of [the clinic] on February 16, 2010, is that of a clinic in which patients collude with one another and with staff members to fabricate urinalysis results and thereby obtain controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose. Although not for the most part directly attributable to Respondent, this misconduct calls into question the legitimacy of APM as a whole.'' ALJ at 44.

There is, however, no evidence that Respondent was aware of this misconduct. It is further noted that while the Government elicited testimony from an Expert on prescribing controlled substances to treat pain, the Expert did not offer any testimony regarding what the standards of professional practice require with respect to the monitoring/supervision of urine tests. I thus do not place any weight on this evidence.

[4] The Government's Expert also testified that it is incumbent on a physician to outline a treatment plan at the time he writes a prescription. *See* Tr. 345–46, 382, 386.

any pending application of Rene Casanova, M.D., to renew or modify the above registration, be, and it hereby is, denied. This Order is effective October 19, 2012.

Dated: August 31, 2012.

Michele M. Leonhart,

Administrator.

Dedra S. Curteman, Esq., for the Government
Bradford Beilly, Esq., for the Respondent

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

I. Introduction

A. The Order to Show Cause

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

The DEA Deputy Assistant Administrator issued an Order to Show Cause (OSC) relating to CORs BC8677746, FC1777260 and FC1881211, dated February 22, 2011, and served on Respondent. The OSC provided notice to Respondent of an opportunity to show cause as to why the DEA should not revoke Respondent's DEA CORs BC8677746, FC1777260 and FC1881211, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification, and any applications for any other DEA registration, pursuant to 21 U.S.C. § 823(f), alleging that Respondent's continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f).

The OSC alleged that Respondent is registered with DEA as a practitioner in Schedules II–V under DEA COR BC8677746 at 750 South Federal Highway, Deerfield Beach, Florida, 33441, under DEA COR FC1777260 at 1655 E. Oakland Park Boulevard, Oakland Park, Florida 33334 and under DEA COR FC1881211 at 640 East Ocean Avenue, Suites 18 and 19, Boynton Beach, Florida 33435, with expiration dates of August 31, 2012. The OSC further alleged that Respondent distributed controlled substances including oxycodone (a Schedule II controlled substance), hydrocodone (a Schedule III controlled substance) and alprazolam (a Schedule IV controlled substance) ''by issuing 'prescriptions' to undercover law enforcement officers for other than a legitimate medical purpose or outside the usual course of professional practice.'' (ALJ Ex. 1 at 2.)

In particular, the OSC alleged that in February 2010, Respondent distributed 180 oxycodone 30 mg tablets and 60 alprazolam 2 mg tablets to an undercover law enforcement officer (UC1) at the request of UC1 after conducting little or no physical examination and without providing any diagnosis warranting the prescriptions. Additionally, the OSC alleged that in February 2010, Respondent distributed 120 hydrocodone 7.5 mg tablets to a second undercover law enforcement officer (UC2) after conducting little or no physical examination and without providing any diagnosis warranting the prescription. The OSC alleged that Respondent distributed controlled substances to UC2 after UC2 informed Respondent that UC2 had obtained hydrocodone tablets from his girlfriend, without a legitimate prescription.

In addition to the OSC, the Government also noticed and alleged additional information in its initial and supplemental prehearing statements. In addition to noticing in greater detail its allegations related to the visits by UC1 and UC2 (*e.g.,* ALJ Ex. 4 at 6–16; ALJ Ex. 7 at 4–5), the Government further alleged that:

1. Vincent Colangelo, the owner/operator of several pain clinics in the Broward County area, including All Pain Management (APM),[1] where Respondent practiced, was involved in an illicit multi-level distribution enterprise of pharmaceutical controlled substances, to include, but not limited to, oxycodone (ALJ Ex. 4 at 4);

2. Mr. Colangelo controlled the issuing, ordering and dispensing of controlled substances for APM, to include among other things a requirement that physicians prescribe the highest quantity of oxycodone and hydrocodone possible (ALJ Ex. 4 at 4–5);

3. Respondent ordered Schedule III–IV controlled substances at his registered location at 750 South Federal Highway, Deerfield Beach, Florida 33441, but did not maintain a current biennial inventory as of February 23, 2011 (ALJ Ex. 4 at 6);

4. A March 29, 2011 on-site inspection and audit of Respondent's registered location for a period from November 16, 2009, through March 29, 2011, revealed that:

a. Discrepancies existed in Respondent's accounting for four controlled substances, constituting a failure to maintain complete and accurate records of controlled substances as required by 21 C.F.R. §§ 1304.21(a) and 1304.22(c) (*see* ALJ Ex. 7 at 2);

b. Respondent failed to note whether required inventory was taken at the open or close of the business day as required by 21 C.F.R. § 1304.11(a) (*see* ALJ Ex. 7 at 3);

c. Respondent failed to properly document the date received on twenty of thirty-seven receiving invoices, as required by 21 C.F.R. §§ 1304.21(a) and 1304.22(c) (*see* ALJ Ex. 7 at 3);

d. Respondent failed to maintain two receiving invoices or packing slips documenting the receipt of controlled substances from Stat Rx as required by 21 C.F.R. § 1304.21(a) (*see* ALJ Ex. 7 at 3);

5. On March 1, 2011, Respondent surrendered for cause DEA CORs FC1777260 and FC1881211 (ALJ Ex. 4 at 6); and

6. Within minutes of one another, Respondent issued nearly identical prescriptions for controlled substances to two patients[2] from Kentucky, who traveled together to see Respondent (ALJ Ex. 7 at 2).

Following prehearing procedures, a hearing was held in Miami, Florida between June 14, 2011, and June 15, 2011, with the Government and Respondent each represented by counsel. Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings have been adopted, they are substantively incorporated into those set forth below.

II. Issue

Whether the record establishes that Respondent's DEA COR as a practitioner BC8677746[3] should be revoked and any pending applications for renewal or modification, and any applications for a new registration, should be denied on the grounds that Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. §§ 824(a)(4) and 823(f).

III. Evidence and Incorporated Findings of Fact[4]

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

A. Stipulated Facts[5]

1. Respondent is registered with the DEA as a practitioner in Schedules II–V under DEA COR BC8677746 at 750 South Federal Highway, Deerfield Beach, Florida 33441.

2. Respondent is licensed by the Florida Department of Health as a medical doctor and has been licensed to practice medicine in Florida since August 12, 1999.

3. Respondent has never been disciplined by the Florida Department of Health.[6]

4. Respondent was registered with DEA as a practitioner in Schedules II–V under DEA COR FC1777260. He surrendered registration FC1777260 on March 1, 2011.

5. Respondent was registered with DEA as a practitioner in Schedules II–V under DEA COR FC1881211. He surrendered registration FC1881211 on March 1, 2011.

[1] The testimony at hearing reflected that APM is located at 3300 Griffin Road, Dania Beach, Florida. (Tr. 209.)

[2] The Government's Supplemental Prehearing Statement referenced three customers and related prescriptions. (ALJ Ex. 7 at 2.)

[3] As noted above, the OSC in this case identified three CORs. (ALJ Ex. 1.) On March 1, 2011, Respondent surrendered CORs FC1777260 and FC1881211. (Gov't Exs. 3 & 4; *see also* Jt. Stips. 4 & 5.) Respondent concedes that he surrendered the CORs but denies having done so for cause. (*E.g.,* ALJ Ex. 5 at 2–3.)

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

[5] *See* ALJ Ex. 9; *see also* Tr. 5–6, 301.

[6] *See* Tr. 448–49. At hearing, Respondent testified that his drug inventory has been audited annually by the Florida Department of Health with no negative results. (*See* Tr. 449.)

6. On February 16, 2010, Respondent saw and treated an individual who identified himself as ''Eugene O'Neal'' at APM Urgent Care, 3300 Griffin Road, Dania Beach, Florida. Respondent wrote the prescriptions listed as Government Exhibit 9 for this individual. The patient file for ''Eugene O'Neal'' as produced by the Government is listed as Government Exhibit 10.

7. On February 16, 2010, Respondent saw and treated an individual who identified himself as ''Alfredo Mondego'' at APM Urgent Care, 3300 Griffin Road, Dania Beach, Florida. Respondent wrote the prescriptions listed as Government Exhibit 13 for this individual. The patient file for ''Alfredo Mondego'' as produced by the Government is listed as Government Exhibit 14.

8. On March 10, 2010, Respondent saw and treated an individual who identified herself as ''Julia Sanchez'' at Coast to Coast Healthcare Management (CCHM), 328 East Hillsboro Boulevard, Deerfield Beach, Florida 33441. Respondent wrote the prescriptions listed as Government Exhibit 17 for this individual. The patient file for ''Julia Sanchez'' as produced by the Government is listed as Government Exhibit 18.

B. Introduction

Respondent is licensed to practice medicine in Florida and Massachusetts. (Jt. Stips. 2, 3; Tr. 412–13.) He possesses a medical degree from Tufts University and currently practices in Deerfield Beach, Florida at MinorEmergi Center—Primary Care, 762 South Federal Highway, Deerfield Beach, Florida, and at MinorEmergi Center—Urgent Care & Walk-In Medicine, 750 South Federal Highway, Deerfield Beach, Florida (collectively ''MEC'').[7] (*See* Tr. 17; Gov't Ex. 5.) He has been at MEC for five to six years. (Tr. 22.)

Respondent testified that he previously practiced in Miami at the emergency room of Westchester Hospital and also at another office in the Miami area. (Tr. 22; *see* Tr. 412.) In addition, he previously worked at a Level Two Trauma Center in Boston, Massachusetts.[8] (Tr. 35, 411–12.) He possesses no board certifications and is not employed as a faculty member of a medical school. (Tr. 454.)

Respondent also worked as a physician at APM one day per week from December 2009 to February 2010 (Tr. 22–24, 28; *see* Gov't Ex. 20) and at CCHM from March to April 2010.[9] (Tr. 22–23.)

The gravamen of the Government's allegations relate to Respondent's recordkeeping at MEC and prescribing practices at APM and CCHM.

C. Evidence

1. Background

(a) Witnesses

The Government's evidence included testimony from eight witnesses, including Respondent and a pain management expert, David M. Glener, M.D. (Dr. Glener). Two witnesses were undercover law enforcement officers who posed as patients and received treatment from Respondent at APM: DEA Special Agent (SA) Gene George Grafenstein, Jr. (SA Grafenstein) and SA Alfred Cortes[10] (SA Cortes). In addition, the evidence included testimony from SA Joe Gill (SA Gill) ''case agent'' for the investigation of APM, as well as Group Supervisor (GS) Susan Langston (GS Langston), Diversion Investigator (DI) William Stockmann (DI Stockmann) and DI James Graumlich (DI Graumlich), all of whom played a role in investigations relating to Respondent.

The Government's evidence also included various audio and video recordings of undercover meetings that occurred at APM and CCHM, along with transcripts of portions of the recordings. (Gov't Exs. 8–18.)

Respondent's evidence included testimony from one witness, Respondent. Respondent testified regarding his education and professional background, as well as his prescribing practices. Respondent's evidence also included a handwritten Biennial Medication Inventory dated November 16, 2009.[11] (*See* Resp't Ex. 1.)

With the exception of Respondent, I find all of the witnesses at hearing to be fully credible in that the testimony was generally internally consistent and evidenced a reasonable level of memory for past events. Each witness presented testimony in a professional manner and the material portions of the testimony were consistent with other credible evidence of record. Respondent's testimony was generally presented in a professional and serious manner, but, in certain instances discussed below, I find Respondent not credible to the extent his statements are contradicted by the weight of the objective evidence of record.

(b) Identified Controlled Substances

Uncontradicted testimony at hearing indicated that Lortab and Vicodin are brand names for hydrocodone, a Schedule III controlled substance. (Tr. 126, 137, 499.) Guaifenesin Ac is a controlled substance because it contains codeine. (Tr. 179.) Ambien is a brand of zolpidem. (*See* Tr. 199.) In addition, I take official notice that Zolvit is hydrocodone, a narcotic and Schedule III controlled substance; Percocet and Roxicodone are oxycodone, narcotics and Schedule II controlled substances; and Xanax is alprazolam, a benzodiazepine and Schedule IV controlled substance.[12]

2. MEC

(a) Background

Respondent testified that his current practice is located at 750 and 762 Federal Highway, consisting of ''two offices that are centrally based that are adjoined through a door * * * one of them is urgent care and one of them is primary care * * * .'' (Tr. 414–15.) Respondent's DEA registration is for 750 South Federal Highway. (Jt. Stip. 1; Tr. 463.) Respondent explained that the primary care practice ''is more of a practice where patients are scheduled to be seen and so forth where they have regularly scheduled visits. * * * They're patients who you know who you've developed a rapport with, who you have developed a treatment plan over an extensive period of time * * * .'' (Tr. 415.) In the urgent care practice, by contrast, ''usually patients come in for an acute issue that has to be dealt with'' urgently, to include patients suffering from acute pain. (*See* Tr. 415.) Respondent explained that ''there is no dispensing of any narcotics at 762'' South Federal Highway and no controlled substances are kept on hand in that portion of the facility. (Tr. 464.)

Consistent with Respondent's testimony, DI Stockmann testified that 750 and 762 South Federal Highway are storefronts. (Tr. 115.) One is a primary care center and the other is an urgent care center, at different ends of the same building. (Tr. 115.) Although each address had a separate entrance, 762 and 750 are physically connected. (Tr. 141.) When inside one office, it is possible to get to the other office via interior access.[13] (Tr. 142–43.)

(b) Dispensing at MEC

Respondent dispenses medication at MEC in conjunction with a company called InstyMeds.[14] (Tr. 17, 416.) InstyMeds

[7] The evidence at hearing tended to show that these two addresses are physically connected and are part of a unified practice, as discussed below.

[8] Respondent also completed an internship in general surgery at St. Elizabeth's Hospital in Boston, Massachusetts for one year and a residency in ear, nose and throat surgery at Tufts Medical School New England Medical Center. (Tr. 410.)

[9] Respondent testified that he dispensed Schedule III and IV controlled substances at these clinics, to include hydrocodone, Roxicodone, Valium and Xanax, as well as muscle relaxants and anti-inflammatories. (Tr. 23.)

[10] Spellings in the transcript vary between ''Cortes'' and ''Cortez.'' Because the Government's exhibits reflect the spelling ''Cortes'' (*e.g.*, Gov't Ex. 12), that spelling is adopted in this Recommended Decision.

[11] Respondent Exhibit 1 appears to be substantially the same as Government Exhibit 19 at 2.

[12] Under the APA, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request, to an opportunity to show to the contrary.'' 5 U.S.C. § 556(e); 21 C.F.R. § 1316.59(e) (2011); *see, e.g., R & M Sales Co.,* 75 Fed. Reg. 78,734, 78,736 n.7 (DEA 2010). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Recommended Decision, which shall begin on the date it is mailed. *See, e.g., Joseph Gaudio, M.D.,* 74 Fed. Reg. 10,083, 10,088 (DEA 2009) (granting respondent opportunity to dispute officially noticed facts within fifteen days of service).

[13] DI Stockmann elaborated that on February 23, 2011, he collected a copy of the clinic's prescription dispensing summary report and two MEC business cards, one of which lists Respondent as Medical Director. (*See* Tr. 109, 136; Gov't Ex. 5.) DI Stockmann testified that the business cards reflect addresses of ''Minor Emergency Center, Primary Care, with Dr. Casanova's name on it, with an address of 762 South Federal Highway, Deerfield Beach, Florida. * * * [T]he second card displays Dr. Casanova's name and also Minor Emergency Center, Urgent Care and Walk-In Medical Center, with an address of 750 South Federal Highway, Deerfield Beach, Florida.'' (Tr. 109; *see* Gov't Ex. 5.)

[14] MEC previously worked with a company called Linear Solutions, but ended the relationship approximately two months before the hearing. (Tr. 18.)

supplied MEC with a machine located in the corner of the waiting room that dispenses a variety of medications to patients, to include antibiotics and Schedule III and IV controlled substances. (*See* Tr. 19–20.) DI Graumlich described it as a ''vending machine where people can get their prescriptions filled after they've been written by the doctor.'' [15] (Tr. 165.) Medications are stored in racks and when patients enter an access code ''it provides them the medication.'' (Tr. 18–19; *see* Tr. 165–66.)

The machine, which is loaded by Respondent's staff, provides medication only while the office is open, and only after patients have received ''all the paperwork from the prescribing provider.'' (Tr. 19, 36–37.) The technology has been available for ten to fifteen years in hospitals and other local facilities. (Tr. 19, 21.) The InstyMeds machine is provided for ease or convenience. (Tr. 21.) Respondent believes using InstyMeds is compliant and assists with all ordering, stocking, dispensing, reporting and recording requirements related to controlled substances.[16] (Tr. 36–37; *see* Tr. 450.) MEC makes a small profit from using InstyMeds to dispense controlled substances. (Tr. 21.)

(c) February 23, 2011 Interview with Respondent

DI Stockmann [17] participated in an investigation of Respondent by serving the OSC and a notice of inspection upon Respondent and interviewing him on February 23, 2011, at MEC. (*See* Tr. 105–06.) DI Stockmann testified that at this interview Respondent identified MEC's hours of operation as Monday to Friday, 9:00 a.m. to 7:00 p.m., and weekends from 9:00 a.m. to 3:00 p.m. (*See* Tr. 106.) Respondent also stated that he employed four to five physician attendants and that his weekly hours were Monday, Wednesday and Friday, 9:00 a.m. to 5:00 p.m., and Tuesdays and Thursdays 9:00 a.m. to 1:00 p.m. (Tr. 106–07.) Respondent saw approximately fourteen or fifteen thousand patients each year, or approximately fifty patients per day. (Tr. 107.) Respondent acknowledged ordering Schedule III and IV controlled substances for MEC. (Tr. 107–08.)

DI Stockmann further testified that he inspected MEC on February 22, 2011, finding ''no evidence of a biennial inventory for that registered location of the controlled substances on hand.'' (Tr. 108.) He testified that Respondent acknowledged this was a violation of federal regulations. (Tr. 108.)

Additionally, DI Stockmann recounted Respondent's surrender of two of his DEA CORs on March 1, 2011. (Tr. 111; *see* Gov't Exs. 3, 4.) Because Respondent was not operating at those locations, DI Stockmann asked Respondent if he would surrender those certificates. (Tr. 130.) At Respondent's request, DI Stockmann called Respondent's counsel and explained he was asking Respondent to surrender licenses for facilities that were not being operated. (Tr. 130.) He did not explain which box he intended to check on the surrender form. (*Compare* Tr. 130, *with* Gov't Ex. 3 at 1; Gov't Ex. 4 at 1.) DI Stockmann explained to Respondent that he had found violations of federal and state law at those locations, to include recordkeeping violations. (Tr. 133.) DI Stockmann further testified that the surrender forms were ''presented to him and [they were] explained to him. And I actually read the top section and he was asked to make sure he read it and understood it.'' (Tr. 139.) The Government's evidence reflects that boxes are checked on the surrender forms next to text indicating that the surrender would be made: ''In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part * * *.'' (Gov't Exs. 3, 4.) Respondent signed at the bottom of the page. (Tr. 139.)

