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DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

[Docket No. 11-20]

RANDALL L. WOLFF, M.D. DECISION AND ORDER

On July 25, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision (also cited as ALJ). Respondent filed Exceptions to the ALJ's decision.

Having considered the record in its entirety, as well as Respondent's Exceptions, I have decided to adopt the ALJ's recommended ruling, findings of fact and conclusions of law with respect to each of the five public interest factors excepted as discussed below. While I reject some of the ALJ's findings of fact and legal conclusions, I conclude that the record as a whole supports the ALJ's ultimate conclusion that Respondent's continued registration would be inconsistent with the public interest and thus will adopt his recommendation that Respondent's registrations be revoked and that any pending applications be denied.

The ALJ made extensive findings of fact and legal conclusions with respect to Respondent's prescribing of controlled substances to eleven undercover officers (UCs); Respondent saw three of the UCs at a clinic known as Commercial Medical Group (CMG) and the remaining eight at a clinic known as Coast to Coast Healthcare Management (CCHM). See ALJ at 10-38; 44-93. With respect to the undercover officers Respondent saw at Commercial Medical Group, the ALJ found that the Government had not proved by substantial evidence that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone to Agents Miller and McClairie; with respect to Agent Bazile, the ALJ found that the Government had not proved that Respondent's prescription

for oxycodone lacked a legitimate medical purpose but that a prescription he issued for Xanax did. <u>Id</u>. at 92.

With respect to the undercover officers Respondent saw at CCHM, the ALJ found that the Government had proved by substantial evidence that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone to Agents Marshall, O'Neil, Doklean, Brigantty, Priymak, Zdrojewski, and Ryckeley. See id. at 44-92 (citing 21 CFR 1306.04(a)). Moreover, the ALJ also found that Respondent had violated various provisions of the State of Florida's Standards for the Use of Controlled Substances for the Treatment of Pain, Fla. Admin Code 64B8-9.013, in prescribing controlled substances to each of the aforementioned UCs. See ALJ at 44-92. However, with respect to Agent Saenz, the ALJ found that while the Government had proved that Respondent kept inaccurate records in violation of Florida's regulations, it had not proved that Respondent lacked a legitimate medical purpose in prescribing controlled substances to her.

Respondent filed Exceptions, most of which are variations on the same theme – that the ALJ erred in finding that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice. He argues that each of the UCs presented as being "[r]eal patients," who "[c]omplain[ed] of chronic real pain," which was "[b]ased on articulable causation." Exceptions at 6. According to Respondent, the ALJ "fail[ed] to appropriately recognize or acknowledge that each of the [UCs] presented themselves with valid Florida driver's licenses, as well as authentic and verified MRI reports that articulated an objective finding that supported the claim of pain." Id. at 6-7 (citing various portions of transcript). Respondent also maintains that he "believed that each [UC] was being truthful in their claim of real pain," "that the Government failed to offer any evidence to rebut [his] testimony . . .

concerning [his] basis for writing each of the prescriptions," that he "exercised his good faith medical judgment that the prescriptions . . . were appropriate" and that "although presented as 'credibility' findings[,] the [ALJ's decision] merely disagrees with his professional judgments [and] crosses outside of the boundary that limits DEA from substituting its judgment for that of a physician." <u>Id</u>. at 7-9. Having considered the exceptions, I reject them for the reasons explained below in my discussion of the evidence pertaining to the various undercover patients.

THE CCHM UC PATIENTS

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¹Respondent also contends that the Government's Expert "lacked qualifications or expertise and displayed a profound lack of knowledge concerning applicable Florida medical regulations, state and federal law, as well as the applicable standard of care." <u>Id.</u> at 3. It is acknowledged that both the Expert report and testimony contained several factual inaccuracies and misstated the law and state standards on several issues.

The record shows that the Government's Expert is a Diplomate of both the American Board of Anesthesiology and the American Academy of Pain Management and has twenty years of experience in practicing pain management. Tr. Vol. 7, at 12. The ALJ thus properly held that he was qualified to testify as an expert. <u>Id.</u> at 41. I further conclude that the ALJ properly evaluated the Expert's testimony and report declining to give weight to both the testimony and the report when it was factually inaccurate; however, with respect to Agent Saenz, I conclude that notwithstanding the Expert's factual errors, other credible testimony supports the conclusion that Respondent violated 21 CFR 1306.04(a) when he prescribed Roxicodone and Xanax to her. In the individual patient findings I discuss in more detail those areas in which the ALJ erred in relying on the Expert's testimony regarding the requirements of federal and state rules.

they think that you're an undercover, okay. And that you're trying to bust his nuts." GX 6, at 26. Marshall returned the next day and obtained controlled substances from another doctor. <u>Id</u>.

On May 4, 2010, Marshall made another visit to CCHM and saw Respondent. The interaction lasted less than three minutes. GX 6 (audio and DVD recordings). After asking Marshall about his age and birthdate, Respondent questioned him as to how everything was working out for him, whether he was working, whether the medicine was helping, whether he was having any complications, whether he was smoking, and if he was doing any exercises and staying limber; Marshall answered "no" to each question. GX 6, at 39-40. Respondent then listened to his breathing and asked him to place his hands out with his palms up, after which Respondent asked Marshall if he had any back pain. <u>Id</u>. at 40. When Marshall answered "no," Respondent asked "Mostly in the Neck?" to which Marshall said "yes." Id. Respondent then asked: "But overall you are doing okay?"; Marshall answered: "Yeah." Id. at 41. Respondent replied: "That's great," and after apparently asking Marshall to confirm his date of birth (notwithstanding that he had already asked it), stated: "Alright, we got you all set." Id. Respondent then issued Marshall a prescription for 120 dosage units of Roxicodone (oxycodone) 30mg, a schedule II controlled substance (for a daily dose of 120 mg), and 30 Xanax (alprazolam) 2mg, a schedule IV controlled substance.

It is true that the ALJ credited Respondent's testimony that he did not recognize Marshall notwithstanding the incident one month earlier. However, this provides no comfort to Respondent as there is ample evidence establishing that the prescriptions he issued lacked a legitimate medical purpose. For example, on the progress note for the May 4 visit, Respondent noted Marshall's pain level as a "5" with medication and apparently a "9" without it. GX 21, at

2. Yet there is no evidence that Respondent, during the brief encounter he had with Marshall, asked him to rate his pain either with or without medication.

Likewise, on the medical history form, Marshall checked "Yes" for whether he had emphysema/asthma, bipolar disorder, and recent depression. <u>Id</u>. 21, at 10. Yet Respondent did not ask Marshall any questions about these conditions and the chart contained no evidence of a psychiatric consultation. Tr. Vol. 4, at 37; Vol. 7, at 67. As the Government's Expert explained: "It's very dangerous to treat people with depression or bipolar disorder with a combination of [an] opioid and [a] benzodiazepine, because they potentiate each other, and you could end up having a patient very, very depressed or even suicidal or even die accidentally from that combination." <u>Id</u>. at 180.

The Government's Expert further noted that Marshall's file contained an MRI from two days before his first visit at the CCHM, yet there was no indication as to which physician had ordered it. Id. at 64; see also GX 21, at 27. Moreover, CCHM's Pain Assessment Form asked: "What Current medications have you been PRESCRIBED to help your pain?" GX 21, at 12. Marshall wrote that he was taking Roxicodone (oxycodone) 30mg, eight times a day; oxycodone 15mg, three times a day; and Xanax 2mg, two times a day. Id. However, nothing in the file indicates who had previously prescribed these drugs to Marshall nor documents how long he had been taking these drugs.

In addition, the Government's Expert noted that although the records for Marshall's first visit indicated that his cervical spine was "mildly painful to touch," he was assessed as having "chronic severe back pain." <u>Id.</u> at 6-7; <u>see also Tr. Vo. 7</u>, at 64. Moreover, with respect to Marshall's April 8 visit, the Expert observed that the progress note indicated "yes" for whether his pain was "under control," yet also included the notation that "pain was not well controlled

[on] present regimen." Tr. Vol. 7, at 69-70; GX 21, at 4. The Expert further explained that "there were no objective findings . . . to really substantiate the level of pain" and that there was "also no mention about the activities that the patient is being precluded from doing." Tr. Vo. 7, at 70.

According to the Government's Expert, "there is no legitimate reason[] why a physician would choose to treat a patient with such large doses of narcotics without going through other channels first, which would include the review of his prior medical records from wherever he was treated to other diagnostic tests that may have been performed to finding out what other drugs had been tried in the past and mentioning in the history of present illness how they were effective or not effective in treating this pain" and "getting more in the way of diagnostics such as x-rays, nerve conduction studies" and an orthopedic consult. <u>Id</u>. at 116. The Expert further explained that "[t]here [wa]s nothing . . . that warrants going to the 'big guns' of narcotics so aggressively and bypassing the conservative treatment that is recommended in the majority of the places [that] practice safe medicine." <u>Id</u>.

Based on the above, I agree with the ALJ's conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing oxycodone and Xanax to Agent Marshall. ALJ at 51-52. However, because there is no evidence that Respondent (as opposed to the doctors Marshall saw on his previous visits) completed the form (GX 21, at 8) in which various discussion items were checked off but which is neither dated

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² It is noted that Respondent issued the same prescriptions as had Dr. C.N. on April 8, 2010, and that Dr. L.C. (another CCHM doctor) had prescribed 120 Oxycodone 15mg and 30 Xanax 2mg. The fact that these two physicians also prescribed both oxycodone and Xanax does not aid Respondent. As the Government's Expert testified, "it was incumbent upon [Respondent] to do his own assessment . . . and not just perpetuate narcotic prescriptions where there may have been other treatments that may have been warranted or may have actually diminished the patient's need for narcotics." Tr. Vol. 9, at 93. The Government's Expert further explained it "would not be within the standard of care in Florida" for a physician to "perpetuate[] the issuance of controlled substances ordered by another doctor without first establishing his own valid doctor-patient relationship." <u>Id</u>. at 135.

nor signed, I reject the ALJ's finding that Respondent violated Fla. Admin Code r. 64B8-9.013(3) by failing to maintain accurate records.

Agent Saenz also visited CCHM on multiple occasions including twice on March 10, as well as on April 8 and May 4, 2010. GX 24. However, Agent Saenz did not see Respondent until May 4, 2010. Id. Agent Saenz testified that she first saw Dr. L.C. on March 10, but he declined to prescribe to her because "he didn't want [her] to be a drug addict" and "didn't think [she] needed it." Tr. Vol. 2, at 300. However, her patient file contains no documentation of Dr. L.C.'s findings. See GX 24.

At her March 10 visit, Agent Saenz presented an MRI which showed that two posterior discs were bulging and that there was bilateral neural foraminal narrowing. Id. at 28-29. She also completed a medical history form in which she checked the "yes" box for whether she had recent depression, id. at 11; on a pain assessment form she submitted, Saenz wrote, with the coaching of a CCHM employee (Tr. Vol. 2, at 271), that her pain was a "9" on a scale of 0 to 10, and that she was currently being prescribed 240 tablets of Roxicodone 30mg (8 tablets per day), 40 tablets of oxycodone 15mg (3 tablets per day), and 60 tablets of Zanax[sic] 2mg (2 tablets a day). Id. at 13. However, the note for Saenz's second visit on March 10, which was with Dr. R.C., indicates that her pain did not "irradiate" [sic], that it did not interfere with her daily activities, that she did not need medication to function or work, and that her pain was in control. Id. at 6. In addition, the form noted the intensity of her "pain without meds" as a "3," but that the intensity of her pain "arter[sic] taken meds" was "5-6." Id. Finally, the note documents that Agent Saenz had not been taking opioids and "[n]o drugs" under toxic habits. At this visit, Dr. R.C. issued her prescriptions for 90 tablets of Vicodin 5/500mg, a schedule III control substance

which combines hydrocodone and acetaminophen, and a 21-tablet Medrol dose pack (a non-controlled steroid) based on a diagnosis of LBP (lower back pain).

As the Government's Expert testified, the information in her file was "very inconsistent" and this is "a tip-off to a pain specialist that the patient isn't being forthright and may not be a suitable candidate for controlled substance prescriptions." Tr. Vol. 7, at 133-34. The Expert further explained that "[w]hen somebody is changing their story, whatever it is, medication, how much they're in pain, whether or not it affects them a certain way, it really . . . shows that they are not a reliable person, and they're not being truthful with their physician." Id. at 134. According to the Expert, this "would make them a poor candidate to receive . . . controlled medication prescriptions." Id.

On April 8, Agent Saenz returned to CCHM and saw Dr. N., who noted that she was "still having moderate amount of lumbar pain" but with "no radiation." GX 24, at 4; Tr. Vol. 2, at 283. Dr. N. also noted that Saenz had said that the Vicodin "didn't do 'much for her." GX 24, at 4. Dr. N. prescribed 90 oxycodone 30mg (one tablet every six hours as needed for a pain) and added 30 Xanax 2mg. <u>Id</u>. However, the note for the visit contains no indication as to Dr. N.'s justification for prescribing the Xanax. <u>See id</u>.

On May 4, Agent Saenz returned to CCHM and saw Respondent. Agent Saenz testified that her entire encounter with Respondent lasted "no more than ten minutes," during which Respondent asked her twice how she was doing (with Saenz responding that she was doing "fine"), what was bothering her, whether her current medications were helping, and whether she had a job.³ Tr. Vol. 2, at 242, 244. Saenz replied that she worked at a day care center and that the prescriptions were helping; she then asked if she could take one more oxycodone 30mg pill a

³ Agent Saenz testified that while she was equipped with an audio recording device, the device failed to record the encounter. Tr. Vol. 2, at 231.

day which Respondent agreed to. <u>Id</u>. at 242-43. Respondent's physical examination was limited to listening to Saenz's heart with his stethoscope; he did not palpate her spine or require her to perform any movements. <u>Id</u>. at 245. _ Also, Respondent did not discuss Saenz's need for Xanax. <u>Id</u>. at 245-46. Respondent then issued Saenz prescriptions for 30 Xanax 2mg, indicating on the prescription that it was "for sleep," and 120 Roxicodone 30mg "for pain." GX 24, at 24.

In the record for this visit, Respondent wrote that Saenz's pain level was a "7" out of 10 "with medication" and a "9" out of 10 "without medication." GX 24, at 2. He also noted that the "Meds helping but not yet relieved @ present dose" and that Saenz was "sleeping better [on] Xanax." Id. The ALJ did not specifically address whether Respondent's notations as to Saenz's pain level with and without medication and whether she was sleeping better were accurate representations of what occurred during the encounter. Based on the testimony of Agent Saenz, which the ALJ found to be "fully credible," ALJ at 9, I find that Respondent falsified the May 4 visit note with respect to the pain levels he documented and whether the Xanax was helping her sleep better.

While Respondent testified that Saenz had been seen previously by two other doctors who had prescribed medication without obtaining relief and had an MRI which showed abnormalities in her lower back, unlike the ALJ, I find that substantial evidence supports the conclusion that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing Roxicodone and Xanax to her. As the Government's Expert testified with respect to Agent Marshall, it "would not be within the standard of care in

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⁴ The ALJ did, however, find that Respondent had documented having discussed various matters such an anti-inflammatory diet, yoga/stretching exercise, the use of fish oil/omega-3, and glucosamine/chondroitin even though Agent Saenz testified that no such discussion occurred. The ALJ found that Respondent violated the State's regulation by failing to maintain accurate records. ALJ at 54 (citing Fla. Admin. Code Ann. R. 64B8-9.013(3)(f)). However, because the evidence shows that Saenz saw other doctors at CCHM and the form on which the ALJ's finding was based on is neither signed, nor dated, and no other evidence establishes that he (as opposed to the other doctors) completed the form, once again, I reject his conclusion as not supported by substantial evidence.

Florida" for a physician to "perpetuate[] the issuance of controlled substances ordered by another doctor without first establishing his own valid doctor-patient relationship." Tr. Vol. 9, at 135.

Thus, I find unavailing Respondent's attempt to justify his prescribing on the ground that he simply replicated what Dr. N. had prescribed to Agent Saenz. See Tr. Vol. 10, at 180. While it is true that Government's Expert misstated the evidence in attributing the April 8 prescriptions issued by Dr. N. to Respondent and by misreading a urine drug test as confirming the presence of various drugs when, in fact, they were not tested for, see ALJ at 21, this does not undermine the validity of the Expert's testimony regarding the obligation of a physician to establish "his own valid doctor-patient relationship" before prescribing large doses of narcotics. Tr. Vol. 9, at 135. In addition, the Expert explained that it was "below the standard of care to treat a patient with her pathologic findings on her MRI and her symptoms primarily only with narcotics and escalating narcotics and [to] not treat [her] with more conservative therapy [such as] physical therapy, anesthesia for nerve block treatments, . . . some other non-habituating medications, [and] behavior modification." Tr. Vol. 7, at 143.