DI Stockmann testified that a ''pill mill'' is an operation containing ''a doctor and a pharmacy, located basically in the same building, and the doctor sees the patients and then he dispenses'' hydrocodone or oxycodone. (Tr. 117.) Pill mills are marked by ''[t]ons of patients in the patient room, they've got patients lined up outside, they've got people that are, for lack of a better term, obsessing about getting in to see physicians.'' (Tr. 118.) DI Stockmann testified that MEC is not a pill mill.[18] (*See* Tr. 118, 127–28.)

Respondent fully and completely cooperated in the inspection of MEC on February 23, 2011, to include granting access to records and inventory. (Tr. 114–15, 119–20.) Without Respondent's consent, the Government would have needed to acquire search warrants. (Tr. 113–14.)

In summary, DI Stockmann saw nothing that was outside the scope of normal medical practice. (Tr. 128.) His statement to Respondent that he could not locate a copy of a biennial inventory was his sole critique. (Tr. 128.)

(d) March 29, 2011 Audit of MEC

DI Graumlich [19] testified that he conducted an inspection and audit of MEC on March 29, 2011. (*See* Tr. 148.) Respondent consented and cooperated, giving agents full access to everything they needed, although he was not required to do so. (Tr. 152, 184; Gov't Ex. 19(a).)

DI Graumlich's audit covered a time frame from November 16, 2009, through March 29, 2011. (Tr. 149.) The audit occurred on-site [20] and reflected a physical hand count verified by members of Respondent's staff of dosage units present (Tr. 171, 174, 196–97), to include two different strengths of hydrocodone, Guaifenesin with codeine, Zolvit and zolpidem. (Tr. 150.)

DI Graumlich requested that Respondent provide any inventory records MEC had taken within the past two years, specifically, the biennial inventory and Respondent's distribution and receiving records. (Tr. 158–59, 174.) Respondent's staff provided a binder containing copies of receiving invoices and pedigree information for drugs purchased, ranging from November 2009 to March 29, 2011. (Tr. 174.) DI Graumlich then calculated the total amount of controlled substances for which Respondent was accountable, as compared to the total amount Respondent had records of distributing or transferring. (*See* Tr. 174–77; Gov't Ex. 19(e).)

At hearing, DI Graumlich testified that Joy Egan, Respondent's office manager (Tr. 26, 153, 202), identified Danny McBride as the representative from Linear Solutions. (Tr. 153–54.) MEC's records indicated that Mr. McBride physically counted all the pills located at the clinic on November 16, 2009, but it is unclear whether this count occurred ''at the beginning or end of the business day, so we didn't know whether to give them credit for the prescriptions that were written that day.'' (Tr. 154, 164; Gov't Ex. 19(b).) DI Graumlich testified that the failure to indicate whether the biennial inventory was taken at the opening or closing of the business day constituted a violation of federal regulations. (Tr. 164, 181, 199.) He stated that Respondent's biennial inventory was also noncompliant because it did not go back a full two years from the date of the audit. (Tr. 200.)

Based on the audit, DI Graumlich found that Respondent was accountable for thirty-five bottles of Guaifenesin Ac but could only account for twenty-seven bottles, resulting in a shortage of eight bottles, a 22.86 percent difference. (Tr. 177, 198–99; Gov't Ex. 19(e).)

[15] Respondent described the machine as a large box, approximately six feet tall and three or four feet wide. (Tr. 19.) He called it a ''vehicle to allow the patients [sic] to get medications after the patient has been seen, treated, examined and determined that the patient needs medications for their [sic] diagnosis.'' (Tr. 18.)

[16] According to DI Graumlich, ''[t]he benefit of the InstyMeds machine * * * was that the computer system tracks what is in the machine and what has been dispensed, and therefore they can tell which drugs they are running low on to place orders for.'' (Tr. 170.)

[17] DI Stockmann testified to having been a DEA DI for the past eight years. (Tr. 104–05.) In this role he investigates and inspects registered locations, seeking to prevent the diversion of controlled substances from legal distribution channels into the illicit market. (Tr. 104.) DI Stockmann previously worked for twelve years as a St. Louis City Metropolitan Police Officer, for the last three of which as a DEA Task Force Officer. (Tr. 105.) His total law enforcement experience is twenty years, and he has a bachelor's degree in criminology and criminal justice. (Tr. 105.)

[18] DI Stockmann testified that the non-controlled substance medications listed in MEC's ''Prescriptions Dispensed Summary Report'' were of the sort that would typically be dispensed in a general medical practice. (Tr. 122; *see* Gov't Ex. 6; *see also* Tr. 389–90 (concurrence in this assessment of Government's expert witness, Dr. Glener).) He also testified that the six prescriptions of the controlled substance Guaifenesin AC Syrup 100 mg recorded as having been dispensed over a two-year period (Gov't Ex. 6 at 15) was not an inordinate amount. (Tr. 125.) He also opined that 145 prescriptions for hydrocodone dispensed over a two-year period (Gov't Ex. 6 at 17) was not consistent with pill mill dispensing. (Tr. 125.) Additionally, the clinic did not buy medication in bulk and then repackage it. (Tr. 126.)

[19] DI Graumlich has worked as a DEA DI for twenty-two years and holds a bachelor's degree. (Tr. 147–48.) His duties include ensuring compliance with the regulations under the Controlled Substances Act (CSA). (Tr. 147.) Consistent with these duties, DI Graumlich has conducted over 100 accountability audits. (Tr. 149.) An accountability audit ensures certain records are being kept and that rules are being followed. (Tr. 148–49.)

[20] As DI Graumlich explained, ''[w]e didn't actually remove hard documents. We copied documents on site at the location and left the original documents with the registrant.'' (Tr. 189.)

Moreover, with respect to Hydrocodone Apap 5/500 30-count bottles, the audit revealed an overage [21] of one bottle, thirty dosage units or 0.89 percent. (Tr. 177–78, 197–98.) With respect to Hydrocodone Apap 7.5/500 30-count bottles, the audit revealed a shortage [22] of five bottles, 150 dosage units or four percent. (Tr. 178–79, 198.) As for zolpidem, the audit revealed a shortage of three bottles, 180 dosage units or twenty-five percent. (Tr. 180, 199.)

DI Graumlich explained that DEA registrants are ''required to maintain records of all controlled drugs received, distributed or otherwise dispensed. And if we have records of all the drugs received or distributed, the account should zero out.'' (Tr. 180–81.) He testified that the fact that Respondent's records of controlled substances did not zero out constituted a failure to maintain complete and accurate records, in violation of federal regulations.[23] (Tr. 181, 203–04.)

In addition, DI Graumlich noted that approximately twenty of MEC's receiving invoices did not reflect the date received, constituting a failure to maintain complete and accurate records. (Tr. 181.) MEC ''provided me with copies of pedigree documents, rather than invoices. * * * They said they * * * had been moved to storage and that they would get those for me. They never did get those for me.'' [24] (Tr. 193.) After Respondent's office provided pedigree records, DI Graumlich gave the clinic several opportunities to provide missing records, to include emailing Ms. Egan after the inspection. (Tr. 202.) He again requested invoices, but ''we were never provided with any other documents. According to Ms. Egan, I believe they could not find the other binder.'' (Tr. 194.)

The audit further revealed ''two receiving invoices that they did not have a record of'' based on ''a printout of their receipts from Stat Rx, their distributor * * *.'' (Tr. 182.)

The audit also reflected MEC's change from using Linear Solutions to InstyMeds. (*See* Tr. 156–57; Gov't Ex. 19(e).) The audit of the InstyMeds machine reflected no discrepancies.

There were, moreover, no discrepancies in the audit of Zolvit oral solution, although ''they originally didn't have any records for that but we had them get copies of their records from their vendor.'' (Tr. 197.)

Although I credit DI Graumlich's uncontested testimony as to his audit's factual findings, I grant no weight to his opinions as to the legality of the findings because these opinions speak to the ultimate issues in the case. A later section of this Recommended Decision addresses the legal ramifications of the March 29, 2011 audit.

(e) Respondent's Position on the MEC Audit

Respondent credibly testified that regarding recordkeeping,

[t]he bottom line is that I ultimately am responsible and was held accountable and I wasn't aware of the fact that he had not gotten the rest of the information. Maybe there was a misunderstanding in regards to the pedigree paperwork and so forth. I am fully aware of that and irrespective of the results of these hearings, I plan to provide all the appropriate information that is required and necessary.

(Tr. 449–50; *see also* Resp't Br. at 8.) Upon inquiry from his attorney, Respondent testified that he ''fully understand[s]'' that audit results need to zero out, and that he ''[o]ne hundred percent'' intends to ensure future deliveries are properly documented. (Tr. 450.)

3. All Pain Management (APM)

(a) Background of Investigation of APM and its Owners

SA Gill [25] testified to being the ''case agent'' for an investigation of APM (Tr. 84), and that Respondent was a physician there. (Tr. 43.) In approximately September 2009, SA Gill received information that a Mr. Vincent Colangelo owned several pain clinics in South Florida. (Tr. 43.) He opened an investigation on Mr. Colangelo and discovered that APM was one of the clinics in which Mr. Colangelo owned an interest in approximately October or November of 2009. (Tr. 43–44.) The investigation also revealed that Mr. Colangelo operated a number of clinics without possessing a DEA COR. (Tr. 44.) Joel Ortega and Maite del Rey were two other co-owners of APM but Mr. Colangelo was the primary owner, although he was not there on a daily basis.[26] (Tr. 44, 46–47.)

SA Gill testified that based on his investigation, Mr. Colangelo was responsible for finding, interviewing and hiring ''doctors that would write scripts and see the number of patients that he wanted to be seen, basically.'' (Tr. 46.) SA Gill testified that Mr. Colangelo would collect the clinic's money or it would be delivered to him at the end of the night or several times per week. (Tr. 46–47.)

Based on information from a confidential source, SA Gill testified that Mr. Colangelo only employed doctors ''that would follow his rules and there weren't specific quantities or types that doctors had to write, but if they weren't writing high enough scripts they would be fired.'' (Tr. 47.) Mr. Colangelo initially had a mandatory prescription ''formula'' of 240/90/90, meaning 240 oxycodone 30 mg dosage units, 90 oxycodone 15mg dosage units, and 90 Xanax 2 mg dosage units. (Tr. 48.) The formula was not something doctors started with initially and not every patient received it. (Tr. 67, 69.) SA Gill explained that ''[o]n the first visit, for someone to get 240/90/90, they would die * * *. So the doctor builds up to that.'' [27] (Tr. 69.) Respondent's prescriptions [28] at APM did not appear to comply with the 240/90/90 rule.[29] (Tr. 67.)

SA Gill testified that the investigation of Mr. Colangelo led to an indictment and superseding indictment against Mr. Colangelo. (Tr. 62.) Respondent is not mentioned in either document, and SA Gill is aware of no evidence that Respondent knew Mr. Colangelo, was in contact with him or knew he owned an interest in APM. (*See* Tr. 63, 82.) SA Gill does not know who hired Respondent. (Tr. 64.) Moreover, SA Gill is aware of no evidence that Mr. Colangelo had anything to do with Respondent's treatment of patients, or what patients he saw or turned away. (Tr. 64–65.)

Similarly, Respondent testified that he had no knowledge of Mr. Colangelo's ownership of APM.[30] (Tr. 462.) He testified that APM was owned by a married couple named Maite and Joel, who also ran the facility. (Tr. 24–25, 38, 458. *But see* Tr. 84.) Respondent testified that Maite and Joel hired him after he interviewed with Maite. (Tr. 39.) Maite told him at his employment interview that she was the owner of APM. (Tr. 39.) He did not look up the ownership records of APM on a Florida government Web site.[31] (Tr. 39.)

(b) Respondent's Employment and Practice at APM

Respondent testified that he worked as an independent contractor at APM for six to eight weeks from December 2009 to February 2010. (Tr. 22–23; *see* Tr. 416, 454–55.) He

[21] An overage occurs ''when they account for distributing more drugs than they can account for purchasing.'' (Tr. 178.)

[22] Shortages can occur for various reasons, to include recordkeeping issues, theft or loss. (Tr. 180.)

[23] He conceded, however, that regulated audits of manufacturers and distributors of controlled substances do not always zero out. (Tr. 187.)

[24] DI Graumlich testified that DEA does not require that physicians maintain pedigree records. (Tr. 194.)

[25] SA Gill testified in substance to having eight years of experience working for the DEA. (Tr. 41.) He has worked for two years in a tactical diversion squad, a working group that focuses on pain clinics, doctors and pharmaceuticals. (Tr. 41.) Prior to joining DEA he worked for three-and-one-half years at a police department in New Jersey and as a crime analyst and statistician. (Tr. 42.) He holds a bachelor's and a master's degree in criminal justice. (Tr. 43.)

[26] SA Gill testified that Mr. Ortega and Ms. del Rey were the original owners of APM. (Tr. 83.) The business was not doing well, and Mr. Colangelo offered to become part owner in exchange for providing patients. (Tr. 83–84.) Mr. Ortega and Ms. del Rey oversaw daily operations. (Tr. 84.)

[27] SA Gill elaborated that ''if you were an existing patient at another clinic and went in and told the doctor that you were currently getting 240/90/90, chances are you would get the maximum or close to it. If you were a new patient and didn't have any prior medical records from the pain clinic then the doctors would start you out lower and build you up to that level.'' (Tr. 85–86.)

[28] SA Gill testified that the Government obtained patient files after executing a search warrant on March 1, 2011, at a storage unit owned by Mr. Colangelo. (Tr. 52.) The Government obtained undercover patient files for SA Grafenstein, SA Cortes and SA Saenz in this manner. (Tr. 56–58.)

[29] For instance, SA Grafenstein received a prescription for 180 oxycodone 30 mg tablets and 60 Xanax 2 mg tablets, SA Cortes received a prescription for 120 hydrocodone 7.5 mg tablets and SA Saenz received a prescription for 90 hydrocodone 5 mg tablets, 90 Motrin 800 mg tablets and a pack of Medrol. (Tr. 67–69; Gov't Ex. 9; Gov't Ex. 10 at 3–4; Gov't Ex. 13; Gov't Ex. 17.)

[30] In light of the evidence, I agree with Respondent that ''the Government has failed to offer any evidence that Dr. Casanova was somehow part of or even aware of Vincent Colangelo's alleged criminal activity and his alleged hidden ownership of All Pain and Coast to Coast.'' (Resp't Br. 29.)

[31] SA Gill testified that *www.sunbiz.org,* the Florida Web site that provides public information as to the form of a business entity, does not provide information as to who owns a corporation. (Tr. 80.) For instance, with respect to APM, Mr. Colangelo's name is not reflected on the Web site. (Tr. 81.)

started working at APM based on a referral from a friend of a friend and intended to conduct clinical research there. (Tr. 455–58.) He testified that he approached patients about possibly participating in clinical research, but acknowledged that he did not ask either SA Grafenstein or SA Cortes. (*See* Tr. 459.)

Respondent further testified that he was not APM's medical director and that his duties included evaluating patients, conducting an appropriate examination and providing appropriate care. (Tr. 416–17.) Respondent did not schedule appointments but believes APM accepted walk-in patients.[32] (*See* Tr. 417.) Respondent explained that most patients came to APM as referrals from other physicians and patients, and from Internet marketing.[33] (Tr. 29–30.) He testified that APM did not dispense controlled substances. (Tr. 24.) He worked one day per week and maintained a separate practice elsewhere. (Tr. 28, 455.)

Respondent testified that APM patients paid a fee of approximately $250 to see him, but those transactions were handled at the front desk. (Tr. 25–26, 456.) APM accepted insurance but most of the patients were private pay. (Tr. 29.) As compensation, Respondent received fifty dollars per patient he saw and did not receive bonuses. (Tr. 27–28; *see* Tr. 456.) Initially he saw between ten and fifteen patients per week, and later between twenty and thirty. (Tr. 28.) Respondent estimated that he saw approximately four or five patients per hour and worked from 2:00 p.m. to 9:00 p.m. (Tr. 28.)

Respondent testified that patients who came to APM brought medical records, to include MRI reports, to the best of their ability. (Tr. 31, 33.) Respondent required an MRI report from every patient. (Tr. 31.) Maite was responsible for verifying the validity of each MRI report. (Tr. 31–32.)

Respondent testified that he performed a physical examination and ''made a diagnosis and we talked about how we're going to progress and provide care'' for each patient he saw. (Tr. 32.) Respondent further testified that paperwork provided to each patient addressed the risks and benefits associated with a course of treatment. (Tr. 32–33.) In addition, Respondent testified that a ''treatment plan was formulated either in terms of the documentation on the paperwork or mentally in terms of the documentation and a plan and a process.'' (Tr. 33–34.)

Respondent testified to being familiar with the term ''track marks,'' which he said referred to people making injections on their arms. (Tr. 34.) He testified that he checked his patients for track marks.[34] (Tr. 34–35.)

Respondent ended his relationship with APM because after a period of time, I was told or I explained that I had certain requirements and so forth and that I was looking to try to provide care on a multi-disciplinary level with a variety of different specialties and so forth and as I proceeded to go on, some of these things were not coming to fruition so I decided to part ways. (Tr. 455.)

(c) Undercover Patient Visits to APM

(i) SA Grafenstein February 16, 2010 Undercover Visit to APM

SA Grafenstein[35] visited APM in an undercover capacity on February 16, 2010, posing as a patient.[36] Aside from noting that APM staff measured his vital signs and did not supervise him while he submitted a urine sample (*see* Tr. 240), SA Grafenstein's testimony related primarily to conversations he overheard in the waiting area and his visit with Respondent.

Among approximately fifteen people in the waiting area, SA Grafenstein conversed with patient [M.B.],[37] who indicated that existing patients were always seen before new patients (Tr. 228) and recommended that SA Grafenstein avoid the pharmacy Generic Drug Depot, because it was ''very hot right now and there were cops all over the place and that there were people standing outside trying to buy pills off the people who came, who just got their prescriptions filled there.'' (Tr. 228–29.) [M.B.] also asked SA Grafenstein to provide a urine sample for [M.B.]'s drug test, and SA Grafenstein complied. (Tr. 231–32.) APM staff left the restroom unsupervised and [M.B.] later left the clinic carrying more than one prescription. (Tr. 232.)

Another patient recounted submitting urine mixed with water from a toilet for a drug screen. (Tr. 235.) SA Grafenstein also testified that patient [M.I.] was carrying a Gatorade bottle containing urine of a person who had driven [M.I.] to the clinic ''because the individual who was seeing the doctor told him that he would give him half of whatever he was prescribed for driving him down there.'' (Tr. 239.) [M.I.] stated that ''two hours prior to that specific time he had gone home and did cocaine, not knowing that he'd have to take a drug test. And after he learned that, he ingested bleach to attempt to detoxify it so that he would be able to beat the drug test.'' (Tr. 237.) SA Grafenstein testified that Respondent later issued a prescription to [M.I.] (Tr. 239.) SA Grafenstein also related overhearing that ''if you failed the drug test for marijuana, you could pay $50 * * * and the administrator would make your hot, or your failed test, clean.'' (Tr. 237.)