Also unavailing is Respondent's testimony that he relied on the truthfulness of the information contained in Saenz's patient file, and that if he had been aware of her misrepresentations, he would not have prescribed to her. Tr. Vol. 10, at 180. Given that Saenz's patient file contained numerous material inconsistencies, Respondent's testimony begs the question of which information he believed was truthful. For example, on the Pain Assessment Form, Saenz wrote that her pain was a "9" on a "0" to "10" scale and that she was currently being prescribed 240 Roxicodone 30mg (a daily dose of eight tablets or 240mg), along with 40 tablets of oxycodone 15mg (for a daily dose of 3 tablets), and 60 Xanax 2mg, with a daily dose of two tablets a day. GX 24, at 13. Yet there was no indication in the file of which physician

was prescribing these drugs to her and the note for her first visit indicated that she had not seen another doctor, that she had not been taking opioids, and listed her pain levels as a "3" without meds and "5-6" with meds. <u>Id</u>. at 6. As found above, Respondent did not question Agent Saenz about any of these inconsistencies and falsified the record he created for the May 4 visit. Thus, I do not find credible Respondent's testimony that he believed Saenz to be a legitimate patient.⁵

Agent O'Neil also visited CCHM on three occasions (March 10, April 7, and May 4, 2010), meeting with Respondent only at the last visit. GX 23. At the first visit, O'Neil wrote on the Pain Assessment Form that his "tummy" was the location of his pain and circled all of the numbers from 0 to 10 for his pain rating; he also wrote that OxyContin 30mg was being currently prescribed to him. GX 23, at 13. Yet the patient record for O'Neil's first visit documents that he complained of having low back pain for twelve years and that Respondent found that he had mild tenderness in his lumbosacral spine and that his right elbow was tender to palpation. Id. at 6-7. In addition, the record states that O'Neil was not seeing another doctor, that he drank six beers a day, that he had been taking opioids for twelve years and that it had been two weeks since his last dose. Id. at 6. A urine test given on that date reported the presence of benzodiazepines. Id. at 27. The attending physician diagnosed O'Neil as having "severe" low back pain, as well "opiate tolerance" and "dependence."

At the May 4 visit, Agent O'Neil arrived with three Agents and asked if they could be seen together. Tr. Vol. 3, at 305. During the triage procedure, a clinic employee asked him if he took the pills. GX 14, at 24. O'Neil answered "Nah," to which the employee laughed and

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⁵ The ALJ also noted Respondent's testimony that the two strengths of oxycodone which Saenz listed on her Pain Assessment Form "might reasonably be prescribed together" for "breakthrough pain." ALJ at 54-55. That may be true, yet as found above, Saenz's patient file contains no indication of who might have prescribed this to her and the note for her first visit indicates that she had not previously seen a doctor or taken opioids.

⁶ The chart also records that O'Neil had "HTN," GX 23, at 8; an abbreviation for hypertension.

replied: "I know you don't take them." Id. at 25. O'Neil asked: "How can you tell?" and the employee answered: "What you mean how can I tell? I'm stupid?" Id.

Later, O'Neil was seen by Respondent and was asked how it was going, his age and birthdate, and "what have we got you on here today?" <u>Id</u>. at 26. O'Neil replied that he took the thirties; that he usually took about 180 fifteens, but the prescription was written "too low last time"; as well as Xanax 2mg "and sometimes Soma." <u>Id</u>. Respondent stated: "Okay, last time he wrote you one-twenty thirties," to which O'Neil interrupted him, stating: "Yeah, it was too low." <u>Id</u>. at 26-27. Respondent continued to note the other drugs (oxycodone 15mg and Xanax 2mg) that had been prescribed at O'Neil's previous visit and asked if he was "[t]aking a blood pressure medicine?" <u>Id</u>. at 27. O'Neil answered "No," and when asked "why," said he "just never filled it." <u>Id</u>. Respondent noted that O'Neil's blood pressure was "up again." <u>Id</u>.

Respondent then asked O'Neil if he had "been on medicine for a while?"; O'Neil stated: "Yeah." Id. Respondent then asked what O'Neil had been "on when you got here?" Id. O'Neil stated 210 thirties and 180 fifteens. Id. O'Neil replied that Dr. C. (who had written O'Neil's previous prescriptions at his April visit) had said the day before: "start, and you can go up each time," and that while Dr. C. only worked Wednesdays, "he said you'd gonna increase it." Id. Respondent then asked how O'Neil was "doing on the present dose"; O'Neil said "[f]ine." Id. Respondent followed by asking "so you're doing okay?" Id. at 28. O'Neil then stated: "No, no.

⁷ As the ALJ explained, "[t]his conversation constitutes evidence that Respondent's staff in this instance possessed actual knowledge of diversion by patients. The staff's open indifference, if not encouragement, of patients seeking controlled substances for no legitimate medical purpose is inconsistent with Respondent's claim that he was unaware of the problems plaguing CCHM." ALJ at 56. As the ALJ explained, "[e]pisodes such as this, while perhaps not on their own dispositive as to Respondent's specific knowledge of staff misconduct, . . . in the aggregate" support a finding that he was "willfully blind to the flagrant indications of diversion and abuse at" CCHM. Id. at 57.

I agree with the ALJ that while this incident by itself would not establish knowledge on the part of Respondent that the CCHM employees were facilitating diversion, the record here contains evidence establishing multiple incidents where employees knew that the undercover patients were seeking drugs either to abuse or sell. To make clear, where, such incidents are as pervasive as they were at CCHM, a registrant cannot reasonably claim ignorance of them.

I need more. But I don't need any less. The present dose is not . . . it would be better if it was more. It's not, you know, not making me feel worse." <u>Id</u>. Respondent stated that he understood and added: "You ran out, or it wasn't enough?" <u>Id</u>. O'Neil answered: "Yeah, I ran out." <u>Id</u>.

After O'Neil and Respondent discussed the former's employment status, Respondent asked: "Where is most of your pain?"; O'Neil replied: "Lower back." Id. at 29._Respondent asked "what happened?"; O'Neil said "[i]t was from football," that he had had back pain since "98" and that Dr. C. "had it in my chart." Id. After the two discussed whether O'Neil could see Respondent or Dr. C., Respondent conducted a physical exam. Id.

During the exam, which lasted thirty-two seconds⁸, Respondent told O'Neil to take a deep breath and then breathe normally, to hold his arms up with his palms up and then put them down, and then had him raise each leg straight up. <u>Id.</u>; <u>see also GX 14 (DVD, Excerpt 2)</u>. Upon completing the exam, Respondent stated that he could bump up O'Neil's medicine "a little" but rejected his request to give him 210 tablets, stating that he might do it "eventually" but could not do it "now." GX 14, at 29-30 and DVD Excerpt 2. Of further note, at no point during the exam did O'Neil complain of pain.

O'Neil then told Respondent that he was also taking "the liquid drops," a reference to a liquid form of OxyContin, which he had obtained from a friend. GX 14, at 30, Tr. Vol. 3, at 312. Respondent replied, "Don't even tell me that," and told him that it was "high abuse," that it could be deadly, and "don't take it." Id. Respondent further told O'Neil to take the oxycodone "just as it says on the bottle" and not to "take anyone else's medicine," or to sell it or share it,

⁸ This was from the moment Respondent got out of his chair (prior to asking O'Neil to breathe deeply) until he returned to it. The DVD also shows that Respondent had turned around and was returning to his chair when he told O'Neil to raise his other leg up. See GX 14 (DVD Excerpt 2).

⁹ At the hearing, Respondent testified that he had made this statement, because he "was very disturbed that he would do such a thing" and what he meant was that "it hurt me to hear that because I don't like to hear patients using that because I think it's a dangerous product." Tr. Vo. 10, at 155. The ALJ did not find Respondent's explanation credible. ALJ at 59. I agree with the ALJ's finding.

noting that "[t]his is serious medicine" and was "not for experimentation." <u>Id</u>. at 31. After a further discussion of the risks of taking someone else's medicine, Respondent added that when "[m]ost pain clinics . . . find out that . . . patients [are] taking other people's stuff," they "instantly" discharge them. <u>Id</u>. at 32. Following a short discussion of the weather, O'Neil asked Respondent if he should just make his next appointment with Respondent, who replied "I'm here for you." <u>Id</u>. at 33._O'Neill thanked Respondent, who replied: "Yeah. We got a bond now" and added that "the goal is not to get up to the highest number possible" but "to get pain relief." Id.

During the above conversation, Respondent printed out and signed prescriptions for 150 Roxicodone 30mg, 90 Roxicodone 15mg, and 30 Xanax 2mg, which he gave to O'Neil, notwithstanding the latter's statement about using liquid oxycodone which he had obtained from a friend. See GX 14, at 54. Moreover, as the ALJ found, Respondent noted on the record for this visit that there was "[n]o indication of substance abuse or diversion." GX 23, at 2. In addition, Respondent noted on the chart that O'Neil's "pain level with medication [was] 7/10" and "without medication 9/10." Id. at 4. Here again, this was a blatant falsification of O'Neil's record as there is no evidence that Respondent asked O'Neil either to rate his pain numerically or had any discussion regarding the intensity of his pain and whether it was affecting his ability to function.

Based on O'Neil's statement that he had been using liquid OxyContin which he obtained from a friend, and Respondent's response to it, the ALJ concluded that "Respondent's failure to reject SA O'Neil as a patient and his decision to issue him controlled substance[] prescriptions is inconsistent with state and federal law." ALJ at 59 (citing and quoting Fla. Admin Code Ann. r. 64B8-9.013(1)(d) ("Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.") and 21 CFR 1306.04(a)). As further support for his conclusion, the ALJ

also cited Respondent's statement that "most pain clinics" would discharge a patient when they found out they were "taking other people's stuff" and reasoned that this "demonstrate[d] [his] awareness of the impropriety in the medical community about prescribing to a patient known to be diverting or abusing controlled substances." <u>Id</u>.

While I agree with the ALJ's ultimate conclusion that Respondent violated 21 CFR 1306.04(a) in prescribing to Agent O'Neil, I conclude that it is unnecessary to wade into the controversy within the medical community as to the propriety of prescribing controlled substances to a person who reports having obtained them illicitly. Instead, I conclude that the entire body of the evidence with respect to Agent O'Neil's prescriptions establishes that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing to him. 21 CFR 1306.04(a).

As previously held, Respondent is not excused from the obligation of establishing a valid doctor-patient relationship because O'Neil had previously received prescriptions from another doctor at the same clinic. As the Government's Expert testified, it "would not be within the standard of care in Florida" for a physician to "perpetuate[] the issuance of controlled substances ordered by another doctor without first establishing his own valid doctor-patient relationship." Tr. Vol. 9, at 135. Notably, while O'Neil's record documented that he had been taking opioids for twelve years and had done so as recently as two weeks before his first visit to CCHM, there was no further documentation of how O'Neil had obtained the drugs, nor any history documenting any prior treatments for his injury and treating physicians. Moreover, more than two months had passed since O'Neil's initial visit to CCHM and yet none of O'Neil's medical records had been obtained.

Finally, as the Expert noted, during O'Neil's visit with Respondent, he did not complain of any pain or symptoms, Tr. Vol. 7, at 120; and Respondent neither asked O'Neil to rate his pain numerically nor questioned him regarding the nature and intensity of his pain.

Nonetheless, Respondent falsified O'Neil's medical record by noting that his pain level was a "7/10" with medication and a "9/10" without medication. Similarly, as found above, Respondent's physical exam took all of thirty-two seconds during which O'Neil did not complain of any pain. Indeed, Respondent had already turned around and was in the process of returning to his chair when he told O'Neil to raise his other leg. Given the totality of the evidence, it is clear that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone and Xanax to Agent O'Neil. CFR 1306.04(a).

Agent Priymak was also among the Agents who also visited CCHM on April 7, 2010 and May 4, 2010. Upon his arrival, Priymak presented his undercover driver's license and an MRI, paid for the visit and was given several forms to fill out. Tr. Vol. 2, at 319. On the Pain Assessment Form, Priymak did not circle any word to describe his pain and drew two circles around the numbers 2 and 3, and 3 and 4, on the pain scales. GX 22, at 10. Priymak also wrote that his pain was "between" being "occasional" and "continuous" and listed his current prescriptions as OxyContin 40mg, four times a day; Xanax, 2 times a day; and Soma, once per day. Id. He also circled "Yes" for whether he was having side effects from the medications and

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¹⁰ As the Government's Expert also testified, it is "definitely below the standard of care to leave out a history and physical in a first-time patient that you're prescribing large doses of narcotics [to]. To not have a history and physical on the chart is absolutely below the standard of care." Tr. Vol. 7, at 117.

¹¹ Here again, the ALJ found that Respondent violated Florida's regulation requiring the maintenance of accurate records by checking off the boxes of a form which contain various discussion items. See ALJ at 60 & n.62 (discussing GX 23, at 9). Once again, the form is neither signed, nor dated, and given that O'Neill had previously seen other doctors at the clinic, there is an insufficient basis to conclude that Respondent completed the form. However, it is clear that Respondent violated the regulation by falsely documenting O'Neill's pain levels on the record for the latter's May 4 visit.

explained that "It Feels Good!" <u>Id</u>. On his Medical History Form, Priymak drew a squiggly line, which for the most part ran through the various "no" boxes for the listed conditions. <u>Id</u>. at 8. However, Priymak clearly checked the "yes" box for whether he drank alcohol and again listed his current medications as OxyContin, Soma, Xanax, and another drug which is indecipherable. <u>Id</u>. at 9. However, below this listing, Priymak did not check either the "yes" or "no" box for the questions: "Are all meds prescribed by a physician?" Id.

Agent Priymak's file also contains a Drug Screen Result Form with the date of his first visit. GX 22, at 25. While this form indicates that opiates, oxycodone, and benzodiazepines were present in his urine specimen, see id., Priymak testified that he was not taking these drugs and did not "recall taking a drug test." Tr. Vol. 3, at 33-34, 37-38. Priymak did, however, recall that while being seen in the "triage room, the staff member checked something in his file and "indicate[d] that 'Yes, you have drugs in your system." Tr. Vol. 3, at 37-38. I agree with the ALJ's finding that Respondent's staff falsified Agent Priymak's Drug Screen to document that he was taking drugs when he was not. ALJ at 75.

Priymak was called by Respondent who asked him if it was his first visit; Priymak said it was. GX 5, at 34. Respondent then stated "Let's see. We gonna help with your pain in your neck." <u>Id.</u> Priymak replied "[y]eap" and then complained that his shoulder was "kind [of] tight" and that the pain had been going on "like . . . since 2001." <u>Id</u>.

After discussing Priymak's age and employment status (he was between jobs),

Respondent asked him how he hurt his neck. <u>Id</u>. at 35. Priymak explained that he had

"tweak[ed]" his neck "playing basketball," and that "since then [he had] tightness in [his] neck."

<u>Id</u>. Priymak further stated that his pain was in the middle of his neck and when asked how bad it

was, replied: "[w]ell[,] [i]t depends." <u>Id</u>. Upon further questioning by Respondent, Priymak

stated that his pain was a "two or three" if he did not take medication and that he currently was not taking any drugs. <u>Id</u>.

Respondent then commented that Priymak's pain level didn't "sound too bad." <u>Id.</u> at 36. Priymak replied that "for the last ten years or so," he had been "taking medication on and off" because his shoulder got tight. <u>Id.</u> Respondent then asked Priymak what medicines he had "been taking." <u>Id.</u> Priymak replied that he had been taking oxycodone 40mg, prompting Respondent to state: "for mild pain." <u>Id.</u>

Respondent and Priymak then discussed the location of the latter's condition. <u>Id</u>.

Priymak stated that "it gives me like tightness between my shoulder blades and then goes to my shoulder" and complained that when he played basketball his shoulder got "really tight." <u>Id</u>.

Respondent then asked if Priymak's condition "mostly . . . affect[ed]" him when he was "playing basketball?" <u>Id</u>. Priymak stated that he also did construction, suggesting that his shoulder bothered him when he "lift[ed] it" and added that he was also "taking some Somas," a non-controlled drug, but this drug was "not helping." <u>Id</u>. at 37.