SA Grafenstein also testified to his interactions with Respondent, which began approximately six hours after the agent arrived at APM. (*See* Tr. 220, 241–44, 247.) SA Grafenstein indicated he was in ''[a] lot of pain. My upper [back] is bother [sic] me, a little sore. My lower, nothing that's * * * like excruciating * * * sometimes I can't move my neck.'' (Gov't Ex. 8 at 33.) He indicated his pain without medication was a two and with medication was a zero, on a scale of one to ten. (*See* Tr. 242.) After reviewing the patient's MRI report, Respondent said ''I can't tell you anything about your neck 'cause you don't have an MRI.'' (Gov't Ex. 8 at 34; *see* Tr. 241.) ''The one you have there tells me that you have some problems in your low back * * * It tells me nothing about your neck.'' (Gov't Ex. 8 at 35.) But Respondent did not order an MRI of the patient's neck. (Tr. 244.)

Respondent directed SA Grafenstein to raise his hands and inhale and listened to his breathing. (Tr. 242; Gov't Ex. 8 at 37, 39.) He also felt along SA Grafenstein's back and neck while asking him to bend over, and performed reflex tests. (Tr. 242–43; Gov't Ex. 8 at 40.)

SA Grafenstein had written in his patient paperwork that he was currently taking 180 oxycodone 30 mg tablets. (Gov't Ex. 10 at 3, 4.) Respondent asked whether the medication was working (Gov't Ex. 8 at 42), to which SA Grafenstein responded in the affirmative and orally requested Xanax. (Gov't Ex. 8 at 42; Tr. 243.) Respondent inquired ''how much Xanax are you taking? 'Cause it didn't get put on there, but I'll, I'll get it for you.'' (Gov't Ex. 8 at 42.) SA Grafenstein responded that he was taking about sixty. (Gov't Ex. 8 at 42.)

Respondent issued SA Grafenstein prescriptions for 180 Roxicodone 30 mg tablets and 60 Xanax 2 mg tablets, reflecting the medications SA Grafenstein had indicated on his patient intake form and requested orally. (Tr. 216, 243; Gov't Ex. 9; Gov't Ex. 10 at 3, 4.) The patient's urine drug screen, contained in the patient file, reflected that SA Grafenstein tested negative for both oxycodone and alprazolam. (Tr. 427–28, 477.)

(ii) SA Cortes February 16, 2010 Undercover Visit to APM

SA Cortes[38] visited APM in an undercover capacity on February 16, 2010, posing as a patient.[39] (*See generally* Jt. Stip. 7.) Aside from noting that office staff measured his vital signs, that he was not supervised while submitting a urine sample and that he overheard a staff member discussing different methods to inject heroin (Tr. 273–75), SA Cortes's testimony related primarily to his visit with Respondent.

Respondent called SA Cortes into his office after a wait of more than five hours. (Tr. 273, 275.) SA Cortes stated that he was ''not really hurt, doc. Um * * * what I'm experiencing

[32] Respondent equivocated on this point, also testifying that the clinic at one point accepted only scheduled appointments and did not accept walk-ins. (Tr. 28–29.)

[33] Respondent never saw the Internet marketing, but the owners told him about it. (Tr. 29.)

[34] In addition, the refund policy at APM indicates that refunds will not be granted for ''signs of IV drug use (track marks).'' (Gov't Ex. 10 at 5.)

[35] SA Grafenstein has worked as a DEA SA for approximately two years. (Tr. 206.) He previously worked for approximately eight and one-half years as an officer with U.S. Customs and Border Protection and as a park ranger in Arlington County, Virginia. (Tr. 207.) He holds a bachelor's degree in criminal justice. (Tr. 207.)

[36] The following summary of SA Grafenstein's undercover visit to APM is supplemented in a later section of this Recommended Decision by additional findings of fact, and by conclusions of law.

[37] To protect patient privacy, initials are used in this Recommended Decision to refer to non-undercover patients.

[38] SA Cortes has worked as a DEA SA for approximately three years, following approximately ten years as a state trooper and local police officer. (Tr. 257.) He holds a bachelor's degree in criminal justice. (Tr. 257.)

[39] The following summary of SA Cortes's undercover visit to APM is supplemented in a later section of this Recommended Decision by additional findings of fact, and by conclusions of law.

is * * * more and more stiffness [in the shoulders and waist] * * * after each practice,'' elaborating that he had been studying martial arts. (Gov't Ex. 12 at 2–3; Tr. 276.) Upon inquiry from Respondent, SA Cortes stated that he worked at a warehouse and that lifting made his discomfort worse. (Gov't Ex. 12 at 6–7.) He rated his pain as a three or four while on medication, and an eight without medication, on a scale from one to ten. (*See* Gov't Ex. 12 at 6; Tr. 277–78.)

SA Cortes told Respondent that he had been taking Tylenol and one or two tablets of his girlfriend's hydrocodone per day. (Gov't Ex. 12 at 3–4; Tr. 276.) He stated that the hydrocodone hadn't been prescribed to him, to which Respondent stated ''I understand.'' (Gov't Ex. 12 at 9; *see* Tr. 278.) SA Cortes's urine drug screen, however, tested negative for hydrocodone. (*See* Tr. 482; *see also* Gov't Ex. 14 at 1.) Moreover, SA Cortes did not indicate he was taking any medication on his Pain Assessment Form. (Gov't Ex. 14 at 2.)

Respondent directed SA Cortes to sit on an examination table and inhale, listened to his breathing and tested his reflexes. (Tr. 278.) Respondent inquired whether SA Cortes was taking three or four hydrocodone pills per day, to which SA Cortes agreed, even though he had previously indicated taking only one or two per day. (*Compare* Gov't Ex. 12 at 9, *with* Gov't Ex. 12 at 3–4.) Respondent issued SA Cortes a prescription for 120 hydrocodone 7.5 mg tablets. (Gov't Ex. 13; Tr. 277, 288.) No diagnosis is listed on SA Cortes's Consent for Chronic Opioid Therapy form, nor are alternative treatments listed. (Tr. 398; *see* Gov't Ex. 14 at 8.)

4. Coast to Coast Healthcare Management (CCHM)

Respondent worked at CCHM in Deerfield Beach, Florida as an independent contractor for six to eight weeks in March to April 2010, approximately two weeks after he stopped working at APM. (*See* Tr. 22–23, 448, 456, 460; Gov't Ex. 20.) He testified that he was told there would be a possibility of conducting clinical research at CCHM.[40] (Tr. 459.) But ''one thing was said and then what happened was actually a different thing and that's why we decided to part on amicable terms.'' (Tr. 460; *see* Tr. 462.)

GS Langston [41] testified to participating in an investigation of Respondent by obtaining from Wood's Pharmacy in Margate, Florida prescriptions written by Respondent at CCHM. (Tr. 89–90; *see* Gov't Ex. 20.) GS Langston recovered the following prescriptions: 90 Percocet 10 mg tablets and 220 Roxicodone 30 mg tablets, dated April 6, 2010, for patient [C.C.] of Wallingford, Kentucky (Tr. 90, 95); 100 Roxicodone 15 mg tablets and 210 Roxicodone 30 mg tablets dated March 31, 2010, for patient [C.G.] of Essie, Kentucky (Tr. 91–92, 96); and 100 Roxicodone 15 mg tablets and 210 Roxicodone 30 mg tablets dated March 31, 2010, for patient [R.C.] of Helton, Kentucky (Tr. 92, 97; Gov't Ex. 20 at 5).

GS Langston testified that in light of her background, training and experience the prescriptions to patients [C.G.] and [R.C.] ''raised red flags to me because they are both prescribed by Dr. Casanova to patients in Kentucky that * * * apparently traveled from Kentucky to see Dr. Casanova at Coast to Coast in Deerfield Beach and then dr[o]ve to Margate to have their prescriptions filled.'' (Tr. 98.) As additional ''red flags,'' GS Langston noted that the prescriptions to [C.G.] and [R.C.] were for the same amounts of drugs (Tr. 98); the prescriptions were filled on the same day at close to the same time at the same pharmacy (Tr. 98); and the cities of Essie, Kentucky and Helton, Kentucky are located close to each other, and approximately 900 to 1000 miles and fifteen to sixteen hours away from Respondent's office in Deerfield Beach, Florida. (Tr. 99.) GS Langston testified that based on the foregoing factors it appeared that patients [C.G.] and [R.C.] traveled together from Kentucky to see Respondent. (Tr. 99.) GS Langston testified that although she had not seen the patients' medical files, the pharmacist should have regarded the prescriptions as suspicious. (Tr. 101.) She did concede, however, that without seeing the patients' medical files, she could not determine whether the prescriptions were medically necessary. (Tr. 103.)

(a) SA Saenz March 10, 2010 Undercover Visit to CCHM

SA Julia Saenz (SA Saenz) visited CCHM in an undercover capacity on March 10, 2010.[42] (*E.g.,* Jt. Stip. 8; Gov't Ex. 18 at 1; Tr. 442; Gov't Ex. 18 at 2, 4–6, 8–11, 13–15, 17.) Although the Government listed SA Saenz as a witness in its prehearing statement (ALJ Ex. 4 at 3, 14–16), the Government did not offer her testimony at hearing. (Tr. 11.) The undercover recording of SA Saenz's visit, her patient file and prescriptions Respondent issued to her were admitted without objection. (Tr. 84–85, 404; *see* Gov't Ex. 16, 17, 18.)

Respondent met with SA Saenz, first asking her age and how she hurt herself. (Gov't Ex. 16 at 4.) She stated she was thirty-four and that she injured herself a week earlier by lifting children at a daycare center where she worked. (*See* Gov't Ex. 16 at 4; Gov't Ex. 18 at 1.) SA Saenz indicated she was taking ''Tones, Dones'' (Gov't Ex. 16 at 7), which Respondent identified at hearing as slang for oxycodone. (Tr. 445.) Similarly, SA Saenz's patient paperwork indicates that she was taking Roxicodone 40 mg tablets eight times per day, oxycodone 15 mg tablets three times per day and 2 mg Xanax tablets twice per day. (Gov't Ex. 18 at 8.) Her urine drug screen, however, was negative for oxycodone. (Gov't Ex. 18 at 18; Tr. 446.)

SA Saenz also told Respondent that she had not seen any doctor for medicines. (Gov't Ex. 16 at 7; *see also* Gov't Ex. 18 at 1.) Respondent testified that he didn't ask SA Saenz how she had obtained the oxycodone and Xanax she had indicated taking. (*See* Tr. 495.) At the patient interview, SA Saenz repeatedly told Respondent that the pain did not interfere with her work or daily activities. (Gov't Ex. 16 at 6.) When Respondent asked SA Saenz whether she had ever taken narcotics before, she responded in the negative. (Gov't Ex. 16 at 13.) Respondent found it ''somewhat confusing that she did state just on tomes and domes and didn't state anything about an anxiolytic with this piece of information and her drug screen was negative.'' (Tr. 446.)

SA Saenz indicated that her pain was about a three while on ibuprofen and a five or six without, on a scale from one to ten. (*See* Gov't Ex. 16 at 7; *see also* Gov't Ex. 18 at 1.) She stated that she drank on occasion (Gov't Ex. 16 at 7–8) and indicated that she suffered from insomnia and depression. (Gov't Ex. 18 at 6.)

Respondent directed SA Saenz to take a deep breath, bend forward and indicate where she had pain. (Gov't Ex. 16 at 9.) She indicated pain on her left side and sensitivity in her neck. (Gov't Ex. 16 at 9.) Respondent demonstrated a stretching exercise and recommended an Icy Hot patch. (Gov't Ex. 16 at 10.) He then prescribed 90 Motrin 800 mg tablets, 90 Vicodin oral 5 mg—500 mg tablets and one pack containing twenty-one Medrol 4 mg tablets. (Gov't Ex. 17.) The portions of her Consent for Chronic Opioid Therapy (Consent Form) indicating a diagnosis and alternative treatment options are blank. (Tr. 494; Gov't Ex. 18 at 15.)

Near the end of the meeting, Respondent asked SA Saenz ''Why, for this kind of thing, you go to a pain management clinic? Why not go see a doctor?'' (Gov't Ex. 16 at 13.) She replied that she didn't have a doctor, and Respondent suggested she visit Respondent's Urgent Care Center. (Gov't Ex. 16 at 13–14.)

5. Government's Expert Testimony and Report

The Government presented the testimony of David M. Glener, M.D., along with a written report he prepared based on his review of patient files, audio recordings and transcripts associated with Respondent's treatment of three undercover agents posing as patients on February 16, 2010, and March 10, 2010. (*See* Tr. 321–22, 353–54.)

(a) Dr. Glener's Background

Dr. Glener, a physician, has practiced in St. Lucie, Florida since April 2002. (Tr. 306, 308–09.) He has practiced medicine for twenty-two years and pain medicine since 1993, and presently treats between six hundred and one thousand patients. (Tr. 309.) Dr. Glener has been board certified by the American Board of Anesthesiology since April 1995 and the American Board of Pain Medicine since February 2005.[43] (Tr. 307–

[40] Respondent did not ask SA Saenz if she would participate in a clinical research project when she visited him at CCHM, posing as a patient. (Tr. 461.)

[41] GS Langston testified to serving as a diversion group supervisor for the DEA for two years, where she manages a group of DIs in Palm Beach County, Broward County and five other counties. (Tr. 88.) She previously worked for approximately thirteen years as a DI and has worked for the DEA for approximately sixteen years. (Tr. 88–89.)

[42] The following summary of SA Saenz's undercover visit to CCHM is supplemented in a later section of this Recommended Decision by additional findings of fact and conclusions of law.

[43] Dr. Glener itemized the prerequisites of certification from the American Board of Anesthesiology to include graduating from an accredited medical school, possessing an unrestricted medical license, completing an internship in one of five categories, accumulating

Continued

08.) After graduating from New York Medical College in 1989, Dr. Glener completed an internship in general surgery and a residency in anesthesiology. (Tr. 309–10; *see* Gov't Ex. 21.) He later worked at two anesthesiology practices. (Tr. 309.) In addition to being a member of the American Society of Interventional Pain Physicians and its subsidiary Florida Society of Pain Physicians, Dr. Glener is a clinic assistant professor at Florida State University School of Medicine and an associate professor at the University of Central Florida School of Medicine. (Tr. 311.) He stays apprised of developments in the field of pain management by reviewing journals, speaking with colleagues, attending meetings of the Florida Society of Interventional Pain Physicians and completing continuing medical education courses. (Tr. 311–12.) Upon the Government's unopposed motion, I qualified Dr. Glener as an expert witness in the area of pain management. (Tr. 312–13.)

(b) Weight of Dr. Glener's Testimony

At hearing and in his post-hearing filings, Respondent raised the issue of whether Dr. Glener possessed bias or prejudice against Respondent. (*E.g.,* Resp't Br. 13–14, 27.) Respondent argues that Dr. Glener displayed ''textbook bias and prejudice[,] which substantially diminished the credibility of Dr. Gleaner [sic] and the weight to be given his testimony.'' (Resp't Br. 27.)

A review of the record reveals some evidence of bias on the part of Dr. Glener. For instance, when asked on cross-examination whether he would ''render an opinion [about Respondent] before looking at the materials'' relating to Respondent, such as patient files and undercover recordings (Tr. 342), Dr. Glener responded as follows:

It's not that I would leap to conclusions, but with all of these cases that I've reviewed in totality for both the state and a couple for the federal government now, I've seen a pattern emerge and there have been problems every single time I've reviewed them. So while I couldn't say with certainty or testify to that fact, I would say there would be a very high likelihood there'd be something inappropriate going on with Respondent's prescribing practices.[44]

(Tr. 343.) Dr. Glener ultimately testified that based on his review of Respondent's medical files, Respondent was incompetent as a physician. (*See* Tr. 357.)

In addition, when asked if he knew whether his expert review of Respondent's medical files was based on complete records, Dr. Glener stated:

I can't say with certainty if the file is complete or not. I asked for materials; materials were provided. Other medical records to these people or files may exist but I would strongly doubt it would change my opinion. In fact, I could tell you with certainty it would not change my opinion.[45]

(Tr. 344.)

In partial mitigation, Dr. Glener explained that the existence of a treatment plan in a file associated with a patient's subsequent visit would not alter his findings regarding Respondent's conduct ''because at the time the prescription was made, it is incumbent upon the physician to outline a treatment plan * * * I don't get that out of guidelines. That's called being a physician and those of us who are qualified to practice know that.'' (Tr. 345.) Although this statement reflects a legitimate basis for concluding that subsequent medical records would be irrelevant to evaluating whether Respondent's previous documentation practices were adequate, Dr. Glener's tone and demeanor at hearing corresponding to his comment about ''those of us who are qualified to practice'' did not reflect the completely dispassionate observations of an objective reviewer.[46]

In light of the evidence that Dr. Glener displayed a degree of prejudice or bias against Respondent, an initial issue is what weight to give Dr. Glener's testimony against Respondent, of whom Dr. Glener was unfailingly critical.[47] Having considered all the evidence, and as further discussed below, I find Dr. Glener's testimony to be generally credible notwithstanding any prejudice or bias, because it is wholly consistent with and is supported by the objective evidence of record.[48]

(c) Dr. Glener's Practice and Testimony Regarding the Florida Standard of Care

Dr. Glener testified that sixty percent of his patients are of retirement or Medicare age, and that he sees all different pain complaints. (Tr. 313.) The majority of his patients are referred to him by other physicians, who provide Dr. Glener with patients' medical records.[49] (Tr. 313–14.) With the exception of existing patients under emergency circumstances, Dr. Glener never sees walk-in patients. (Tr. 314.) Instead, new walk-in patients are scheduled for future appointments and Dr. Glener's office attempts to obtain the patients' prior medical records in the interim. (Tr. 314–15.)

Dr. Glener testified that except in ''extraordinary circumstances,'' he would not likely prescribe controlled substances to a patient who had not provided medical records. (Tr. 315.) Dr. Glener further testified that he would inquire what other physicians the patient has seen, and would consult the assembled medical records, which he noted ''sometimes have very little clinical value'' if they are irrelevant to the pain complaint. (Tr. 316–17.)

Dr. Glener testified that in his practice ''I take a history. * * * I ask [patients] to show me where they're having their pain and I ask them what's the quality of the pain, and I help them along with a few adjectives if they're at a loss for words.'' (Tr. 317.) He tries to ''ascertain what increases the pain, what decreases the pain, what other therapies they may have had * * * what medications have been tried and failed.'' (Tr. 317.) Dr. Glener further explained that ''I can't say, well, the patient uttered the word 'pain,' therefore, I'm entitled and I should be prescribing a controlled substance.'' (Tr. 396.)

After taking a patient history, Dr. Glener completes a physical examination, to include examination of the body system relevant to the patient's pain complaint.[50] (Tr. 316.) He also records ''a complete medical history, current medications, previous medical problems, previous surgeries [and] allergies.'' (Tr. 316.) Additionally, Dr. Glener records ''a complete history of present illness which is really the who, what, where, when and why of their pain.'' (Tr. 316.)