Respondent then stated "maybe we're not communicating," emphasizing that Priymak had stated that his pain was "mild about two or three and mostly you . . . when you play basketball. Is that right?" Id. Priymak answered "yes," and Respondent stated: "otherwise you're okay, I mean . . . otherwise you do pretty good?" Id. _Priymak then stated: "No. I just . . . I need that . . . to get through the day." Id. Respondent asked "why?" and Priymak answered, "because of the pain," which prompted Respondent to ask: "I mean how bad is the pain?" Id. Priymak answered: "[I]t depends. It comes, it comes and goes. Goes up and down." Id. Respondent then asked: "from what to what? Two or three, maybe?" Id._Priymak

answered that it "must be higher than that." <u>Id</u>. Respondent replied: "I don't know. You tell me, I'm listening." <u>Id</u>. Priymak stated: "Ah . . . five." <u>Id</u>.

Respondent then asked Priymak if he was "sleeping [o]kay?" <u>Id.</u> Priymak said "[n]o" and explained that he was waking up three or four times a night and that he had been taking between one half to two bars of Xanax. <u>Id.</u> However, at no point in the visit did Respondent ask how Priymak was getting the Xanax.

Respondent then questioned Priymak regarding various medical issues including whether he had "used intravenous drugs." Id. at 38._Priymak stated he had "a long time ago," and upon being asked how long ago, stated "like five or six years ago." Id. Respondent then asked: "Is there any history of drug abuse or drug dependence?" Id. Priymak answered that he had been "taking Oxies for . . . a while." Id. Respondent then asked how much oxycodone Priymak was taking; Priymak stated that it depended, that the drugs were "kind of expensive," that he bought the forties and that he was taking up to four pills a day. Id. at 39; see also GX 5 (DVD).

Respondent asked if Priymak had seen a doctor "lately?" GX 5, at 39. Priymak said "no," and acknowledged that he was getting the drugs off the street. Id. Priymak also admitted that he drank three or four beers, three times a week, and emphasized that he was doing so because he did not have a job. Id.

Respondent then asked Priymak what other drugs he was taking; Priymak said he was "taking Xanax and Soma sometimes to like relax me," but added that he did not think it was helping him. <u>Id</u>. Respondent and Priymak discussed how much of each drug he was taking and why he was taking Xanax; Priymak said he was taking one half to one and a half Xanax and doing so "to sleep." <u>Id</u>. at 40.

Respondent then conducted a physical exam, which lasted approximately one minute, during which he listened to Priymak breathe in and out, had him do several motions with his arms and turn his neck. <u>Id.</u> During the exam, Respondent asked him what drug he took intravenously (which Priymak did not answer) and whether he still played basketball (with Priymak saying that it was hard for him because his shoulder got tight). <u>Id</u>.

Upon conclusion of the exam, Respondent told Priymak that he thought Priymak was "taking a lot of medicine for mild pain." <u>Id</u>. Priymak asserted that he was big and that taking one pill did not "help" him. <u>Id</u>. Respondent replied that "we don't write OxyContin" and that "we write . . . what's appropriate." <u>Id</u>. at 41. Respondent then added: "And sounds to me like your requirements for medication are way out of proportion for the degree of pain you have. I don't think I'm going to be able to help you." <u>Id</u>.

Priymak replied: "Are you serious Doc?" GX 5 (DVD). Priymak answered: "Yeah. Your pain is way less than what would be indicated to be on what you're on. Does that make sense to you?" GX 5 (Tr. at 41). After Priymak answered "No," Respondent explained that "somebody who has pain two or three doesn't need to be on one hundred and sixty milligrams of OxyContin. It's just way out of proportion." Id. Priymak asked why it was "way out of proportion," prompting Respondent to answer: "Because in my judgment it is." Respondent then explained: "You're on way too much and I, I can't imagine that . . . I wouldn't even write anything for somebody who has pain at a two or three." Id. Priymak reminded Respondent that they had talked about his "pain as five." Id. Respondent replied: "Yeah, whatever it is. I just think that this is too many problems here . . . too many bottles of beer and . . . a history of . . . drug abuse." Id.

¹² Having reviewed both the transcript and the DVD of this visit, I find that Priymak made this statement.

Priymak asked "what do you mean?" <u>Id</u>. Respondent answered: "I just don't think that I'm gonna be able to help you." <u>Id</u>. at 42._Priymak then asked: "Can you help me with something less than that amount?" <u>Id</u>.; <u>see also GX 5 (DVD)</u>. Respondent asked "Like?" and Priymak replied: "I won't be able to function, like thirties, like twenties." <u>Id</u>. Respondent advised that "thirties is all we write," and Priymak asked for thirties. <u>Id</u>. Respondent then stated: "I just don't see it for . . . what you have." <u>Id</u>. Priymak asked: "Can you give me fifteens?" and Respondent stated: "You know, maybe I'll give you some fifteens." <u>Id</u>. Priymak then thanked Respondent. <u>Id</u>.

Next, Respondent told Priymak that he should go "to some sort of rehab facility and get on Suboxone." <u>Id</u>. Priymak then maintained that he needed the drugs "to get through the day and work." <u>Id</u>. Respondent stated that he understood but that it was still his "suggestion" that Priymak go to rehab. <u>Id</u>. However, Respondent then asked Priymak if he "want[ed] some Xanax?" <u>Id</u>. Priymak answered "yeah," Respondent said "okay," and then asked Priymak if he was "allergic to anything." Id.

On the History and Physical Examination on which Respondent checked his diagnosis and plan, Respondent wrote that "PT has been on OxyContin 40 4x/day which is out of proportion to amt of pain. Will give Pt Rx for oxycodone 15 # 150 and refer to rehab. Rec. pt see MD for Suboxone." GX 22, at 6. However, as found above, while Respondent did suggest that Priymak go to rehab, he did not refer him to any rehab center or a physician who is

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¹³ Respondent and Priymak also discussed the latter's use of Soma (carisoprodol), a drug which is currently not controlled under federal law. GX 5, at 43. However, Respondent did not prescribe this drug.

Priymak also sought some Viagra, stating that he wanted to try it because he was going to a party and would like to try it. ALJ at 76 (discussing GX 5, at 43-44). Respondent asked Priymak if he had "some problems" for which the drug would be prescribed and whether it was "just for the party." <u>Id.</u> at 44._After Priymak acknowledged that it was, Respondent said "good try" and did not prescribe the drug. Because Viagra is not a controlled substance and DEA is not a medical board, I do not adopt the ALJ discussion regarding the propriety of Respondent's decision. <u>See ALJ at 77</u>.

authorized to prescribe Suboxone to treat addiction. Instead, Respondent issued Priymak prescriptions for both 150 tablets of Roxicodone (oxycodone) 15mg and 30 Xanax 2mg. GX 22, at 24.

On May 4, 2010, Agent Priymak returned to CCHM and again saw Respondent. Tr. Vol. 2, at 237; GX 22, at 22. After paying for the visit and completing the triage procedure, Respondent called Priymak's name and the two went to the former's office. Tr. Vol. 2, at 328. According to Agent Priymak, "[i]t was a very short visit" during which Respondent asked him how he was, if he had any problems or complications, if the medication was helping, and if he was smoking. Id. at 328-29; GX 5, at 54-56.

Respondent then asked Priymak "[w]here is most of your pain?" GX 5, at 56. Priymak answered that it was on the "right side" of his "neck," but that it was "going on and off[,] [k]ind of between my shoulders. Id. Respondent then asked: "Before you were having back[,] uh, neck pain?" Id. Priymak stated that back in 2000, 2001, he had "kind of like tweaked my neck roll." Id. Respondent stated "yeah," instructed Priymak to "take some breaths in and out," had him do something with arms and hands," id. at 56; and then "move [his] head from left to right." Tr. Vol. 2, at 329-30. Priymak testified that he completed the movements without showing pain, id. at 330, and the rest of the visit was spent discussing where Priymak was from (the Ukraine), the city of Kiev, and the time it took to travel to Kiev and Moscow. GX 5, at 57-58.

Respondent did not ask Priymak to rate his pain even though he documented on the form for the visit that Priymak's pain was a "5/10" with medication and "9/10" without it. GX 22, at 22. He also checked the box indicating that there was "[n]o indication of substance abuse or diversion," notwithstanding the information he had obtained and documented at the first visit.

Id. Moreover, Respondent did not engage in any further discussion with Priymak regarding the

latter's entering rehab. Nonetheless, Respondent issued Priymak two more prescriptions for 150 tablets of Roxicodone 15mg and 30 tablets of Xanax 2mg. <u>Id</u>. at 338; <u>see also GX</u> 22, at 21.