Following these steps, Dr. Glener forms a differential diagnosis and orders appropriate diagnostic studies, if necessary, and recommends a treatment plan. (Tr. 318.) He ''discuss[es] the most common side effects and adverse events that can occur as well as the benefit'' from proposed medications, although he ''do[es]n't go through every possible side effect right down to one or two percent incidents * * * .'' (Tr. 318.)

Dr. Glener emphasized that it is extremely important to document a patient's medical history, physical exam, diagnosis, treatment plan and discussion of risks and benefits,[51] adding that it is the standard of care, ''the law and it's appropriate medical practice.''[52] (Tr. 318–319.) Dr. Glener allowed that the medical record need not appear like a transcript from a court proceeding, but should be a ''useful tool'' reflecting ''a cogent record of what has transpired, what the physician was thinking at the time.'' (Tr. 319.) In case the patient later moves to a

three years of training in anesthesiology and passing written and oral examinations. (Tr. 307.) The certification process for the American Board of Pain Medicine is slightly different, in ways not pertinent to the instant proceeding. (*See* Tr. 308.)

[44] Dr. Glener conceded that he was unfamiliar with Respondent before the Government asked him to testify. (Tr. 321).

[45] Moreover, when asked if it was important to review the complete medical files of the patients he was asked to analyze, Dr. Glener answered in the negative. (Tr. 343.)

[46] After opining that Respondent's behavior was consistent with that of a pill-mill physician (Tr. 352), Dr. Glener was asked on cross-examination ''Would it also be fair to say that you don't like what you call pill mill doctors?'' (Tr. 353.) Dr. Glener responded: ''I don't like what they do, I don't like what they represent, I don't like the damage they inflict on society and individuals in the practice of medicine as a whole, but other than that, I'm sure they're great people.'' (Tr. 353.)

[47] Dr. Glener testified at one point that ''I was just trying to illustrate that the doctor's incompetent, not that he—whether he was or—treating pain. * * * [H]e's clearly incompetent.'' (Tr. 357.)

[48] For instance, as discussed below, Dr. Glener's observations about missing documentation are fully supported by the objective evidence of record, to include patient files and undercover recordings.

[49] Dr. Glener explained that he obtains patients' prior medical records if they have not already been provided. (Tr. 313.)

[50] ''If there was a question to their overall health,'' Dr. Glener testified, ''then I'd probably listen to their heart, maybe their lungs.'' (Tr. 316.)

[51] Dr. Glener finds it more effective to conduct an oral discussion of risks and benefits of opioid therapy, but conceded that not all doctors rely on verbal consent. (Tr. 399.) If he were to use a written consent form, however, he testified that he would ensure its completeness. (Tr. 399.)

[52] Dr. Glener testified that taking the patient's medical history, performing a physical exam, formulating a diagnosis and treatment plan and discussing risks and benefits of a treatment plan is essential whether or not treating a patient with controlled substances. (Tr. 319.)

different physician, ''it's incumbent upon [the physician] to document [the physician's] thought process * * *.'' (Tr. 319.)

Dr. Glener does not treat all his patients with controlled substances. (Tr. 319–20.) He recognizes, however, that ''[t]he Florida Board of Medicine considers prescribing or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds.'' (Gov't Ex. 22 at 2.) As alternative therapies to controlled substances, Dr. Glener recommends stretching, over-the-counter drugs, physical therapy, chiropractic and massage therapy, interventional pain procedures,[53] nerve blocks and referral to the appropriate medical specialist.[54] (Tr. 320.)

(d) Dr. Glener's Review of Respondent's Patient Files, Generally

Dr. Glener reviewed patient files, audio recordings and transcripts reflecting consultations with Respondent by DEA Special Agents using the undercover names Julia Sanchez, Eugene O'Neil, and Alfredo Mondego.[55] (*See* Tr. 321, 353–54; Gov't Ex. 14.) His review of the patient files pertained to the adequacy of Respondent's performance across elements such as history of present illness, physical examination, medical and surgical history, family history, social history and possibly a review of systems, with reference to the Florida Standards for the Use of Controlled Substances for the Treatment of Pain (Florida Standards), Fla. Admin. Code Ann. r. 64B8–9.013 (2003). (Tr. 322–23; Gov't Ex. 22 at 2; *see* Gov't Ex. 23.) Based on his review, Dr. Glener prepared a report (*see* Gov't Ex. 22) and concluded that ''[i]n all of the cases, the doctor prescribed controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose.'' (Tr. 338–39.)

Dr. Glener called the level of documentation in Respondent's patient files ''substandard,'' ''cookie cutter'' and ''very sketchy.'' (Tr. 337.) He opined that with respect to each patient, Respondent ''did not support the need for controlled substances with appropriate documentation establishing a valid medical need and treatment plan.'' (Gov't Ex. 22 at 2.) He criticized Respondent for prescribing controlled substances ''rather than refer[ring] to [a] physician with the appropriate expertise'' to include a physical therapist, orthopedic surgeon, physiatrist, neurologist, neurosurgeon or interventional pain specialist'' (Gov't Ex. 22 at 2) and testified that there was no record that Respondent made any such referrals. (Tr. 336–37.) Although acknowledging that the patient files contained medical histories and diagnostic, therapeutic or laboratory results (Tr. 377–78), Dr. Glener called Respondent's histories and physical examinations ''perfunctory.'' (Gov't Ex. 22 at 2.) He further testified that Respondent ''did not by professional standards perform a proper evaluation as has been defined by my medical training and experience.'' (Tr. 378.)

In addition, Dr. Glener testified that every time a physician prescribes an opioid, there should be a treatment plan. (Tr. 382.) Dr. Glener testified that with respect to all three undercover patients, Respondent did not discuss the risks and benefits of medications he prescribed; did not take the appropriate history; did not perform an appropriate physical examination; did not document a treatment plan other than the prescription of controlled substances;[56] and did not indicate a rationale for treatment. (Tr. 334–35, 379.)

Dr. Glener concluded that ''[a]fter reviewing the totality of the above three patient encounters, Dr. Casanova has established a pattern of behavior that indicates he regularly prescribes controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose.'' (Gov't Ex. 22 at 2.) As to all three patients, Dr. Glener testified that ''the treatment definitely deviated from the standard of care, was not appropriate in all cases and the focus of treatment appeared to be the prescription of controlled substances.''[57] (Tr. 324–25.)

6. Additional Aspects of Respondent's Professional History and Outlook

In addition to his employment history as summarized previously, Respondent testified that he gained experience dealing with acute and chronic pain patients and treating them with opioids while working at Westchester Hospital in Florida. (Tr. 414.) During this time he familiarized himself with the Florida Standards. (Tr. 414.) With respect to the three undercover patients at CCHM and APM, Respondent testified that he executed a treatment objective, not a treatment plan:

Q: And you've testified that you executed a treatment plan, isn't that true?
A: The treatment objective.
Q: You executed a treatment objective?
A: Correct.
Q: And why didn't you execute a treatment plan?
A: Because as I've mentioned previously, a treatment plan is something in my opinion that differs from other physicians. I believe that a treatment plan doesn't happen over one visit, it happens over time when you garner all the information and collect all the data and put it together and slowly but surely whittle things down and put everything together.

(Tr. 467.) He elaborated that ''a treatment objective begins the treatment plan and that develops over time.'' (Tr. 467.)

In addition, Respondent testified that he no longer works at any pain management facilities other than MEC, and that ''I don't have any plans to ever do that again.'' (Tr. 448.) He testified that he would be willing to enter into an agreement with the Government that he would never work in a pain clinic and that he would never prescribe Schedule II opioid narcotic controlled substances.[58] (Tr. 452–53.)

Finally, Respondent testified that while working at APM and CCHM, he turned away a large number of patients ''that I thought might have issues with medications, issues potentially with the injection of medications and so forth,'' to include patients presenting with track marks. (Tr. 500.)

IV. Discussion

A. The Applicable Statutory and Regulatory Provisions

The CSA provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[59] ''A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner'' with a corresponding responsibility on the pharmacist who fills the prescription.[60] It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.[61] Federal law also provides a detailed framework for keeping records of controlled substances a practitioner orders, receives and dispenses. *E.g.,* 21 C.F.R. §§ 1304.11, 1304.21, 1304.22. In addition, I conclude that the reference in 21 U.S.C. § 823(f)(5) to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in § 824(a).[62]

B. The Public Interest Standard

The CSA, at 21 U.S.C. § 824(a)(4), provides, insofar as pertinent to this proceeding, that the Administrator may revoke a COR if she finds that the registrant's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. § 823(f). In determining the public interest, the Administrator is required to consider the following factors pursuant to Section 823(f):

[53] An interventional pain procedure is ''where I actually do a procedure to make the patient better instead of giving [her] a medication or a noninvasive therapy * * *. It involves the spine and at least a three and a half-inch needle, but it's not exclusive to that.'' (Tr. 320.)

[54] Dr. Glener testified that the appropriate medical specialist is often an orthopedic surgeon, neurologist, neurosurgeon, physiatrist, internist or infectious disease specialist. (Tr. 320.)

[55] These materials reflect undercover visits to see Respondent by SA Saenz, SA Grafenstein and SA Cortes.

[56] The only exception Dr. Glener noted was that Respondent prescribed ''an inappropriate combination of high doses of nonsteroidals and steroidal medications * * * with a recommendation for an Icy Hot patch'' to SA Saenz. (Tr. 335.)

[57] Dr. Glener provided additional and specific analysis of Respondent's prescribing practices with respect to each patient. This analysis is discussed in a later section of this Recommended Decision.

[58] Respondent also testified that he ''could consider'' agreeing not to prescribe Schedule III controlled substances, and that he would be willing to agree not to prescribe Schedule II–III medications for a limited period of years. (Tr. 499, 502.)

[59] 21 U.S.C. § 822(a)(2); 21 U.S.C. § 802(10).

[60] 21 C.F.R. § 1306.04(a).

[61] 21 U.S.C. § 844(a).

[62] *See Kuen H. Chen, M.D.,* 58 Fed. Reg. 65,401, 65,402 (DEA 1993).

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

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

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

(4) Compliance with applicable state, federal or local laws relating to controlled substances.

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

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: the Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 Fed. Reg. 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 Fed. Reg. 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 Fed. Reg. 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16,422, 16,424 (DEA 1989). Application of the public interest factors requires an individualized determination and assessment of prescribing and recordkeeping practices that are ''tethered securely to state law . . . and federal regulations.'' *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009). Additionally, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[63] The burden of proof shifts to the respondent once the Government has made a prima facie case.[64]

C. The Factors To Be Considered

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

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid unrestricted medical license in Florida and has never been disciplined by the Florida Department of Health. (*E.g.,* Jt. Stips. 2, 3; Tr. 448–49.) Although not dispositive, Respondent's possession of a valid unrestricted medical license in Florida weighs against a finding that Respondent's continued registration would be inconsistent with the public interest. *See Robert A. Leslie, M.D.,* 68 Fed. Reg. 15,227, 15,230 (DEA 2003) (identifying state licensure as necessary but not sufficient condition for registration).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. (*See* Tr. 502.) I therefore find that Factor Three, although not dispositive, *see Leslie,* 68 Fed. Reg. at 15,230, weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.

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

As Respondent correctly argues, the record reflects that Respondent ''has significant experience in prescribing controlled substances. Dr. Casanova has practiced medicine for approximately [twenty] years and, in that time, has treated both chronic and acute pain and has prescribed controlled substances for the treatment of pain.'' (Resp't Br. 30–31.) But the record also contains substantial evidence that on multiple recent occasions, Respondent failed to comply with applicable federal and state law relating to keeping records of and prescribing controlled substances.

1. Respondent's Recordkeeping Practices

Pursuant to federal regulations such as 21 C.F.R. §§ 1304.03, 1304.11(a), 1304.21(a), 1304.22(a)(2)(iv), 1304.22(a)(2)(ix), and 1304.22(c), a registered individual practitioner is required to maintain records of controlled substances in Schedules II–V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address and registration number of the distributor. It is unlawful to fail to make, keep or furnish required records.[65] Under longstanding Agency precedent, ''the failure to comply with record keeping requirements is a basis for revoking a registration.'' *Alexander Drug Co.,* 66 Fed. Reg. 18,299, 18,303 (DEA 2001) (citing *Singer-Andreini Pharmacy, Inc.,* 63 Fed. Reg. 4,668 (DEA 1998); *Arthur Sklar, d/b/a King Pharmacy,* 54 Fed. Reg. 34,623 (DEA 1989); *Summer Grove Pharmacy,* 54 Fed. Reg. 28,522 (DEA 1989); and *The Boro Pharmacy and Bell Apothecary,* 53 Fed. Reg. 15,151 (DEA 1988)). The CSA's emphasis on recordkeeping constitutes '''an attempt to regulate closely the distribution of certain substances determined by Congress to pose dangers, if freely available, to the public at large.''' *United States v. Poulin,* 926 F. Supp. 246, 250 (D. Mass. 1996) (quoting *United States v. Averi,* 715 F. Supp. 1508, 1510 (M.D. Ala. 1989)). The evidence offered at hearing reflected a number of recordkeeping violations by Respondent.

(a) February 22, 2011 Absence of Biennial Inventory at MEC

DEA registrants are required to maintain ''a complete and accurate record of all controlled substances on hand * * *.'' 21 C.F.R. § 1304.11(a). They must ''take a new inventory * * * at least every two years.'' 21 C.F.R. § 1304.11(c). The inventory ''must be kept by the registrant and be available[] for at least 2 years'' from the date of its creation. 21 C.F.R. § 1304.04(a). As noted above, the record reflects that DI Stockmann conducted an inspection of MEC on February 22, 2011, and he found ''no evidence of a biennial inventory for that registered location of the controlled substances on hand.'' (Tr. 108, 128, 137.) The absence of a biennial inventory as of February 22, 2011, constitutes a violation of these requirements. *See* 21 C.F.R. § 1304.11(a).

(b) March 29, 2011 Discovery of McBride Biennial Inventory

Federal Regulations require that DEA registrants ''take a new inventory * * * at least every two years.'' 21 C.F.R. § 1304.11(c); *see also* 21 C.F.R. § 1304.04(a) (''every inventory * * * must be kept by the registrant and be available * * * for at least two years from the date of such inventory * * *'').[66] ''The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.'' 21 C.F.R. § 1304.11(a). The record reflects that DI Graumlich conducted an accountability audit of MEC on March 29, 2011, covering a period from November 16, 2009, to March 29, 2011. (*E.g.,* Tr. 148, 149.) At this audit, Respondent's staff produced a biennial inventory completed by Mr. McBride of Linear Solutions, dated November 16, 2009.[67] (Tr. 153–54, 163; Gov't Ex. 19(b).) DI Graumlich testified, and the document reflects, that the inventory does not indicate whether it was taken at the opening or closing of the business day, in violation of 21 C.F.R. § 1304.11(a). (Tr. 164, 181, 199.) The evidence also reflected that Respondent's biennial inventory did not go back a full two years from the date of the audit. (Tr. 200.) Respondent ''has not disputed the results of the audit and inspection, but instead has acknowledged that he will take steps to cure the violations * * *.'' (Resp't Br. at 30.) Consistent with the consensus reached by the parties, I find that Respondent has violated 21 C.F.R. § 1304.04(a) in failing to keep a biennial inventory covering a full two years of activity.

(c) March 29, 2011 Audit Results Indicating Shortage and Overage

The March 29, 2011 audit of Respondent's controlled substances and records covering a period from November 16, 2009, to March 29, 2011, revealed a number of irregularities. DI Graumlich found that Respondent was accountable for thirty-five bottles of Guaifenesin Ac but could only account for twenty-seven, resulting in a shortage of eight bottles or 22.86 percent. (Tr. 177, 198–99; Gov't Ex. 19(e).) Moreover, with respect to Hydrocodone Apap 5/500 30-count bottle, the audit revealed an overage of one bottle, thirty dosage units or 0.89 percent. (Tr. 177–78, 197–98.) Regarding Hydrocodone Apap 7.5/500 30-count bottles, the audit revealed

[63] *See* 21 CFR § 1301.44(e) (2011).

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

[65] 21 U.S.C. § 842(a)(5).

[66] Although the Government's prehearing statements did not explicitly cite 21 C.F.R. § 1304.04, the Government did allege violations of recordkeeping regulations, to include failure to maintain complete and accurate records (*see* ALJ Ex. 7 at 2), as well as failure to comply with requirements for biennial inventories (*see* ALJ Ex. 7 at 3). In the absence of an objection by Respondent, there is no basis to depart from the conclusion that Respondent was fairly apprised ''that this allegation would be litigated.'' *CBS Wholesale Distribs.,* 74 Fed. Reg. 36,746, 36,749 (DEA 2009).

[67] The record is unclear as to why this report was not made available to DI Stockmann on February 22, 2011.

a shortage of five bottles, 150 dosage units or four percent. (Tr. 178–79, 198.) With respect to Zolpidem, the audit revealed a shortage of three bottles, 180 dosage units or twenty-five percent. (Tr. 180, 199.)

Although various factors can contribute to audit results indicating a shortage, to include recordkeeping issues, theft or loss (Tr. 180), DEA registrants are nevertheless ''required to maintain records of all controlled drugs received, distributed or otherwise dispensed. And if we have records of all the drugs received or distributed, the account should zero out.'' (Tr. 180–81.) *See* 21 C.F.R. §§ 1304.11(a) (''Each inventory shall contain a complete and accurate record of all controlled substances on hand * * *.''), 1304.21(a) (registrants required to keep ''a complete and accurate record of each such substance * * * received, sold, delivered * * * or otherwise disposed of * * *.''), 1304.22(c) (''records shall be maintained of the number of units * * * dispensed * * *.''). The evidence of two shortages in Respondent's controlled substances records, one by more than twenty percent, and one overage, is inconsistent with the requirement to maintain accurate and complete records. *See* 21 C.F.R. §§ 1304.04(a), 1304.22(c).

(d) Twenty Undated Receiving Invoices and Two Missing Stat Rx Invoices

In addition to the foregoing issues, DI Graumlich testified that approximately twenty of the receiving invoices provided by Respondent did not reflect the date received. (Tr. 181.) DI Graumlich gave the clinic ''several'' opportunities to provide missing records, including emailing MEC's office manager Ms. Egan after the inspection and asking whether the clinic had located the missing documents. (Tr. 202.) He again requested invoices, ''and we were never provided with any other documents. According to Ms. Egan, I believe they could not find the other binder.'' (Tr. 194.) DI Graumlich further testified that the March 29, 2011 audit revealed ''two receiving invoices that they did not have a record of and we found that out when we got a printout of their receipts from Stat Rx, their distributor * * *.'' (Tr. 182.)

Federal regulations require that practitioners ''shall maintain on a current basis a complete and accurate record of [controlled substances] received * * *, '' 21 C.F.R. § 1304.21(a), further providing that ''[i]n recording dates of receipt * * * the date on which the controlled substances are actually received * * * shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).'' *Id.* at § 1304.21(d). Respondent's failure to indicate the date received on approximately twenty receiving invoices constitutes a violation of 21 C.F.R. § 1304.21. Moreover, the evidence that Respondent had no records of two receiving invoices from Stat Rx reveals a violation of the requirement to keep a current, ''complete and accurate record of each such substance * * * received, sold, delivered * * * or otherwise disposed of * * *.'' *Id.* at § 1304.21(a).