Regarding the April prescriptions, Respondent testified that he had prescribed less than half the dosage of oxycodone that Priymak had told him he had been taking and that he made a "medical judgment based on [his] interpretation and assessment" as to the degree of pain Priymak had and that "he tr[ied] to correlate that with a commiserate[sic] dose of medication" which would be "more appropriate." Tr. Vol. 10, at 108. Respondent further maintained that Priymak was "convinc[ing] and represented that he had significant pain." Id. He also asserted that there had been a "considerable period of time" since Priymak had stated that he had used intravenous drugs, id. at 113, and that he "didn't want to totally cut [Priymak] off of medication and have him go into withdrawal, but thought it would be more appropriate that he be on a lower dose, something that I thought [was] more reasonable." Id. at 128. Respondent also asserted that Priymak's MRI shows "a lot of changes . . . that would be consistent with a patient having significant neck pain." Id. at 138.

With respect to Priymak's second visit, Respondent testified that "there was no immediate reason to refer him to rehab" or to even discuss the issue because Priymak "made no representation . . . that he had any withdrawal problems or that his pain was not sufficiently addressed by the dose" he had prescribed. <u>Id</u>. at 140-41. Respondent further justified his prescribing, stating that Priymak "was no longer having to get his medicine on the street" and that "he was in a more controlled environment" because he was being "taken care of by a doctor." <u>Id</u>. at 141.

The ALJ addressed the credibility of only a part of Respondent's testimony, apparently finding credible that he prescribed at the first visit because did not want SA Priymak to suffer

from withdrawal symptoms, while finding not credible his testimony regarding why, at the second visit, he did not discuss Priymak's entering rehab. ALJ at 77. While I agree with the ALJ's finding as to Respondent's testimony regarding the second visit, I do not find credible his testimony regarding his prescribing at the first visit because the transcript and recording of that visit make clear – in Respondent's own words - that Priymak complained only of "mild pain," notwithstanding Respondent's successful efforts to coach him to eventually provide a higher pain level, and that Priymak's "requirements for medication [were] way out of proportion for the degree of pain" Priymak had. As Respondent further stated during the visit, "I wouldn't write anything for somebody who has pain at a two or three." Thus, Respondent's own statements during Agent Priymak's visit manifest that his testimony - that he believed that Priymak "had significant pain" and made a medical judgment to prescribe something more appropriate to Priymak's pain level - is patently disingenuous. As for Respondent's testimony that he did not "want to totally cut [Priymak] off of medication and have him go into withdrawal," even if this is credible, it provides no comfort to Respondent because federal law clearly prohibits prescribing a schedule II narcotic drug for this purpose. See 21 CFR 1306.07.14

Given the evidence of the undercover visits, expert testimony is hardly necessary to conclude that Respondent lacked a legitimate medical purpose in prescribing controlled substances to Agent Priymak. Nonetheless, it is further noted that the Government's Expert testified that Respondent's prescriptions to Priymak were not "warranted as [a] first-line, first-day treatment with this particular patient, who gave a history of being an intravenous drug abuser and purchasing drugs illicitly on the street." Tr. Vol. 7, at 92. The Expert further explained that

¹⁴ To make clear, Respondent was not registered to provide maintenance or detoxification treatment under 21 U.S.C. § 823(g). Under federal law, a practitioner who lacks such a registration is authorized only to administer (and not prescribe) a schedule II narcotic drug "to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral to treatment" and may administer no more than one day's dose of medication "at one time," and do so for no more than three days. <u>See 21 CFR 1306.07(b)</u>.

there were other forms of treatment including "physical therapy," a "short course" of "anti-inflammatory medications," and possibly "injection therapy" which were never discussed. <u>Id</u>. Finally, the Expert observed that there was no significant information documented in Priymak's patient file for his second visit to justify the additional prescriptions. I therefore conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing controlled substances to Agent Priymak at both visits. ¹⁵ 21 CFR 1306.04(a).

On July 23, 2010, Agent Doklean, along with nine other Agents, went as part of a "crew" to CCHM for the purpose of obtaining controlled substances. Tr. Vol. 1, at 179. Upon her arrival, Doklean paid a clinic employee \$300 for the office visit and gave her an MRI report (of her lumbar spine) and her undercover driver's license. <u>Id</u>. at 186. Several minutes later, another Agent, who posed as the crew's ringleader and sponsor, discussed with a clinic employee what the charge would be to obtain expedited or VIP service; the Agent then told the other Agents to pay the clinic employee an additional \$200 for VIP service. <u>Id</u>. at 187.

Agent Doklean testified that she had intentionally left blank various questions on the patient forms she had been given, and that subsequently, another clinic employee told her that she "needed to fill everything out." <u>Id</u>. This employee also gave Doklean "examples of words to put on" the form. <u>Id</u>. Doklean also testified that following her visit with Respondent, she had a conversation with another CCHM employee, R.M. <u>Id</u>. at 188. R.M. related to Doklean that Respondent "had concern over the fact that we . . . were not putting the proper things [on] our

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¹⁵ I also do not adopt the ALJ's rumination that "Respondent's testimony that he didn't want SA Priymak to suffer from withdrawal symptoms and the fact that Respondent's prescription of oxycodone was less than half of the dosage that SA Priymak represented he was previously taking perhaps mitigate[s] in Respondent's favor." ALJ at 77. As explained above, Priymak never complained of anything more than mild pain, which Respondent recognized did not warrant oxycodone, and clearly presented as a drug abuser. Thus, Respondent cannot credibly claim to have been duped by Priymak. In short, this was a blatant drug deal.

paperwork, that we needed to say that we were in pain on the paperwork and that any other undercover that had not been seen yet . . . needed to make sure that they put on the paper work and . . . needed to tell the doctors that they were in pain even if they were not." <u>Id</u>.

On her pain assessment form, Agent Doklean wrote that her pain was located in her "neck" and circled the words: "Tiring," "Evening/Night," and "Occasional." GX 25, at 9. Doklean did not circle any number on the pain scale and wrote that she was not on any current medications. <u>Id</u>. On a separate medical history form, Doklean again noted her pain was located in her "Neck" and checked "Yes" for whether she drank alcohol and had "ever been treated for addiction." Id. at 7-8.

Upon meeting Agent Doklean, Respondent asked her "what is your pain that we're going to help you with today?"; she answered: "over my neck." GX 4, at 31. Respondent asked how long the pain had been going on; Doklean replied "six months." Id. Respondent then asked if she had hurt herself; Doklean replied "No. I don't know where it came from." Id. After again confirming with Doklean that she was having neck pain, Respondent asked, "what are we doing with an MRI of your back?" Id. Doklean answered: "That's what the other... you know, what a doctor prescribed for. So ... that's what I went for." Id. Respondent noted: "But your pain is in your neck." Id. Doklean replied "Well, I mean it, it, it starts in the neck and towards the end of the day . . . it moves." Id. Referring to her MRI, Doklean then asked: "Well, I mean, I don't know how to read that, what does that say?" Id. Respondent replied that "this just has to do with your back" and explained that the MRI was of Doklean's lower back. Id. at 31-32. Notably, Respondent did not ask for the name of the doctor who had ordered the MRI.

After taking a phone call, Respondent again asked Doklean if she had neck pain, and after she said "yes," Respondent told her: "I guess I'm confused. You have pain in your neck

but you have an MRI of your back." <u>Id</u>. at 32. Doklean interrupted Respondent saying that she thought the pain "kind of radiates"; Respondent explained that there was a "disconnect" and that "we need to get an MRI of your neck." <u>Id</u>. at 32-33. Doklean then explained that "[b]y the end of the night it goes up and down" and that "sometimes it goes all the way through" and she felt "stiffness . . . down at the bottom." Id. at 33.

After asking Doklean about her employment status (she was unemployed), Respondent then confirmed that there was no trauma, with Doklean explaining that: "maybe, running after the kids" and that she had "two small kids." <u>Id</u>. Respondent then asked her how bad her pain was on a scale of one to ten. Id. Doklean answered:

It fluctuates. Sometime is down, you know like a two or three, sometimes it goes up. I mean, it really depends on the day . . . sometimes I feel more than others if it's a cloudy day or if it's a rainy day it'll go up, if not, I'm running after the kids . . . if out running around, it, it fluctuates. Sometime, you know, it's getting to a point where . . . I can't even. Sometimes even . . . hang out with the kids or like do anything with them.

<u>Id</u>.

Respondent then asked Doklean if she was allergic to any medicines, with Doklean answering "no," and how much she smoked, with Doklean stating that she did not. <u>Id</u>. However, upon being asked whether she drank, Doklean stated that she had been in rehab in November of the previous year (eight months earlier) but that she was now clean and sober. <u>Id</u>. at 33-34. However, Respondent did not inquire further as to where she had been treated and who were her physicians. <u>Id</u>. at 34; <u>see also</u> Tr. Vol. 1, at 204.

After a question about her medical history, Respondent asked Doklean if she had been taking medication. GX 4, at 34. Doklean stated that she would "take some Advils," but added that "every now and then . . . I have a friend who would help me out a little bit with some of the blues" (a term which is street slang for oxycodone 30 mg, see Tr. Vol. 1, at 204) that seemed to

help, so she decided to go "see a pain doctor." GX 4, at 34. Respondent then asked Doklean "how long" she had "been taking the blues?" Id. Doklean stated that she had been taking them "on and off for like six months," but it was "kind of hard" because "it's expensive." Id. Next, Respondent asked Doklean if "you just take a few of those?" Id. Doklean answered that she did so "every couple of days, when thing get really bad" and that they seemed to help her. Id.

Respondent then asked Doklean to "describe the pain." <u>Id</u>. at 35._Doklean replied: "It radiates. I mean, sometimes I get like massive headaches . . . and it'll start up in my head and it'll go like from . . . here and towards in here and it'll go back down and then, that's why I say I feel it in the neck and it'll go, it'll shoot down." Id.

Respondent then proceeded to perform a physical exam (which took fifty seconds); the exam consisted of his placing his stethoscope on her back and instructing her to breath in and out, as well as several range of motion exercises including having her move her arms, open her fingers and then make a fist, raise each of her legs straight up, then stand up and bend over. <u>Id</u>. at 35; GX 4 (recording of visit); Tr. Vol. 1, at 206-08. According to the credited testimony of Agent Doklean, she was able to completely bend over and touch the ground in "a swift maneuver," which prompted Respondent "to chuckle." Tr. Vol. 1, at 206.

Next, Respondent had Doklean turn her head both left and right as well as up and down.

GX 4, at 35. Respondent asked if doing this caused her any pain; Doklean stated "not right now" and added that "[t]oday is a good day." <u>Id</u>. Respondent stated "[t]hat's good," and asked Doklean if she had pain "in [her] back occasionally?" <u>Id</u>. Doklean replied "Do I? Yeah, It goes, like I said, it, it radiates. It goes different ways. Sometimes it starts up from. . . I get . . . most I get the headaches and then it, it just goes all the way down." <u>Id</u>. at 36. Respondent did not, however, palpate either her neck or lower back. Tr. Vol.1, at 208.

Respondent then asked Doklean if she was "[t]aking anything now?" GX 4, at 36.

Doklean said "No" and Respondent replied "[w]ell, let's just get you started on some medicine and see if we can't get you some relief" and instructed her to "[t]ake the medicine just as it says on the bottle," and not to buy, sell or share it. Id. Doklean then asked: "Do I get some of the blues?" Id. Respondent answered: "Yeah. Let's . . . let me look at your chart, we'll see how we're gonna help you today" and told her to "[h]ave a seat out front. We'll . . . see what we can do for you." Id. Subsequently, Respondent issued Doklean a prescription for 120 tablets of Roxicodone 30mg and a prescription for an MRI of her cervical spine. GX 4, at 59.

On the History and Physical Examination Form, Respondent noted that "upon questioning," Doklean had reported that her pain was an "8 throughout the day, [with] flareups of ... 10" on a scale of 0 to 10. GX 25, at 2. Respondent also put check marks indicating that her pain was "aggravated by" "lifting," "twisting," and "sitting or standing in one position too long." Id. He also checked the "yes" box indicating that "the pain deplete[d] [her] energy/motivation," that she was irritable and moody because of it, that it "affect[s] [her] relationship," and that "it cause[d] problems at work." Id. While Respondent noted that Doklean "has taken Roxi" and gotten drugs from friends and the street, he also wrote that she was "off any meds now and having great difficulty." Id.

As shown by the recording and transcript of her visit, Doklean never complained of having pain at the level Respondent documented and Respondent never asked whether her pain was aggravated by any of the activities which he checked as doing so. Moreover, Respondent did not question her about whether the pain affected her energy, made her irritable and moody, affected her relationships and caused problems at work. Indeed, Doklean had told him that she was unemployed.

In addition, on pages two and three of the form, Respondent made numerous notations as to his purported findings of his physical examination. GX 25, at 3-4. As the Government's Expert observed, there were "extremely serious improprieties" as Respondent fabricated in the medical record "numerous findings, such as HEENT exam, heart exam, abdominal exam, cervical and lumbar spine exams, range of motion testing, reflex testing, sensory testing, peripheral pulses palpation, neurological testing [and the] presence of muscle spasm." GX 32, at 18-19.

In his testimony, the Government's Expert further explained that Doklean "came in complaining of neck pain but had a lumbar MRI spine report, not a cervical MRI, so [Respondent] really was prescribing her medication prior to a definitive diagnosis of what was going on in her neck." Tr. Vol. 7, at 148. Moreover, when Respondent questioned why her MRI was for her lower back and not her neck, the Expert observed that Doklean had "pointed to her entire spine, in a diffuse manner" and that "this is a common maneuver in a malinger patient." GX 32, at 14. The Expert also noted "that while the patient also was complaining of 'massive' headaches, he never performed a cranial evaluation, such as cranial nerve testing." Id. at 17.

Additionally, the Expert testified that Doklean's "MRI shows just mild bulging of three disks in her lumbar spine, which is normally treated conservatively with non-steroidal anti-inflammatory medications and physical therapy." <u>Id.</u> at 148-49. The Expert further observed that Doklean had "stated that her pain rating was a '2 or 3,' but could increase during the day and vary with the weather. Certainly this pain is not of the severity that usually requires high-dose narcotic therapy." GX 32, at 14.

The ALJ found "dubious" Respondent's testimony that he interpreted Doklean's pain as actually being higher. ALJ at 63 (citing Tr. Vol. 10, at 190-91 & 201). I go a step further and

find that it is not credible. In addition, the ALJ was not impressed by Respondent's testimony that he thought Doklean had gotten "controlled substances from friends because 'she didn't have the money to see a doctor previously" and that he would be "prescrib[ing] medication for her in a controlled way . . . [t]hat prevents diversion and prevents her from continuing to have to get medicine in an illegitimate way." <u>Id</u>. at 64.

As the ALJ found, after Doklean's meeting with Respondent, R.M., a clinic employee, related that Respondent "had concern over the fact that we ... were not putting the proper things [on] our paperwork, that we needed to say that we were in pain on the paperwork and that any other undercover that had not been seen yet ... needed to make sure that they put on the paper work and ... needed to tell the doctors that they were in pain even if they were not." Tr. Vol.1, at 188; see also ALJ, at 64. As this statement makes plain, Respondent's concern was not with prescribing only for legitimate medical purposes, but rather, with being able to justify illegitimate prescribing. In any event, even were I to give no weight to R.M.'s statement, there is overwhelming evidence that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing to Agent Doklean. 21 CFR 1306.04(a).¹⁶

Agent Zdrojewski was another member of the "crew" which visited CCHM on July 23, 2010. As with the other Agents, Zdrojewski testified that upon his arrival at the clinic he paid \$300 for the visit and submitted an MRI and his undercover driver's license, that he received forms to fill out, and that another Agent, who posed as the ringleader, had a discussion with a clinic employee after which the ringleader told the other agents to pay over another \$200 for VIP

¹⁶ I also adopt the ALJ's finding that Respondent violated Florida's regulation by failing to maintain accurate records regarding Agent Doklean. <u>See ALJ</u> at 65. In addition, while the ALJ found that Respondent violated 21 CFR 1306.04(a) in prescribing to Agent Doklean, he also opined that the prescription "was not wholly without some indicia of medical purpose." ALJ at 66. Because the ALJ provided no further explanation as to the meaning of this statement, and the basis for it, I do not adopt it.

treatment, which Zdrojewski did. Tr. Vol. 3, at 72. Zdrojewski testified that after the Agents paid the additional fee for VIP treatment they joked around and made comments in front of clinic employees that they were not going to make any money off of the visit. <u>Id.</u> at 73. Agent Zdrojewski further testified that he was required to provide a urine sample, but was not supervised in doing so, and that when he turned over his sample, he told clinic employees that he had put water in his sample and was laughing about it, but that none of the employees said anything to him about this. <u>Id.</u> at 78-79.