(e) Evidence of Compliant Records

The results of the audit with respect to the InstyMeds machine reflected no discrepancies.[68] (Tr. 195.) There were no discrepancies in the audit of Zolvit oral solution, although Respondent's staff ''originally didn't have any records for that but we had them get copies of their records from their vendor.'' (Tr. 197.)

(f) Conclusion With Respect to Recordkeeping

The record reveals multiple violations of federal recordkeeping regulations.[69] This conclusion weighs in favor of a finding under Factors Two and Four that Respondent's continued registration would be inconsistent with the public interest.

2. Respondent's Prescribing Practices at APM and CCHM

The evidence at hearing centered in substantial part on office visits by three undercover agents posing as patients in February and March 2010. In addition to the testimony of two of the agents and records associated with all three agents, the Government presented the testimony of a medical expert witness, Dr. Glener. Dr. Glener provided a written report and testified as to his review of the three patient files and associated undercover recordings and medical records, opining whether Respondent prescribed controlled substances for a legitimate medical purpose in the usual course of professional practice. Respondent also testified as to his standard of care and treatment for each of the three patients, along with his past experience.

Evaluation of Respondent's prescribing conduct in this case is governed by federal and state law. The applicable standard under federal law is whether Respondent's prescriptions for controlled substances were ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 C.F.R. § 1306.04(a) (2011). This standard of care refers to that generally recognized and accepted in the medical community rather than a standard unique to the practitioner. *Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,832 n.11 (DEA 2011) (citing *Brown v. Colm,* 11 Cal.3d 639, 642–43 (1974)). Although state law is a relevant factor in determining whether a practitioner is acting in the ''usual course of professional practice,'' it is appropriate in the context of an inquiry under federal law to also consider ''generally recognized and accepted medical practices'' in the United States. *Bienvenido Tan, M.D.,* 76 Fed. Reg. 17,673, 17,681 (DEA 2011). Moreover, ''[u]nder the CSA, it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act 'in the usual course of * * * professional practice' and to issue a prescription for a 'legitimate medical purpose' as required by 21 C.F.R. § 1306.04(a).'' *Gilbert Eugene Johnson, M.D.,* 75 Fed. Reg. 65,663, 65,666 (DEA 2010) (citing *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20,727, 20,731 (DEA 2009) (citing *United States v. Moore,* 423 U.S. 122, 135, 143 (1975))). ''The CSA generally looks to state law to determine 'whether a doctor and patient have established a bona fide patient relationship.'" *Id.; see also Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54,931, 54,935 (DEA 2007); *United Prescription Services, Inc.,* 72 Fed. Reg. 50,397, 50,407 (DEA 2007).

As for the principles of Florida law applicable to this case, the Florida Standards constitute, as Respondent correctly argues, the ''guiding law as to prescribing controlled substances.'' [70] (Resp't Br. 24, 31.) The Florida Standards emphasize the importance of ''prescribing, dispensing, [and] administering controlled substances including opioid analgesics[] for a legitimate medical purpose[] that is supported by appropriate documentation establishing a valid medical need and treatment plan.'' Fla. Admin. Code Ann. r. 64B8–9.013(1)(b) (2003). The Florida Standards further provide that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes,'' and that ''prescribing must be based on clear documentation of unrelieved pain * * * .'' *Id.* at r. 64B8–9.013(1)(d)–(e). In support of these principles, the Florida Board of Medicine has adopted a list of standards for the use of controlled substances for pain control. *See id.* at r. 64B8–9.013(3). Pertinent obligations include the following:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned * * * .

(c) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of controlled substances with the patient * * * .

* * * * *

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment * * * . Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion * * * .

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

[68] The audit reflected Respondent's office's change from using Linear Solutions to InstyMeds. (*See* Tr. 156; Gov't Ex. 19(e).)

[69] *E.g.,* 21 C.F.R. §§ 1304.04(a), 1304.11(a) & (c).

[70] Due to the effective dates of the applicable state regulation, Florida Administrative Code Rule 64B8–9.013 (2003) applies to conduct between October 19, 2003, and October 16, 2010; Rule 64B8–9.013 (2010) applies to conduct thereafter. *See generally https://www.flrules.org/gateway/ruleNo.asp?id=64B8–9.013.*

1. The medical history and physical examination, including history of drug abuse and dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. [D]iscussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic Reviews * * * .

Fla. Admin. Code Ann. r. 64B8–9.013(3) (2003). ''Each case of prescribing for pain will be evaluated on an individual basis.'' Fla. Admin. Code Ann. r. 64B8–9.013(1)(f).

Turning to the evidence in the instant case, the record reveals violations of federal and state law relating to Respondent's prescribing of controlled substances to undercover agents posing as patients at APM and CCHM.

(a) SA Grafenstein February 16, 2010 Undercover Visit to APM

The record reflects that SA Grafenstein visited APM in an undercover capacity on February 16, 2010. (Tr. 208.) He arrived at approximately 1:45 p.m. and provided the receptionist with a Florida driver's license, $250 and a copy of a legitimate MRI report of another person's body labeled with SA Grafenstein's undercover name. (Tr. 208, 221.) He filled out patient intake forms, including forms that asked about his pain, on which he indicated occasional aching and that he was taking 180 oxycodone 30 mg tablets. (Tr. 222; *see* Gov't Ex. 10 at 3.) After submitting the forms to the receptionist, SA Grafenstein sat down in the waiting area. (Tr. 222.)

Approximately fifteen people were in the waiting area when SA Grafenstein first arrived. (Tr. 223.) He conversed with a patient named [M.B.][71] (Tr. 226.) SA Grafenstein testified that [M.B.] remarked that it was [M.B.]'s second visit to the clinic and that at the first visit, he waited approximately five hours before a doctor saw him. (Tr. 227–28.) [M.B.] further indicated that follow-up patients were always seen before new patients, regardless of the order they arrived. (Tr. 228.) [M.B.] also advised SA Grafenstein to go to Rise and Shine Pharmacy in Pembroke Pines, Florida, because ''he said that it was cheap and that you can get whatever you wanted to get there.'' (Tr. 228.) [M.B.] also said to ''stay away from a pharmacy called Generic Drug Depot, because it was very hot right now and there were cops all over the place and that there were people standing outside trying to buy pills off the people who came, who just got their prescriptions filled there.'' (Tr. 228–29.) Based on his training and experience, SA Grafenstein believed [M.B.]'s remarks indicated that some APM patients engaged in illegal activity. (Tr. 229.)

While waiting to be called by a doctor, SA Grafenstein stepped outside to the front of the clinic to make a phone call. (Tr. 230.) ''[W]hile I was on the phone * * * a security guard * * * came up to me and said that I couldn't talk in front of the building, but I could go to the side or to the rear of the building and continue my phone call.'' (Tr. 230.)

Upon returning to the waiting area, [M.B.] approached SA Grafenstein and asked him to provide a urine sample for [M.B.]'s drug test. (Tr. 231–32.) SA Grafenstein followed [M.B.] to the restroom, entering and partially closing the door. (Tr. 232.) [M.B.] gave SA Grafenstein [M.B.]'s cup, and SA Grafenstein urinated into it, closed it, placed it on the sink and left. (Tr. 232.) [M.B.] then entered the restroom and picked up the cup and submitted it as [M.B.]'s own. (Tr. 232.) No staff members supervised or watched the restroom during this interchange. (Tr. 232.) SA Grafenstein later saw [M.B.] leaving the clinic carrying more than one prescription. (Tr. 232.)

SA Grafenstein also recounted that a person in the waiting area ''was informing the group as a whole that when he had to take his urine test * * * he had the cup in his hand but he forgot to go to the bathroom in it, so once he realized it after he was done, he scooped into the toilet and just grabbed a bunch of urine and water and submitted it as his drug sample.'' (Tr. 235.) Moreover, SA Grafenstein testified that an unidentified individual, who was waiting but did not intend to see a doctor, urinated into a Gatorade bottle carried by patient [M.I.] ''and then they both came back together and [M.I.] informed us all what had happened but also showed us the Gatorade bottle full of urine, which he kept in his pocket.'' (Tr. 238.) The individual who urinated in the Gatorade bottle said that he drove a patient ''down to the clinic * * * because the individual who was seeing the doctor told him that he would give him half of whatever he was prescribed for driving him down [t]here.'' (Tr. 239.) SA Grafenstein testified that this behavior indicated that ''the patients ran the clinic. * * * [I]f I could go in and urinate in the cup and * * * pass it off as somebody else's, you know, the patients were the ones that ran the show there.'' (Tr. 238.)

After [M.B.] left, SA Grafenstein asked the receptionist how much longer the wait would be. (Tr. 232.) She responded that the doctor on the premises was only seeing follow-up patients, but that in approximately one hour or one-and-one-half hours, another doctor would arrive.[72] (Tr. 232–33.)

SA Grafenstein returned to the waiting area. A ''female in the group stated that the doctor that was currently there did not have a valid DEA registration so that anyone that had received a script from this doctor would not get their prescriptions filled that day.'' (Tr. 234.) He overheard someone ''inquire[] to the female how strict the doctor was. To which she replied, not very. He also asked the female if the doctor checked for trackmarks, and she said he had not.''[73] (Tr. 235.) Although not dispositive, SA Grafenstein testified that he did not recall Respondent checking him for track marks. (Tr. 236. *But see* Tr. 34–35.)

Another individual in the waiting area ''mentioned that the new doctor that would be coming in has a valid DEA registration so that whoever was seen by that doctor would be able to get their prescriptions filled that day.'' (Tr. 236–37.) Respondent arrived at the clinic at approximately 4:30 or 5:00 p.m. (Tr. 246.)

SA Grafenstein further testified that he overheard [M.I.] state that two hours earlier ''he had gone home and did cocaine, not knowing that he'd have to take a drug test. And after he learned that he ingested bleach * * * to beat the drug test.''[74] (Tr. 237.) Respondent later issued a prescription to [M.I.][75] (Tr. 239–40.)

SA Grafenstein also related that ''[a]nother individual in the group stated that if you failed the drug test for marijuana, you could pay $50 to the drug test administrator and the administrator would make your hot, or your failed test, clean.'' (Tr. 237.)

SA Grafenstein was eventually called to have his vitals taken and submit a urine sample. (*See* Tr. 240.) Security did not watch as SA Grafenstein provided a urine sample. (Tr. 240.)

The foregoing evidence regarding patient conversations in the APM waiting area and the lack of supervision and fabrication of drug tests, although partially based upon hearsay, is internally consistent, contains indicia of reliability and is generally consistent with other evidence of record. The emerging image of APM on February 16, 2010, is that of a clinic in which patients collude with one another and with staff members to fabricate desirable urinalysis results and thereby obtain controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose. Although not for the most part directly attributable to Respondent, this misconduct calls into question the legitimacy of APM as a whole.

Approximately six hours after SA Grafenstein arrived at APM, Respondent called SA Grafenstein into his office. (Tr. 241; 247; *see* Gov't Ex. 8 at 33.) SA Grafenstein sat approximately three feet from Respondent, on the other side of a desk. (Tr. 241.) Respondent asked SA Grafenstein's age and how he hurt himself. (Gov't Ex. 8 at 33.) SA Grafenstein responded ''[b]asically * * * kind of, sort of, maybe just from work stuff. So I ache in the upper and lower * * * .'' (Gov't Ex. 8 at 33.) Respondent inquired whether he was in a car accident or fell, to which SA Grafenstein responded ''[m]ore * * * like a lot of lifting, monotonous daily [stuff].'' (Gov't Ex. 8 at 34.) At hearing, SA Grafenstein testified that he informed Respondent that he was not in any pain but had ''mainly tightness, soreness and achiness

[71] SA Grafenstein later looked up the patient's name in the Florida driver's license database and identified the patient by photo. (Tr. 226.)

[72] SA Grafenstein testified that the initial doctor was Dr. [S.B.], who left when Respondent arrived. (Tr. 233.)

[73] SA Grafenstein testified that the term ''track marks'' refers to indications of extensive intravenous needle usage consistent with drug addiction. (Tr. 235–36.)

[74] SA Grafenstein believed [M.I.] actually ingested bleach. (Tr. 248.) At hearing, Respondent testified that ''if you were to swallow bleach, you would get a severe esophagitis—You would have to require an immediate endoscopy and you would be acutely ill.'' (Tr. 501–02.)

[75] SA Grafenstein did not actually see the prescription, but the patient said ''the doctor had hooked him up.'' (Tr. 249.)

[due] to a tight lower back, upper back and neck area.'' [76] (Tr. at 241.) Respondent marked in SA Grafenstein's record that his pain was a ten on a scale of one to ten (Gov't Ex. 18 at 18), and conceded at hearing that SA Grafenstein never gave him that number (Tr. 475).

Respondent told SA Grafenstein that ''the issue is that I can't tell you anything about your neck 'cause you don't have an MRI.'' (Gov't Ex. 8 at 34; *see* Tr. 241.) ''The one you have there tells me that you have some problems in your low back * * * It tells me nothing about your neck.'' (Gov't Ex. 8 at 35.) Respondent asked SA Grafenstein how bad the pain was with and without medicines, on a scale of one to ten. (Gov't Ex. 8 at 36.) At hearing, SA Grafenstein testified that ''I said that my tightness and soreness with medication was zero and without medication it was a [two].'' [77] (Tr. 242.) SA Grafenstein testified that Respondent wrote two or three in the patient chart. (Tr. 242; *see* Gov't Ex. 10 at 18. *See generally* Tr. 220.)

Upon inquiry from Respondent, SA Grafenstein stated that standing, bending or sitting made his pain worse; that he did not use drugs, alcohol or cigarettes; and that he had not had surgery and had no allergies or medical problems. (Gov't Ex. 8 at 36.)

At approximately 8:00 p.m., Respondent directed SA Grafenstein to sit on an examination table. (Tr. 242, 247.) Respondent told SA Grafenstein to raise his hands (*see* Gov't Ex. 8 at 37) and inhale deeply (Gov't Ex. 8 at 39) while Respondent listened with a stethoscope (Tr. 242). Respondent also asked SA Grafenstein to bend over and felt along SA Grafenstein's back and neck with his hand. (Tr. 242; Gov't Ex. 8 at 40.) He asked where the pain was and performed reflex tests. (Tr. 242–43.)

Respondent asked SA Grafenstein whether he was taking medication six times a day and whether ''that seems to work out good for you?'' (Gov't Ex. 8 at 42.) SA Grafenstein responded in the affirmative [78] and stated that he was also taking Xanax. (Gov't Ex. 8 at 42; Tr. 243.) Respondent inquired ''how much Xanax are you taking? 'Cause it didn't get put on there, but I'll, I'll get it for you.'' (Gov't Ex. 8 at 42.) SA Grafenstein responded that he was taking about sixty. *Id.*

Respondent issued SA Grafenstein prescriptions for 180 Roxicodone 30 mg tablets and 60 Xanax 2 mg tablets, reflecting the medications SA Grafenstein indicated on his patient forms and requested orally.[79] (Tr. 216, 243; Gov't Ex. 9; Gov't Ex. 10 at 3, 4.) Dr. Glener opined that of the files he reviewed associated with Respondent's patients, ''the most egregious is [SA Grafenstein], where [Respondent] prescribe[d] a potentially fatal combination of oxycodone and alprazolam [80] without any justification whatsoever.'' [81] (Gov't Ex. 22 at 2; *see* Tr. 329–30.)

In response, Respondent testified that he prescribed Xanax based on the patient's representation that he was taking the medication, despite being aware that the patient had tested negative for both oxycodone and alprazolam.[82] (Tr. 427–28, 476.) Respondent also testified that he performed an appropriate and complete history and physical examination on SA Grafenstein, made findings and developed a treatment objective, and that his treatment of SA Grafenstein with controlled substances was based on sound clinical grounds, to include an MRI report.[83] (Tr. 418, 433.) I reject Respondent's testimony in this regard as not credible and inconsistent with the weight of the evidence. Although Respondent may have been concerned that the patient would experience withdrawal symptoms without Xanax, Respondent conceded at hearing that he did not ask the patient when he had last taken the Schedule IV controlled substance. (*See* Tr. 476–77.) Moreover, although the existence of an MRI report evincing ''an abutment of the nerve * * * that can lead to pain * * * .'' (Tr. 419) suggests some medical basis for prescribing an opioid analgesic, Dr. Glener credibly testified that the combination of oxycodone and alprazolam was both ''egregious'' and ''potentially fatal.'' (Tr. 329; Gov't Ex. 22 at 2.) Upon consideration of all the evidence, to include the competing evaluations of Respondent's conduct by Respondent and by Dr. Glener, I find by substantial evidence that Respondent's prescriptions to SA Grafenstein were outside the usual course of professional practice or for other than a legitimate medical purpose, in violation of state and federal law. *See* 21 C.F.R. § 1306.04(a); Fla. Admin. Code Ann. r. 64B8–9.013(1)(b).

The record further reflects that although he knew the MRI report focused on the wrong area of SA Grafenstein's body (*see* Gov't Ex. 8 at 33; Tr. 241), Respondent did not order a new MRI, nor did he discuss a treatment plan or the risks and benefits of the medication he provided. (Tr. 244.) On cross-examination, SA Grafenstein conceded that he had received and signed a Consent Form, containing a discussion of risks and benefits. (Tr. 245; *see* Gov't Ex. 10 at 9–10; *see also* Tr. 429–30.) The Consent Form, however, reflects an empty space next to the line reading ''Dr. Rene Casanova is prescribing opioid medicine * * * for a diagnosis of:'',[84] (Gov't Ex. 10 at 9; Tr. 253) and SA Grafenstein testified that Respondent did not provide him with a diagnosis. (Tr. 253.) Dr. Glener opined that the Consent Form is incomplete because the diagnosis is not listed, but the box is checked, and because no alternative treatments were listed, but that box is checked as well. (Tr. 398; *see* Gov't Ex. 10 at 9.) In addition, the patient's signature is not witnessed. (Tr. 399.) The foregoing evidence is inconsistent with the Florida Standards, which provide that ''[t]he physician is required to keep accurate and complete records * * * .'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(f).

Dr. Glener further opined that ''[SA Grafenstein] stated his pain without medication was 2/10, a complaint of minimal pain, and a huge dosage of oxycodone was prescribed. Alprazolam 2 mg twice daily was then prescribed without documenting any anxiety. Prescription of other psychotropic medication or referral to a mental health professional was not considered.'' (Gov't Ex. 22 at 2; *see also* Tr. 333.) Respondent further conceded that he did not refer SA Grafenstein to a specialist.[85] (Tr. 476.) Respondent's conduct is inconsistent with Florida Administrative Code Rule 64B8–9.013(3)(e), which provides that ''[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment * * * .'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(e).

The record reflects additional irregularities in Respondent's treatment of SA Grafenstein. Consistent with his report, Dr. Glener testified at hearing that he found it interesting that SA Grafenstein stated that his pain was two out of ten, ''which is extremely mild pain'' and ''the very definition of tenderness.'' (Tr. 328–29; *see also* Tr. 393 (describing difference between pain and

[76] A transcript of the undercover recording reflects that SA Grafenstein described his pain as ''[a] lot of pain. My upper is bother me [sic], a little sore. My lower, nothing that's * * * like excruciating * * * .'' (Gov't Ex. 8 at 34.) The audio recording of the conversation is inconsistent with the transcript with regard to SA Grafenstein's reference to ''[a] lot of pain'', and is consistent with SA Grafenstein's testimony that he did not use the word pain. (Gov't Ex. 7, UC Audio Pt 2.002 at 19:51:43–19:52:00.

[77] In fact, the record of the undercover visit reflects that Respondent asked SA Grafenstein to ''[g]ive me a number'' to which SA Grafenstein responded ''Two.'' (Gov't Ex. 8 at 36.)

[78] Consistent with the transcript of the visit, SA Grafenstein completed a patient form indicating he was currently taking 180 oxycodone 30 mg tablets. (Gov't Ex. 10 at 3 & 4.)

[79] SA Grafenstein testified that following his meeting he checked out with the receptionist, who gave him prescriptions and scheduled a follow-up appointment for March 16, 2010. (Tr. 244.) There is no indication that SA Grafenstein kept the appointment.

[80] Regarding his comment as to the dangers of prescribing alprazolam 2 mg tablets with oxycodone 30 mg tablets six times daily, Dr. Glener remarked that ''[t]he potential for disaster is very high * * * .'' (Tr. 332.) He explained that ''most people would be rendered unconscious and very many of those people would die from using the medications as prescribed so they are almost certainly being diverted on that basis.'' (Tr. 330.) In Dr. Glener's opinion, a dosage of .25 or possibly .5 milligrams of alprazolam would be more appropriate because ''there is really little indication for the ongoing prescription of large doses of a short-acting benzodiazepine * * * . Most physicians will use a long-acting benzodiazepine if they even feel one is necessary.'' (*See* Tr. 330–31.)

[81] Dr. Glener further explained: ''Dr. Casanova makes no notation that the patient is experiencing anxiety in his Review of Systems, the only reason to prescribe this medication.'' (Gov't Ex. 22 at 2.)

[82] In mitigation, Respondent explained that alprazolam has a short half-life and can quickly vanish from a person's system, meaning that patients ''can potentially experience some withdrawal'' to include a risk of seizure. (Tr. 428.)

[83] For instance, he identified findings in the MRI report evincing ''an abutment of the nerve * * * that can lead to pain * * * .'' (Tr. 419.) He concluded that the patient was suffering from low-back pain and occasional neck pain. (Tr. 422–23.)

[84] The Consent Form also reflects an empty space next to the line reading ''[t]he other alternatives discussed include acupuncture, massage'' (Gov't Ex. 10 at 9), and Respondent did not discuss acupuncture, massage or any other alternative treatments with SA Grafenstein. (Tr. 253–54.)

[85] Respondent explained that he intended to ''make some decisions relative to consultations or referrals'' at a follow-up visit. (Tr. 476.) There was no follow-up visit.

tenderness).) Dr. Glener wrote that Respondent ''found lower lumbar tenderness on physical examination, also noting 'pain with palpation,' indicating that he does not understand that this is the definition of tenderness.'' (Gov't Ex. 22 at 1.) At hearing, Dr. Glener elaborated that ''I was just trying to show that even a medical student knows what that means and what kind of expertise could this doctor have if he doesn't even know something a first-year medical student would know.'' (Tr. 394–95.) He also wrote that Respondent ''[w]ould not evaluate [SA Grafenstein]'s neck because he had no MRI report, consistent with a common belief among 'pill mill' doctors that having pathology on an MRI report somehow justifies the prescription of controlled substances.'' [86] (Gov't Ex. 22 at 2.)

At hearing, Respondent asserted that SA Grafenstein's medical file contains a physical examination, history of drug abuse and dependence and diagnostic, therapeutic and laboratory results as required by the Florida Standards. (Tr. 423.) He argued that it is difficult to develop a treatment plan over the course of a single visit and instead, a treatment plan slowly progresses over time. (Tr. 425–26.) Although I accept Respondent's testimony that a treatment plan progresses over time, Respondent was still bound to document a treatment plan compliant with the Florida Standards [87] before issuing a prescription for controlled substances. *See Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,832 n.11 (DEA 2011) (practitioner's standard of care refers to that generally recognized in medical community, rather than standard personal to practitioner).

Respondent also explained that he had inadvertently transposed numbers on SA Grafenstein's history and physical examination form, erroneously indicating that SA Grafenstein's pain while on medication was a ten and his pain without medication was a two or three, on a scale of one to ten. (*See* Tr. 474; *see also* Gov't Ex. 10 at 18.) Although apparently inadvertent, Respondent's inaccurate notation in SA Grafenstein's patient file is inconsistent with the Florida Standards. *See* Fla. Admin. Code Ann. r. 64B8–9.013(3)(f) (''[t]he physician is required to keep accurate and complete records * * * .''); *see also* Tr. 319 (expert testimony that ''it's incumbent upon [the physician] to document [the physician's] thought process * * * .'').

In summary, the record reveals numerous violations of standards and regulations concerning Respondent's prescribing of controlled substances in the context of SA Grafenstein's undercover visit to APM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Grafenstein lacked a ''legitimate medical purpose * * * that is supported by appropriate documentation establishing a valid medical need and treatment plan,'' in violation of Florida Administrative Code Rule 64B8–9.013(1)(b) (2003), and was outside the usual course of professional practice, in violation of 21 C.F.R. § 1306.04(a).

(b) SA Cortes February 16, 2010 Undercover Visit to APM

SA Cortes visited APM in an undercover capacity on February 16, 2010, and wore a functioning concealed audio recording device. (Tr. 257–58, 263.) He submitted new patient paperwork, provided a fictitious MRI report [88] and undercover Florida driver's license and picked up a business card for Simfa Rose pharmacy. (Tr. 272–73; *see* Tr. 268–69.) He intentionally left blank the section of the paperwork inquiring about current medications. (Tr. 265.) He also checked a box indicating that he was not in pain. (Tr. 266; *see* Gov't Ex. 14 at 3.) After paying for the visit, SA Cortes waited in the waiting area for approximately five-and-one-half hours.[89] (Tr. 265, 273.)

During his wait, a staff member named Jeremiah Flowers conducted triage procedures to include measuring blood pressure and weight and performing a urinalysis. (Tr. 273–74.) There was no supervision while SA Cortes provided a urine specimen. (Tr. 274.) Mr. Flowers evaluated the urine drug test in SA Cortes's presence, stating that the test was negative, meaning no opioids or controlled substances were detected. (Tr. 274–75.) SA Cortes's testimony regarding the absence of supervision during his urine drug screen is consistent with, and tends to corroborate, other evidence of record indicating that APM did not carefully supervise urine drug screens, among other deficiencies.[90]

After SA Cortes had waited more than five hours, Respondent called him into his office. (Tr. 273, 275.) Respondent directed him to sit across from him at a desk, approximately three feet away. (Tr. 275.) Respondent asked SA Cortes how old he was and how he hurt himself. (Gov't Ex. 12 at 2.) SA Cortes responded ''Uh * * * not really hurt, doc. Um * * * what I'm experiencing is * * * more and more stiffness * * * after each practice.'' (Gov't Ex. 12 at 2; Tr. 275–76.) Respondent asked where, and SA Cortes indicated his shoulders and lower waist. (Gov't Ex. 12 at 2.) Respondent asked how it happened, to which SA Cortes responded that he was studying martial arts and that ''lately, more and more, after each practice, it's getting * * * worse.'' (Gov't Ex. 12 at 2–3.)

Although there had not yet been any discussion of medication and SA Cortes did not indicate he was taking any medication on his Pain Assessment Form (Gov't Ex. 14 at 2), Respondent asked how long SA Cortes had been taking ''these medications'' and then asked ''Are you taking? You didn't write anything.'' (Gov't Ex. 12 at 3.) SA Cortes asked if his responses were confidential, to which Respondent answered in the affirmative. (Gov't Ex. 12 at 3.) SA Cortes explained that he had been taking Tylenol and his girlfriend's hydrocodone left over from her gallstone surgery.[91] (Gov't Ex. 12 at 3–4; Tr. 276.) Respondent asked how the medication worked for him and how many he was taking per day. (Gov't Ex. 12 at 4.) SA Cortes responded in the affirmative and indicated ''only about one (1) or two (2) a day.'' (Gov't Ex. 12 at 4.) Respondent attempted to identify the strength of the dosage, and SA Cortes identified the medication as a white oval tablet. (Gov't Ex. 12 at 5; Tr. 277.) Respondent asked if he experienced any side effects and SA Cortes said he felt woozy for a couple of days but the wooziness wore off. (Gov't Ex. 12 at 5.)

Contrary to SA Cortes's statements to Respondent that he had been taking his girlfriend's hydrocodone, SA Cortes's urine drug screen tested negative for that controlled substance. (*See* Tr. 482; *see also* Gov't Ex. 14 at 1.) Moreover, Dr. Glener testified that ''when someone admits to felonious behavior in my office, that certainly would prompt a follow-up.'' (Tr. 396.) By contrast, Respondent offered that he did not ask SA Cortes when he had last taken his girlfriend's hydrocodone because ''based on the information from the drug screen, given the half-life of the medicine and so forth, you can sort of backtrack that information.'' [92] (*See* Tr. 482.) Nor did he inquire whether SA Cortes had obtained a prescription for hydrocodone from another doctor. (Tr. 482.) Respondent testified that the information SA Cortes gave him was privileged [93] and that

[86] Dr. Glener explained that ''it's very prevalent * * * that physicians who are engaged in this sort of practice demand an MRI in order to use that as what I like to call the golden ticket to prescribe opioid analgesics. * * * An MRI is nothing magical. It's simply a diagnostic tool. Finding pathology on an MRI does not entitle any practitioner to prescribe a controlled substance. You need to connect the dots.'' (Tr. 336; *see also* Tr. 364–66, 373–74.)

[87] *See* Fla. Admin. Code Ann. r. 64B8–9.013(3)(b) (''The written treatment plan should state objectives that will be used to determine treatment success * * * '' as well as other elements).

[88] SA Cortes testified that he didn't know anything specific about the MRI report he provided, other than that it listed his undercover name and birth date and that it contained information about the spine or back area. (Tr. 281–82.)

[89] SA Cortes testified that he spent approximately eight-and-one-half hours at APM on February 16, 2010. (Tr. 273.)

[90] SA Cortes also testified that he overheard a conversation between Mr. Flowers and an unknown individual discussing different methods to inject heroin. (Tr. 275.)

[91] SA Cortes acknowledged on cross-examination that his statement to Respondent that he was taking opioids was false and was part of the undercover operation. (Tr. 283.)

[92] At the interview, SA Cortes remarked that the hydrocodone prescription had run out without being renewed (Gov't Ex. 12 at 4), but Respondent did not address this point at hearing.

[93] Consistent with his testimony at hearing, Respondent argues that SA Cortes's statement that he was using his girlfriend's hydrocodone was privileged. (Resp't Br. 18.) But ''privileges can be waived if the parties affirmatively do something to destroy the privilege * * * .'' *Harley v. Health Center of Coconut Creek, Inc.,* 469 F. Supp. 2d 1212, 1212 (S.D. Fla. 2006). Therefore, assuming, *arguendo,* that SA Cortes held a privilege in the contents of his communications with Respondent, SA Cortes waived that privilege by testifying at hearing. *E.g., Matter of Certain Complaints Under Investig. by an Investig. Cmtee. of the Judicial Council of the Eleventh Circuit,* 783 F.2d 1488, 1523 n.32 (11th Cir. 1986) (''the holder of a privilege can also waive it by permitting a breach of the privilege in his presence''), *superseded by statute on other grounds as stated in In re McBryde,* 120 F.3d 519 (5th Cir. 1997). More importantly, Respondent failed to ''refer the patient as necessary for additional evaluation and treatment'' or give

because SA Cortes indicated his girlfriend's hydrocodone was ''providing some sort of relief * * * my thought process was to bring him into a plan under physician supervision to provide him appropriate treatment for his medical ailments.'' (Tr. 435.) Having carefully considered all the evidence, I find that Respondent's reaction to SA Cortes's confessed diversion of controlled substances and his failure to follow up in the face of contradictory information were inconsistent with the Florida Standards, which state that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes.'' Fla. Admin. Code Ann. r. 64B8–9.013(1)(d).

Respondent asked SA Cortes how bad his pain was with and without medication, on a scale from one to ten. (Gov't Ex. 12 at 5.) SA Cortes replied that the pain was three or four while on medication. (Gov't Ex. 12 at 6.)

CASANOVA: With the medicines?
S/A: Right.
CASANOVA: And without?
S/A: And without * * * um * * * worse than that. I mean, I [unintelligible]
CASANOVA: Eight (8) or a nine (9)?
S/A: Yeah * * * eight (8) or * * *

(Gov't Ex. 12 at 6; Tr. 277–78.) Respondent asked whether SA Cortes's pain radiated, to which SA Cortes replied in the negative. (Tr. 279.) Respondent asked SA Cortes where he worked, and SA Cortes responded that he worked the midnight shift at a warehouse, loading trucks. (Gov't Ex. 12 at 6.) He stated that lifting made his discomfort worse. (Gov't Ex. 12 at 7.)

Respondent asked whether SA Cortes smoked, used drugs or alcohol or had any surgery, allergies or medical problems, to which SA Cortes replied in the negative, indicating only that he was allergic to aspirin. (Gov't Ex. 12 at 7.) Respondent directed SA Cortes to sit on an examination table and to inhale while Respondent listened to his respiration with a stethoscope and tested his reflexes. (Tr. 278.) Respondent inquired again whether SA Cortes was taking hydrocodone. (Gov't Ex. 12 at 8; Tr. 278.) SA Cortes responded in the affirmative and that it wasn't prescribed to him, and Respondent stated ''I understand.'' (Gov't Ex. 12 at 9; *see* Tr. 278.) Dr. Glener testified that in Respondent's interaction with SA Cortes ''there really was no significant physical examination pertaining to the appropriate organ systems * * * .'' (Tr. 327.) Respondent testified to the contrary (*see* Tr. 434), but I find the objective evidence of record supports Dr. Glener's conclusion and also find that Respondent's conduct was contrary to Florida Administrative Code Rule 64B8–9.013(3)(f)(1), which provides that a ''physician is required to keep accurate and complete records to include, but not be limited to * * * [t]he medical history and physical examination * * *.'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(f)(1).

Despite SA Cortes's previous indication that he had been taking only one or two hydrocodone pills per day (Gov't Ex. 12 at 4; Tr. 279), Respondent said:

CASANOVA: You said you were taking about three (3) or four (4) a day?
S/A: Yes. [PAUSE: 00:09:02–00:09:31]
CASANOVA: Correct? * * * I'm going to give you four (4) * * * a day. Alright?
S/A: Okay.
CASANOVA: Alright?
S/A: Hopefully that works.

(Gov't Ex. 12 at 9.) Respondent explained that SA Cortes was to take one tablet four times per day, and that ''I gave you, uh, the higher dose: the seven point five (7.5) milligrams.'' (Gov't Ex. 12 at 10; Tr. 279.) Respondent issued SA Cortes a prescription for 120 hydrocodone 7.5 mg tablets on February 16, 2010. (Gov't Ex. 13; Tr. 277, 288.)

At hearing, Respondent conceded that he did not discuss the risks and benefits of the medication because ''[t]he information was provided in the documentation that is here that a patient checked off and signed off.'' [94] (Tr. 483.) But SA Cortes's Consent Form reflects an empty space next to the line reading ''Dr. Rene Casanova is prescribing opioid medicine * * * for a diagnosis of:'' (Gov't Ex. 14 at 8; Tr. 267.) In addition, Respondent did not discuss a diagnosis or treatment plan with SA Cortes, nor did he document a treatment plan in the patient file.[95] (Tr. 279–80, 486–87.) Moreover, the Consent Form reflects an empty space next to the line reading ''[t]he other alternatives discussed include acupuncture, massage [and]:'' (Gov't Ex. 14 at 8), and Respondent failed to discuss acupuncture, massage or any other alternative treatments with SA Cortes. (*See generally* Gov't Ex. 12.) As Dr. Glener observed, the Consent Form in SA Cortes's patient file is incomplete because the diagnosis is not listed, but the box is checked, and because no alternative treatments were listed, but that box is checked. (Tr. 398; *see* Gov't Ex. 14 at 8.)

In light of the foregoing, I find that Respondent failed to comply with the Florida Standards requiring that physicians maintain accurate and complete records, *see* Fla. Admin. Code Ann. r. 64B8–9.013(3)(f) (''The physician is required to keep accurate and complete records * * * .''), discuss the risks and benefits of the use of controlled substances, *see* Fla. Admin. Code Ann. r. 64B8–9.013(3)(c) (''The physician should discuss the risks and benefits of the use of controlled substances with the patient * * * .'') and document a written treatment plan,[96] see Fla. Admin. Code Ann. r. 64B8–9.013(3)(f).

In addition, Dr. Glener testified that Respondent's prescription of hydrocodone to SA Cortes was ''entirely inappropriate'' because ''[o]nce the patient emphasized that [he was] having stiffness and not pain, there's no indication for treatment with an opioid analgesic.'' (Tr. 327.) Dr. Glener elaborated that opioid analgesics are indicated for pain, and that the patient's comments suggested the existence of a muscular problem for which referral to a physical therapist would be appropriate. (Tr. 327.) Respondent conceded that he did not refer SA Cortes to a specialist,[97] (Tr. 476) notwithstanding the Florida standard stating that ''[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(e).

In summary, the record reveals numerous violations of standards and regulations concerning Respondent's prescribing of controlled substances in the context of SA Cortes's undercover visit to APM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Cortes lacked a ''legitimate medical purpose * * * that is supported by appropriate documentation establishing a valid medical need and treatment plan,'' in violation of Florida Administrative Code Rule 64B8–9.013(1)(b) (2003), and was outside the usual course of professional practice, in violation of 21 C.F.R. § 1306.04(a).

(c) SA Saenz March 10, 2010 Undercover Visit to CCHM

The transcript of SA Saenz's March 10, 2010 undercover visit to CCHM reflects that when Respondent met with SA Saenz, he first asked her age and how she hurt herself. (Gov't Ex. 16 at 4.) She stated she was thirty-four years old and that she thought she injured herself by lifting children at a daycare center where she worked. (*See* Gov't Ex. 16 at 4; Gov't Ex. 18 at 1.) Respondent stated that he assumed SA Saenz had lower back pain, to which she responded ''Uh-um, sometimes * * * about a week'' and indicated that she had hurt herself one week earlier. (Gov't Ex. 16 at 5, 8–9.)

SA Saenz's patient file includes an MRI report dated March 8, 2010.[98] (Gov't Ex. 18 at 19–20.) Respondent asked if she obtained the MRI two days ago, to which she responded in the affirmative. (Gov't Ex. 16 at

''[s]pecial attention * * * to those pain patients who are at risk for misusing their medications and those who * * * pose a risk for medication misuse or diversion.'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(e).

[94] Similarly, on cross-examination, SA Cortes acknowledged that the Consent Form discusses risks and benefits of taking opioids. (Tr. 284.)

[95] Respondent conceded that the Florida Standards required a written treatment plan. (Tr. 486–87.) *See also* Fla. Admin. Code Ann. r. 64B8–9.013(3)(f).

[96] I accordingly reject Respondent's contention at hearing that his treatment of SA Cortes was, on the whole, proper. Respondent's assertion in this regard consisted of a number of claims, some demonstrably false. For instance, Respondent asserted that he formulated a treatment objective and on that basis treated the patient (Tr. 434); that the medical file contains the complete required documentation for medical records under the Florida regulations, to include medical history, diagnostic tests, evaluation, treatment objective and discussion of risks and benefits, albeit not orally (Tr. 439); that the treatment plan ''is formulated over time with numerous visits to gather more information, get all the appropriate documentation and so forth and review all the data'' (Tr. 439); and that his prescription of controlled substances to SA Cortes was based on accepted scientific knowledge of the treatment of pain and based on sound clinical grounds. (Tr. 441.)

[97] Respondent explained that he intended to ''make some decisions relative to consultations or referrals'' at a follow-up visit. (Tr. 476.) There was no follow-up visit.

[98] Respondent had not ordered the MRI; SA Saenz brought it with her on her own accord. (*See* Tr. 443.)

5.) At hearing, Respondent testified that the MRI report was consistent with her complaints of pain. (Tr. 444.)

At the patient interview, Respondent asked SA Saenz ''[a]re you taking any medicines for this? I assume not, 'cause it's just a week. Right?'' (Gov't Ex. 16 at 5.) SA Saenz responded that she was taking ''[i]buprofen and stuff.'' (Gov't Ex. 16 at 5.) Respondent asked if she was taking anything else, to which she responded ''Uh * * * what did I had [sic] * * * Tones, Dones'' (Gov't Ex. 16 at 7), which Respondent identified at hearing as slang for ''[o]xycodone, some kind of a narcotic pain medication.'' (Tr. 445–46.) Consistent with this interpretation, patient paperwork that SA Saenz completed indicates she was taking Roxicodone 40 mg tablets eight times per day, oxycodone 15 mg tablets three times per day and 2 mg Xanax tablets two times per day, a not inconsequential quantity of controlled substances. (*See* Gov't Ex. 18 at 8.) An examination note in her patient file also reflects the notion ''dones.'' (Gov't Ex. 18 at 1.) Her urine drug screen, however, was negative for oxycodone. (Gov't Ex. 18 at 18; Tr. 446.) And, notably, SA Saenz told Respondent that she had not seen any doctor for medicines (Gov't Ex. 16 at 7; *see also* Gov't Ex. 18 at 1), raising the questions of how she obtained them and whether she was using them, and suggesting that she had participated in the diversion or abuse of controlled substances.[99]

If Respondent had any concerns about SA Saenz's apparent diversion or abuse of controlled substances, or irregularities in her statements and medical file, there is no evidence that he voiced them. Indeed, Respondent testified at hearing that he did not ask SA Saenz how she had obtained oxycodone and Xanax. (*See* Tr. 495.) This omission reflects a degree of willful blindness by Respondent to issues of diversion, especially given that he proceeded to prescribe controlled substances to SA Saenz. (Gov't Ex. 17.) Moreover, under the Florida Standards, ''[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. *Special attention should be given to those pain patients who are at risk for misusing their medications and [who] * * * pose a risk for medication misuse or diversion.''* Fla. Admin. Code Ann. r. 64B8–9.013(3)(e) (emphasis supplied). In light of her negative drug screen, her use of slang to refer to oxycodone and her statement that she had not seen a doctor for the controlled substances she admitted taking, SA Saenz's ''risk for medication misuse or diversion'' was patent. But at hearing, Respondent conceded that he did not refer SA Saenz to a specialist (Tr. 476), and there is no indication that Respondent otherwise displayed ''special attention'' to her heightened risk of diversion.[100] Respondent's conduct in this regard is inconsistent with Florida Administrative Code Rule 64B8–9.013(3)(e).

In partial mitigation, SA Saenz did confirm to Respondent that the medication was helping with her pain. (Gov't Ex. 16 at 7.) Moreover, Respondent explained at hearing that because SA Saenz's urine drug screen was negative, he was concerned she might suffer from withdrawal symptoms. (Tr. 446.) But Respondent's statement in this regard is not credible, as neither the transcript of Respondent's interview with SA Saenz nor handwritten notes in the patient file contain any reference to withdrawal,[101] and physicians are required to document their thought processes in the medical record. *E.g.,* Tr. 319. *See generally* Fla. Admin. Code Ann. r. 64B8–9.013(3)(f) (''The physician is required to keep accurate and complete records * * * .''). I do credit, however, Respondent's statement that ''this was somewhat confusing that she did state just on tomes and domes and didn't state anything about an anxiolytic with this piece of information and her drug screen was negative.'' (Tr. 446.) I also find that Respondent's conduct is inconsistent with a physician's duty to ''be diligent in preventing the diversion of drugs for illegitimate purposes.'' Fla. Admin. Code Ann. r. 64B8–9.013(1)(d). I moreover reject Respondent's argument that he ''had no reasons to believe that the undercover agents were lying or otherwise falsifying information to illegally obtain medication.'' (Resp't Br. 28.) To the contrary, by prescribing controlled substances (Gov't Ex. 17) in the face of a drug screen revealing negative results for the very controlled substances the patient claimed she was taking without a prescription, Respondent failed to give ''[s]pecial attention * * * to those pain patients who are at risk for misusing their medications and * * * [who] pose a risk for medication misuse or diversion * * * .'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(e).

The record reflects that during the patient meeting, Respondent asked SA Saenz to describe her pain. (Gov't Ex. 16 at 5.) She responded that the pain was dull and throbbing, but was not constant, and that it bothered her mostly in the morning. (Gov't Ex. 16 at 5–6.) At hearing, Respondent testified that SA Saenz had circled a number of adjectives to describe her pain on her Pain Assessment Form (Tr. 444), to include words such as ''sharp,'' ''aching,'' ''tender,'' ''shooting,'' ''numb,'' ''throbbing'' and ''unbearable'' (Gov't Ex. 18 at 8).

Respondent also asked SA Saenz whether the pain interfered with her ''daily activities, your ability to function at work.'' (Gov't Ex. 16 at 6.) SA Saenz responded in the negative, simply stating ''No.'' (Gov't Ex. 16 at 6.)

CASANOVA: It doesn't?
UC: I suck it up.
CASANOVA: So then, but that's, those are two (2) different answers.
UC: Oh.
CASANOVA: Yes or no?
UC: Uh-um, no.
CASANOVA: Does it interfere with your activities?
UC: No.
CASANOVA: Does it interfere would mean * * * function or your ability to work.
UC: Not enough.

(Gov't Ex. 16 at 6.) This interchange reveals Respondent's persistence in inquiring whether SA Saenz's pain interfered with her ability to work, repeatedly pressing her even after she indicated that the pain did not interfere with her lifestyle. At hearing, Respondent denied that his treatment objective was to get SA Saenz back to work and noted that SA Saenz presented as ''stoic'' with respect to her pain from an acute injury. (Tr. 443, 447.) A note in SA Saenz's patient file contains circles around the word ''no'' associated with questions whether the pain interferes with daily activities and whether the patient needs medication to function or work. (Gov't Ex. 18 at 1.)

When Respondent inquired into the intensity of SA Saenz's pain (Gov't Ex. 16 at 7), she indicated that when she took Motrin the pain was about a three on a scale from one to ten and without Motrin her pain was about a five or a six. (Gov't Ex. 16 at 7; *see also* Gov't Ex. 18 at 1.) Respondent inquired whether SA Saenz had any surgeries or allergies or had gotten any medicines from other doctors, to which SA Saenz responded in the negative. (Gov't Ex. 16 at 7.) Respondent asked if she used drugs or alcohol, to which she replied that she drank socially on occasion. (Gov't Ex. 16 at 7–8.) He asked about her parents' health, and she responded that her parents both had high blood pressure and her father had high cholesterol. (Gov't Ex. 16 at 8.)

In addition, upon inquiry by Respondent, SA Saenz stated that she did not have any other medical problems. (Gov't Ex. 16 at 8.) SA Saenz's statement in this regard contradicted notations she made on her medical history indicating she suffered from insomnia and depression. (Gov't Ex. 18 at 6.) Respondent made no attempt to clarify this disparity, and the record reveals no evidence that he was even aware of it. The Florida Standards recognize that ''[t]he management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(e). Respondent's failure to notice the disparity between SA Saenz's written and oral statements, let alone perform ''extra care, monitoring and documentation,'' is facially inconsistent with the Florida Standards.

Respondent next conducted a physical examination of SA Saenz, asking her to uncross her legs, take a deep breath, bend forward and indicate where she had pain. (Gov't Ex. 16 at 9.) She indicated pain on her left side and sensitivity in her neck. (Gov't Ex. 16 at 9.) Respondent demonstrated a

[99] In an additional inconsistency, a medical history form completed by SA Saenz indicated she was not currently taking any medication. (Gov't Ex. 18 at 7.)

[100] Respondent explained that he intended to ''make some decisions relative to consultations or referrals'' at a follow-up visit. (Tr. 476.) There was no follow-up visit.

[101] Gov't Ex. 18. Respondent similarly suggested at hearing that he prescribed Xanax to SA Grafenstein out of a concern that SA Grafenstein would experience withdrawal symptoms without such a prescription. (Tr. 476–77.) Respondent conceded, however, that he never asked SA Grafenstein when he had last taken Xanax. (Tr. 477.) In any event, Respondent did not adequately address the heightened risk of diversion in either situation.

stretching exercise and recommended an Icy Hot patch. (Gov't Ex. 16 at 10.) Respondent stated he would prescribe high dose Motrin 800 mg, an anti-inflammatory ''and then I'm gonna write you for some narcotic pain medicine.'' (Gov't Ex. 16 at 11.) Respondent prescribed 90 Motrin 800 mg tablets, 90 Vicodin oral 5 mg—500 mg tablets and one pack containing twenty-one Medrol 4 mg tablets. (Gov't Ex. 17.) At hearing, Respondent explained that he prescribed a steroid to ''balance[] the effects of the medications.'' (Tr. 446.)

The record reflects that Respondent documented in the patient file conversations that did not occur. In particular, SA Saenz's patient file includes a document entitled ''Plan'' with handwritten check marks through boxes corresponding to the following text:

- Discussed anti-inflammatory diet, handout given to patient
- Patient has been counseled on risks/benefits of medications above; Pt. Will take exactly as prescribed
- Fish Oil/Omega-3 recommended at 3–6 grams per day
- Glucosamine + Chondroitin Sulfate recommended
- Strict avoidance of alcohol has been discussed at length
- Recommended avoidance of soda
- Goal is to wean off all medications has been explained to patient

(Gov't Ex. 18 at 4.) But the transcript of SA Saenz's undercover visit with Respondent contains no record of a discussion of an anti-inflammatory diet, the risks and benefits of medications, fish oil, Omega-3 or chondroitin sulfate. (*See* Gov't Ex. 16.) And as Respondent conceded on cross-examination, he did not have a conversation with SA Saenz regarding risk and benefits of the medications he gave her, and the portions of her Consent Form indicating a diagnosis and alternative treatment options are blank. (Tr. 496; Gov't Ex. 18 at 15.) This conduct is inconsistent with Florida Standards. *See* Fla. Admin. Code Ann. r. 64B8–9.013(3)(c) (''The physician should discuss the risks and benefits of the use of controlled substances with the patient.* * *'')

Moreover, the notation in the chart that ''[s]trict avoidance of alcohol has been discussed at length'' is patently false, given that Respondent merely asked whether SA Saenz drank, and when she answered in the affirmative, he asked whether she drank socially. (Gov't Ex. 16 at 7–8.) There is no suggestion in the record that Respondent counseled her ''at length'' to ''strictly'' avoid alcohol. Finally, there is no support in the record for the assertion that Respondent recommended that SA Saenz avoid soda or that he counseled her that a goal of treatment included weaning her off all medications. (Tr. 372–73.) By substantial evidence, I find that Respondent failed to keep accurate medical records in violation of Florida Administrative Code Rule 64B8–9.013(3)(f) (''The physician is required to keep accurate and complete records. * * *'') Moreover, in light of Dr. Glener's critique of Respondent for failing to inquire whether the patient had a substance abuse history or history of addiction (Tr. 372–73), a critique which is fully supported by the record, I find Respondent's conduct inconsistent with Florida Administrative Code Rule 64B8–9.013(3)(e), which states that a physician should ''refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' Fla. Admin. Code Ann. r. 648–9.013(3)(e).

After Respondent had already voiced his decision to prescribe controlled substances, he asked SA Saenz whether she had ever taken narcotics before, to which she responded in the negative. (Gov't Ex. 16 at 13.) That Respondent's inquiry into SA Saenz's history with narcotics occurred only after he had already decided to prescribe controlled substances is striking. Additionally, SA Saenz's statement that she had never before taken narcotics is flatly contradicted by her notations in her medical file and her statements to Respondent that she was presently taking oxycodone. (Gov't Ex. 16 at 7; *see* Gov't Ex. 18 at 8.)

Near the end of the meeting, Respondent stated: ''I, let me . . . let me ask you a question, you seem like a smart young lady. Why, for this kind of thing, you go to a pain management clinic? Why not go see a doctor?'' (Gov't Ex. 16 at 13.) She replied that she didn't have a doctor, and Respondent suggested she visit Respondent's Urgent Care Center on Federal Highway. (Gov't Ex. 16 at 13–14.) He explained that seeing him at the CCHM pain clinic would cost $400 or more, but she could see him for free and possibly get referred to an orthopedist or physical therapist if she filed for worker's compensation and saw him at his Urgent Care Center.[102] (*See* Gov't Ex. 16 at 15; *see also id.* at 11–12.)

Dr. Glener testified that Respondent's treatment of SA Saenz ''deviated from the standard of care and prescription of controlled substances were [sic] inappropriate.'' (Tr. 333.) Based on Respondent's comment ''Why not go see a doctor?'' (Gov't Ex. 16 at 13), Dr. Glener opined that Respondent ''admits that he is functioning other than as a doctor * * *'' while at CCHM. (Gov't Ex. 22 at 2; Tr. 334.)

Respondent testified at hearing that SA Saenz's patient file contained all the items required by Section 3(f) of the Florida Standards. (Tr. 447.) But in light of Respondent's concession on cross-examination that he did not document a treatment plan or treatment objectives in SA Saenz's medical record (Tr. 490–92), the fact that the ''History and Physical Examination'' form describing objects of treatment and the portions of her Consent Form describing the diagnosis and alternative treatments are completely blank (Gov't Ex. 18 at 5, 15) and the lack of a history of substance abuse or addiction as noted above, I reject this testimony as not credible. Moreover, Respondent's admission that ''[t]here is no specific treatment plan . * * *'' (Tr. 492; *see also* Tr. 493) is inconsistent. with the Florida Standards. *See, e.g.,* Fla. Admin. Code Ann. r. 64B8–9.013(1)(b) (describing parameters of ''appropriate documentation''); Fla. Admin. Code Ann. r. 64B8–9.013(3)(b) (contemplating a ''written treatment plan''). On the weight of the record evincing numerous violations of laws and regulations relating to Respondent's prescription of controlled substances to SA Saenz, I afford little weight to Respondent's assertion that his treatment was based on accepted scientific knowledge of the treatment of pain and was supported by sound clinical grounds. (Tr. 447.)

In summary, the record reveals numerous violations of standards and regulations concerning Respondent's prescribing of controlled substances in the context of SA Saenz's undercover visit to CCHM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Saenz lacked a ''legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan,'' in violation of Florida Administrative Code Rule 64B8–9.013(1)(b) (2003), and was outside the usual course of professional practice, in violation of 21 C.F.R. § 1306.04(a).

(d) Evaluation of Expert Testimony

As discussed above, the evidence at hearing included opinions from Dr. Glener and Respondent regarding Respondent's prescribing practices. Expert testimony regarding a physician's prescribing practices is an important but not indispensable part of evaluating whether a practitioner is acting for a ''legitimate medical purpose'' in the ''usual course of his professional practice.'' [103] The Agency has previously held that ''[w]here, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of federal law.'' *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19,450, 19,450 (DEA 2011).

As for the opinion of a treating physician, in the context of a DEA administrative hearing a treating physician's opinion should not automatically be given greater weight than the opinion of a non-examining physician. ''Despite a certain degree of lingering confusion among the courts of appeals, it has become overwhelmingly evident that the testimony of the 'treating physician' receives no additional weight.'' *Eastover Mining Co. v. Williams,* 338 F.3d 501, 509 (6th Cir. 2003). Unlike a Social Security benefit determination that is governed by a regulation giving deference to a treating physician, no such regulation pertains to a DEA administrative hearing.[104] Accordingly, I have not given Respondent's testimony greater weight simply because of his status as a treating physician, particularly given the short duration of his treatment of each undercover patient.[105]

[102] Respondent also asked SA Saenz to call him in a week to assess how she was feeling. (Gov't Ex. 16 at 11.) He offered to write her a note for work ''[b]ecause you shouldn't be lifting kids at work'' or do certain kinds of bending. (Gov't Ex. 16 at 11, 16.)

[103] 21 C.F.R. § 1306.04(a).

[104] *See* 20 C.F.R. §§ 404.1527(d)(2), 416.927(d)(2).

[105] I accordingly reject Respondent's argument that ''Dr. Casanova's testimony as to his compliance with Rule 64B8–9.013, Florida Administrative Code must be given great weight'' (Resp't Br. 25) and instead give Respondent's testimony weight where credible.

As noted above, based on his review of the undercover patient files, Dr. Glener found that ''[i]n all of the cases, the doctor prescribed controlled substances outside the usual course of professional practice or for other than a legitimate medical purpose.'' (Tr. 338–39.) After an extensive review of the record, I find Dr. Glener's opinion to be supported and corroborated by objective evidence. Therefore, although as noted above the record supports a finding that Dr. Glener demonstrated some bias against Respondent, Dr. Glener's conclusions as to Respondent's conduct discussed in this Recommended Decision are fully supported by the record.[106] Moreover, the discussions above relating to each undercover patient visit reveal multiple instances in which expert testimony is not required to make findings under 21 U.S.C. § 823(f) because the conduct is plainly and facially inconsistent with straightforward provisions of law. *See generally Cadet,* 76 Fed. Reg. at 19,450. I therefore reject as not credible and unfounded Respondent's testimony and argument that he complied with Florida Administrative Code Rule 64B8–9.013. (*E.g.,* Resp't Br. 24–25.) As detailed above, the record reveals numerous instances in which Respondent failed to maintain complete and accurate records or document a treatment plan consistent with the Florida Administrative Code, among other deficiencies.

(e) Summary of Undercover Patients

After reviewing the entire record, I find that substantial evidence that is both objective and otherwise reliable supports Dr. Glener's conclusion that Respondent's treatment of three undercover agents posing as patients ''deviated from the standard of care, was not appropriate in all cases and the focus of treatment appeared to be the prescription of controlled substances.'' (Tr. 324–25.) I further find by substantial evidence that Respondent issued three sets of controlled substance prescriptions for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of federal and state law.[107] This finding weighs heavily in favor of a finding under Factors Two and Four of 21 U.S.C. § 823(f) that Respondent's continued registration would be inconsistent with the public interest.

Respondent's argument in mitigation that he ''complied with many aspects of the law'' (Resp't Br. 25; *see also id.* at 26) is misplaced; in DEA registration proceedings compliance with one provision of law does not generally excuse the failure to comply with another. *Cf. Michael J. Aruta, M.D.,* 76 Fed. Reg. 19,420, 19,420 n.3 (DEA 2011) (holding that even ''evidence that a practitioner has treated thousands of patients'' in circumstances that do not constitute diversion ''does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest'' (citing *Jayam Krishna-Iyer,* 74 Fed. Reg. 459, 463 (DEA 2009))); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 386 & n.56 (DEA 2008) (noting that pharmacy ''had 17,000 patients,'' but that ''[n]o amount of legitimate dispensing[] can render * * * flagrant violations 'consistent with the public interest'''), *aff'd, Medicine Shoppe—Jonesborough v. DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). ''While such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices,'' it is entitled to no weight where a practitioner fails to acknowledge his wrongdoing.[108] *Krishna-Iyer,* 74 Fed. Reg. at 463. ''Put another way, even where the Government proves only a few instances of illegal prescribing in the 'entire corpus' of a practitioner's experience, the Government has nonetheless made out a prima facie case and thus shifted the burden to the registrant to show why he should be entrusted with a new registration.'' *Id.* at 464.

(f) Respondent's Prescribing to Kentucky Patients at CCHM

The testimony adduced at hearing reflects that three Kentucky patients visited Respondent at CCHM. On April 6, 2010, Respondent prescribed 90 Percocet 10 mg tablets and 220 Roxicodone 30 mg tablets to patient [C.C.] of Wallingford, Kentucky. (Tr. 90, 95; Gov't Ex. 20 at 1–2.) Neither party offered additional evidence relating to patient [C.C.], and there is no basis to conclude that Respondent's prescription to [C.C.] was improper.

The record further reflects that on March 31, 2010, Respondent issued identical prescriptions of 100 Roxicodone 15 mg tablets and 210 Roxicodone 30 mg tablets to patient [C.G], age fifty, of Essie, Kentucky, and patient [R.C.], age forty-eight, of Helton, Kentucky. (Tr. 91–92, 96–97; Gov't Ex. 20 at 3, 5.)

On the same day, at Wood's Pharmacy in Margate, Florida (Tr. 90), [C.G.] filled [C.G.]'s prescriptions at 4:07 p.m. and [R.C.] filled [R.C.]'s prescriptions at 4:01 p.m. and 4:11 p.m. (Gov't Ex. 20 at 4 & 6.)

The record therefore reflects that Respondent issued identical prescriptions on the same day to two Kentucky patients of similar age; that the prescriptions were filled at the same Florida pharmacy within a single ten-minute window; and that the cities of Essie, Kentucky and Helton, Kentucky are located close to each other but approximately 900 to 1000 miles and fifteen to sixteen hours away from Respondent's office in Deerfield Beach, Florida (Tr. 98–99).

Respondent argues that ''the Government's Exhibit 20 and [GS] Langston's testimony do not provide any indication whatsoever that Dr. Casanova improperly wrote prescriptions or otherwise violated any law.''[109] (Resp't Br. 29–30.) Although these circumstances may be suspicious (*see* Tr. 98–99), there is no indication that the prescriptions were other than for a legitimate medical purpose or pursuant to the usual course of professional practice, because the patient files are not in evidence and were not discussed at hearing. (*See* Tr. 101–03.) Accordingly, I do not find the evidence of record with regard to the three Kentucky patients sufficient to constitute substantial evidence that Respondent's prescriptions and conduct violated any applicable law or regulation.

(g) Respondent's Positive Experience in Dispensing Controlled Substances

Respondent offered testimony and pointed to evidence of his past positive experience in dispensing controlled substances, including his experience at MEC. Additionally, DI Stockmann testified that MEC is not a pill mill, and that aside from the absence of a biennial inventory on February 23, 2011, MEC appeared to be within the scope of a normal medical practice. (*See* Tr. 118, 127–28, 137.) Additionally, Respondent offered testimony that he gained experience dealing with acute and chronic pain patients and treating them with opioids, and familiarized himself with the Florida Standards, while working at Westchester Hospital in Florida. (Tr. 414.) Finally, Respondent testified that while working at APM and CCHM, he turned away a large number of patients ''that I thought might have issues with medications, issues potentially with the injection of medications and so forth,'' to include patients presenting with track marks. (Tr. 500.)

[106] Respondent argues that ''to Dr. Gleaner [sic], the only acceptable method of practicing medicine or treating pain would be his way and his way only.'' (Resp't Br. 26.) This statement is not supported by the record. Dr. Glener's testimony as to standard of care refers to ''the law . . . and appropriate medical practice'' as well as the expectations of other physicians. (Tr. 318–19.) Additionally, his testimony as to the requirements of Florida law is internally consistent and corroborated by general and specific statements contained in the Florida Administrative Code. *Compare* Tr. 319 (emphasizing importance of discussion of risks and benefits, performing a physical examination and formulating a diagnosis and treatment plan), *with* Fla. Admin. Code Ann. rr. 64B8–9.013(3)(c), (3)(a), (3)(f)(1) & (3)(b).

[107] *See, e.g.,* 21 C.F.R. § 1306.04(a) (controlled substances prescription must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.''); Fla. Admin. Code Ann. r. 64B8–9.013(1)(b) (controlled substances prescription must be for a ''legitimate medical purpose * * * that is supported by appropriate documentation establishing a valid medical need and treatment plan''); *see also, e.g.,* Fla. Admin. Code Ann. r. 64B8–9.013(1)(d) (physician's duty to ''be diligent in preventing the diversion of drugs for illegitimate purposes''); Fla. Admin. Code Ann. r. 64B8–9.013(3)(b) (''The written treatment plan should state objectives that will be used to determine treatment success * * *'' as well as other elements); Fla. Admin. Code Ann. r. 64B8–9.013(3)(c) (''The physician should discuss the risks and benefits of the use of controlled substances with the patient * * *''); Fla. Admin. Code Ann. r. 64B8–9.013(3)(e) (''[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment* * * Special attention should be given to those pain patients who are at risk for misusing their medications and [who] * * * pose a risk for medication misuse or diversion.''); Fla. Admin. Code Ann. r. 64B8–9.013(3)(f) (''The physician is required to keep accurate and complete records to include, but not be limited to .* * * [t]he medical history and physical examination * * *'').

[108] As discussed below, I find that Respondent has failed to accept responsibility for his prescribing-related misconduct.

[109] Making a finding that Respondent's prescribing in these instances was improper would require engaging in pure speculation. ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith v. Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt v. Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)).

Agency precedent has held that such evidence is entitled to some evidentiary weight only in cases where a practitioner credibly demonstrates an acceptance of responsibility and reform of past practices.

[E]vidence that a practitioner has treated thousands of patients does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest. While such evidence may be of some evidentiary weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight.

Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (DEA 2009).

Although I have carefully considered the evidence of Respondent's past positive experiences in dispensing controlled substances, to include his present practice at MEC, I find those experiences are considerably outweighed by the substantial evidence of Respondent's repeated misconduct in issuing controlled substance prescriptions to undercover law enforcement officers for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of federal and state law. The weight of Respondent's prior positive experiences is further diminished by Respondent's failure on the whole to admit or accept responsibility for any wrongdoing with regard to his prescribing-related misconduct at APM and CCHM.[110]

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

Under Factor Five, the Administrator is authorized to consider ''other conduct which may threaten the public health and safety.'' 5 U.S.C. § 823(f)(5). The Agency has accordingly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola,* 74 Fed. Reg. 20,727, 20,734 (DEA 2009).[111] ''[A]n applicant/registrant is required not only to accept responsibility for [his] misconduct, but also to demonstrate what corrective measures [he] has undertaken to prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. 8,194, 8,236 (DEA 2010) (quoting *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 464 n.8 (DEA 2009)).

A ''[r]espondent's lack of candor and inconsistent explanations'' may serve as a basis for denial of a registration. *John Stanford Noell, M.D.,* 59 Fed. Reg. 47,359, 47,361 (DEA 1994). Additionally, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio, M.D.,* 74 Fed. Reg. 10,083, 10,094 (DEA 2009).

Respondent argues generally that the Government has failed to establish by a preponderance of evidence that Respondent's continued registration would be inconsistent with the public interest. (Resp't Br. 23.) To the contrary, after balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's registration.[112]

Once DEA has made a prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall v. DEA,* 412 F.3d 165, 174 (DC Cir. 2005); *Humphreys v. DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72, 311 (DEA 1980). Respondent argues that if the Government has ''met its burden and made a prima facie case for the revocation of Dr. Casanova's license, Dr. Casanova has put forth sufficient mitigating evidence to assure the DEA Deputy Administrator that he can be entrusted with a Certificate of Registration.'' (Resp't Br. at 23.)

In fact, Respondent's testimony pertaining to whether he accepted responsibility for his past misconduct is ambivalent. To his credit, Respondent testified that regarding his recordkeeping violations,

[t]he bottom line is that I ultimately am responsible and was held accountable and I wasn't aware of the fact that he had not gotten the rest of the information. Maybe there was a misunderstanding in regards to the pedigree paperwork and so forth. I am fully aware of that and irrespective of the results of these hearings, I plan to provide all the appropriate information that is required and necessary.

(Tr. 449.) Upon inquiry from his attorney on direct examination, Respondent testified that he ''fully understand[s]'' that audit results need to zero out, and that he ''[o]ne hundred percent'' intends to take all steps necessary to make sure that any future deliveries are properly documented. (Tr. 450.) In addition, it is undisputed that Respondent fully and completely cooperated in the inspection of his registered location on February 23, 2011, to include access to records and inventory. (Tr. 114–15, 119–20.) Moreover, Respondent consented to a March 29, 2011 inspection of his registered location and cooperated, giving agents full access to everything they needed, although he was not required to do so. (Tr. 152, 184; Gov't Ex. 19(a).) Respondent's expression of remorse for his recordkeeping violations, his cooperation with authorities throughout the inspection and audit process and his promise of future compliance all reflect favorably on Respondent and weigh in favor of a finding that Respondent's continued registration would be consistent with the public interest.

In stark contrast to his acceptance of responsibility regarding his recordkeeping violations, however, Respondent in numerous instances declined to accept responsibility for his prescribing-related misconduct. For instance, Respondent unapologetically stated at hearing that he adheres to a standard of conduct that is different than that of other doctors. (*See* Tr. 446–47.) Under the Florida Administrative Code, a treatment plan is one of the standards for the use of controlled substances for pain control. *See* Fla. Admin. Code Ann. r. 64B8–9.013(3). ''The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function and should indicate if any further diagnostic evaluations or other treatments are planned * *.'' Fla. Admin. Code Ann. r. 64B8–9.013(3)(b). But when asked whether his own approach complied with the Florida Standards, Respondent became evasive and testified that ''a treatment plan is something [that] in my opinion differs from the other physicians. I believe that a treatment plan doesn't happen over one visit, * * *.'' (Tr. 467.) Respondent's belief that he is entitled to follow standards that depart from those promulgated by the Florida Department of Health is not consistent with accepting responsibility and showing evidence of likely future compliance.[113]

The following colloquy is illustrative:

Q: Wouldn't you agree that the Florida guidelines require that you execute a treatment plan for every patient according to these guidelines, [Fla. Admin. Code Ann. r. 64B8–9.013(3)(b)], page two?

A: I would agree that I have done the—I have taken the proper steps to start a treatment objective and a treatment plan and that with only one visit that I had for the patient, I did everything that was necessary based on the information that I had in front of me.

(Tr. 468.) Respondent further testified that ''[n]ot everything is down on paper. Just because it's [not] down on paper, it's not something that didn't happen.'' [114] (Tr. 470.) This comment is flatly inconsistent with the Florida Standards, which contemplate a ''*written* treatment plan,'' *see* Fla. Admin. Code Ann. r. 64B8–9.013(3)(b) (emphasis supplied), and written records generally. While I find credible Respondent's testimony that just ''[b]ecause it's not written down on paper doesn't mean that there wasn't a

[110] The extent, *vel non,* of Respondent's acceptance of responsibility for his misconduct is discussed below.

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

[112] I base this conclusion on Factors Two and Four of 21 U.S.C. § 823(f) for the reasons described above, and on Factor Five for reasons discussed in this Section.

[113] Respondent proposes that ''it was not possible to develop a proper treatment plan as treatment plans develop over time based on further information and physical examinations.'' (Resp't Br. 16 (internal citations omitted).) But before prescribing controlled substances, Respondent was nevertheless required to document a treatment plan and other elements ''not intended * * * [as] complete or best practice[s], but rather * * * what the Board considers to be within the boundaries of professional practice.'' Fla. Admin. Code Ann. r. 64B8–9.013(1)(g). Conduct falling below the minimal requirements of the Florida Standards is therefore outside the usual course of professional practice.

[114] Respondent also testified that a ''treatment plan was formulated either in terms of the documentation in the paperwork or mentally in terms of the documentation and a plan and a process.'' (Tr. 33–34.)

thought process * * *.'' (Tr. 486), the Florida Standards are unequivocal in their demand for records *documenting* the thought process, ''maintained *in an accessible manner and readily available for review.''* Fla. Admin. Code Ann. r. 64B8–9.013(3)(f)(9) (''Periodic reviews.'') (emphasis supplied). The standard of care against which Respondent's conduct is measured is not his own personal standard, but is instead a standard generally accepted and recognized in the medical community. *Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,832 n.11 (DEA 2011).

Moreover, when repeatedly asked to identify the location of his treatment plan in SA Grafenstein's patient file, Respondent conceded that both the treatment plan and the treatment objective for SA Grafenstein consisted solely of the medications listed in the patient's discharge summary.[115] (*See* Tr. 470–72; *see also* Gov't Ex. 10 at 1.) A plain reading of the Florida Standards, however, reveals that a medication alone cannot constitute a treatment plan. Instead, the Florida Standards provide that a treatment plan should

state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function and should indicate if any further diagnostic evaluations or other treatments are planned* * * . [T]reatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Fla. Admin. Code Ann. r. 64B8–9.013(3)(b). At a minimum, Respondent's treatment plan for SA Grafenstein lacks: (1) ''objectives that will be used to determine treatment success'' and (2) ''indicat[ions of whether] any further diagnostic evaluations * * * are planned.'' *Id.* Respondent's refusal to acknowledge these deficiencies is incompatible with a finding that Respondent has accepted responsibility for his past misconduct.

In addition, regarding his prescribing of Xanax to SA Grafenstein without first inquiring when SA Grafenstein had last taken that controlled substance, Respondent stated that ''I don't agree that by me not doing that that was [not] preventing the diversion of controlled substances.'' (Tr. 481.) Respondent's comment indicates that in similar circumstances involving real patients exhibiting warning signs of abuse or diversion, Respondent would likely repeat the same course of conduct in the future. Respondent's evidence fails to overcome the rebuttable presumption that ''past performance is the best predictor of future performance * * *.'' *Medicine Shoppe—Jonesborough,* 73 Fed. Reg. at 387 (citing *ALRA Labs, Inc. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995)).

Respondent's testimony at hearing provided additional indications that he believes the Florida Standards do not necessarily apply to him and that he might not comply with them in the future. As noted above, Respondent failed to discuss the risks and benefits of the controlled substances he provided to SA Cortes (Tr. 482–83; *see* Gov't Ex. 14 at 8), in violation of Florida Administrative Code Rule 64B8–9.013(3)(c). His testimony suggested that he did not engage in such a discussion during SA Cortes's initial visit, but that he might on a subsequent visit. (*See* Tr. 483.) When asked if the Florida Standards contained an exception for the first visit, Respondent testified ''[i]t could be a matter of style or what have you in terms of how you do things with the initial visits and follow-up visits and so forth.'' (Tr. 484.) Yet Respondent later acknowledged that ''[t]here's no particular exemptions here for the first visit.'' (Tr. 484.) Respondent barely acknowledges that he violated the informed consent provision of the Florida Standards, much less accepts responsibility for the violation and promises future compliance.

Similarly, Respondent acknowledged on cross-examination that he failed to document a treatment plan in SA Saenz's patient record (Tr. 490–91, 492), but also stated: ''I think you keep on using and harping on treatment plan in regards to being an issue. An appropriate treatment care [sic] was delivered for this acute injury without question.'' (Tr. 491.) Respondent's statement is not consistent with accepting responsibility for his violation of Florida Administrative Code Rule 64B8–9.013(1)(b) (describing parameters of ''appropriate documentation'' to include a treatment plan); and Rule 64B8–9.013(3)(b) (contemplating a ''written treatment plan''). To the contrary, Respondent's testimony reflects an attempt to trivialize his noncompliance.

Additional examples of Respondent's failure to accept responsibility for past misconduct exist but further elaboration is unnecessary. In summary, Respondent's testimony reflected an overall lack of admission of his past misconduct with respect to his prescribing practices, let alone acceptance of responsibility. In light of the foregoing, Respondent's evidence as a whole fails to sustain his burden to accept responsibility for his misconduct and to demonstrate that he will not engage in future misconduct. I find that Factor Five weighs in favor of a finding that Respondent's continued registration would be inconsistent with the public interest.

V. Conclusion and Recommendation

Under Factors Two, Four and Five of 21 U.S.C. § 823(f), I recommend that Respondent's DEA COR BC8677746 be revoked on the grounds that Respondent's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. §§ 824(a)(4) and 823(f).

Dated: September 29, 2011

Timothy D. Wing
Administrative Law Judge

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[115] Respondent also stated that the treatment plan ''begins with the diagnosis and * * * includes the medications * * * and that is the initial process of the treatment plan * * *.'' (Tr. 469.)

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0054]

Proposed Renewal of Existing Information Collection; Fire Protection (Underground Coal Mines)

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration is soliciting comments concerning the extension of the information collection for 30 CFR 75.1100–3, 75.1103–5(a)(2)(ii), 75.1103–8(b) and (c), 75.1103–11, 75.1501(a)(3), and 75.1502(a) and (b). OMB last approved this information collection request on January 8, 2010. The package expires on January 31, 2013.

DATES: All comments must be postmarked or received by midnight Eastern Time on November 19, 2012.

ADDRESSES: Comments concerning the information collection requirements of this notice must be clearly identified with ''OMB 1219–0054'' and sent to both the Office of Management and Budget (OMB) and the Mine Safety and Health Administration (MSHA). Comments to MSHA may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Facsimile:* 202–693–9441, include ''OMB 1219–0054'' in the subject line of the message.
- *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939. For hand delivery, sign in at the receptionist's desk on the 21st floor.

Comments to OMB may be sent by mail addressed to the Office of