On the pain assessment form, Agent Zdrojewski wrote that his head was the location of the pain and that his pain was "bothersome"; while he also circled that his pain was "Occasional," he did not circle any of the other descriptors printed on the form. GX 28, at 9. On the numeric pain scale, Zdrojewski drew a single circle around the numbers "O" and "1" and wrote that "offshore boating" made his pain worse. Id. Zdrojewski listed his current medications as 90 OxyContin 80mg, 240 oxycodone 30mg, and Xanax, and indicated that he was not having any side effects from the medications. Id.

Agent Zdrojewski also completed a medical history form. On this form, Zdrojewski checked the "yes" box indicating that he had high blood pressure, bipolar disorder, ¹⁷ and headaches. GX 28, at 7.

Upon meeting Respondent, Zdrojewski was asked if it was his first visit; Zdrojewski said it was and that he had gone to Tampa Bay Wellness, a clinic which was now closed. GX 8, at 11. Respondent then asked Zdrojewski where his pain was and how long it had been ongoing; Zdrojewski replied that he had "neck" pain and that it had been probably going on for "a year and a half." Id. Respondent asked Zdrojewski about his employment status; the latter said he worked as a "charter captain." Id.

 $^{^{\}rm 17}$ Zdrowjeski checked both the "yes" and "no" boxes for bipolar disorder. GX 28, at 7.

Next, Respondent asked Zdrojewski how he had hurt his neck. Id. Zdrojewski replied that he did not know and that "it just . . . over time . . . There's a bump here and its kind [of] in here and it goes up." Id. at 12. Zdrojewski further explained "that this comes on. It's like, it doesn't always . . . If it moves a certain way it gets better." Id. After stating that he had "gone through chiropractor stuff and traction," Zdrojewski explained that "[t]he last doctor was giving me crazy amounts but I didn't even fill [all those]. Dude was giving me ninety count eighties." Respondent confirmed with Zdrojewski that he had gotten eighties, with the latter adding that the clinic was "closed now. So, I put down on the sheet what I was getting. They were giving me sixty two-milligrams Xanax[,] and two hundred forty Thirties[,] and then ninety count eight[ies]." Id. Zdrojewski added that he didn't "need all that." Id.

Respondent then asked Zdrojewski to describe his pain; Zdrojewski replied that it "comes and goes" and was "intermittent" but "the word wasn't on there." <u>Id</u>. Respondent then asked Zdrojewski how his pain was on a one to ten scale with ten being severe, and added: "You got zero to one, is that right?" <u>Id</u>. Zdrojewski said "Oh," and Respondent said "that means . . . you don't have pain." <u>Id</u>. According to the credited testimony of Agent Zdrojewski, he then told Respondent to "top it" and Respondent circled the numbers 8 through 10 on the pain assessment form. Tr. Vol. 3, at 97.

Respondent then asked: "So the pain's been pretty bad?," to which Zdrojewski said "[it] can be." GX 8, at 12. Respondent asked if "it pretty much stays there on the neck?" <u>Id</u>. at 13. Zdrojewski said: "You can say stay." <u>Id</u>. Upon further questioning, Zdrojewski stated that the pain did not go into his arms. <u>Id</u>. Respondent then asked how the pain affected his life, work and home. <u>Id</u>. Zdrowjewski stated that he "control[ed] it" and that he had "to function, so I function. . I'm just not gonna sit around." <u>Id</u>.

Next, Respondent asked: "what makes you want to be on pain medicine?" <u>Id</u>. Zdrojewski answered that it "makes me feel better. It's not illegal like weed or something like that." <u>Id</u>. Respondent then asked if when he took it before, it allowed him to function; Zdrojewski answered "Yeap." <u>Id</u>. Respondent then said: "Meaning that without it you have difficulty functioning?" <u>Id</u>. Zdrojewski replied: "Without it, I've got pain." <u>Id</u>.

Upon questioning by Respondent, Zdrowjeski stated that he did not know of any allergies to medicines and that he had quit smoking six years earlier. <u>Id</u>. However, upon Respondent's questioning him about his use of alcohol, Zdrojewski said that on weekends, he drank a case of beer but that he was "trying to stay off the hard liquor." <u>Id</u>. at 14. Respondent then asked him if he had "any medical problem" such as high blood pressure or diabetes and whether he had had any surgeries. <u>Id</u>. Zdrojewski stated that he had high blood pressure and was taking a drug for that; he also stated that he had had knee surgery and eye surgery when he "was a kid." <u>Id</u>.

Respondent then asked Zdrojewski if he used any recreational or IV drugs and if he had ever had any drug abuse or dependence problems. <u>Id</u>. Zdrojewski asked if "it's between us?" and when Respondent said "yeah," stated that he used "marijuana." <u>Id</u>. at 14-15. Respondent then asked him where had been going for his pain medicine, when he had last been there, and "[h]ow long were you over there?" <u>Id</u>. at 15. Zdrojewski again said that he had gone to Tampa Bay Wellness, that he had gone there for three or four months and that he had last been there "maybe" "two months ago." <u>Id</u>. Respondent again asked what drugs they (Tampa Bay Wellness) had him on; Zdrojewski again said 90 count of 80 milligrams, 240 count of thirty milligrams, and 60 count of Xanax two milligrams. <u>Id</u>.

Respondent then asked: "And you're not taking anything now?" <u>Id</u>. Zdrojewski replied that he did not "have anything," and Respondent asked: "Then, how are you doing?" <u>Id</u>.

Zdrojewski answered that he was "self-medicating," and when asked what "with," Zdrojewski asked if we can "wait till there is nobody in here?" <u>Id</u>. Respondent said "yeah," and eventually, Zdrojewski again said marijuana. <u>Id</u>.

Respondent then conducted a physical exam, which involved his listening to Zdrojewski's breathing, followed by various movements of his arms, legs, and fingers. <u>Id</u>. at 16. The exam lasted a total of 38 seconds. GX 8 (recording of visit). During the exam, Zdrojewski did not complain that any of the movements caused him pain. Id. at 16.

After the exam, Respondent asked Zdrojewski if anyone had ever reviewed his MRI with him; Zdrowjeski said "No." Respondent then explained:

You've got a little inflammation going on in the joints between your vertebrae and your neck but it's very minimal. That they described it as trace [T]hat's what your MRI says. Other than that it's normal. There's no disc herniations, everything else is in place. So that's good. That there's nothing else going on.

Id . at 16.

Zdrojewski then asked what was causing his headaches. <u>Id.</u> Respondent stated: "Oh, my God, there's nothing. I...I don't know. There's nothing around here that ... explains that." <u>Id.</u> Zdrojewski stated that "the last doctor said it radiated up and can cause it." <u>Id.</u> Respondent stated: "[Y]es if you have significant problems in your neck, it then ... it could do that, but I'm just saying, you[r] MRI doesn't show that." <u>Id.</u> Respondent then asked Zdrojewski to stand up and apparently to bend over, but Zdrojewski stated that he could not do so. <u>Id.</u>

Respondent then said: "Well . . . we have a little issue here. First of all your MRI doesn't show much of anything and secondly, drinking a case of beer is not compatible with taking a strong medicine like this." <u>Id</u>. at 17. Zdrojewski asserted that he could "pull that off." <u>Id</u>. Respondent then stated he was "not sure how you lived through all of this Oxy," and Zdrojewski replied: "I told you I didn't take, I didn't take all of that." <u>Id</u>.

Respondent explained that he "would feel very uncomfortable prescribing all this strong medicine . . . when I have knowledge that beer is being consumed." Id. Continuing,

Respondent stated that beer "has alcohol and that coupled with OxyContin and oxycodone and Xanax is being [a] very bad combination, as in you need to worry about death." Id. After Zdrojewski said "okay," Respondent explained that he had some people who told him that they "drink three or drink four cans of beer and I say, 'Listen, you need [to] drink or you take medicine.' They say, 'Fine, I, I won't drink but it's going to be hard for me to give up a case of beer a weekend.' That's some serious drinking." Id. After Zdrojewski said: "Well to make the headaches go away," Respondent asked: "You understand what I'm saying?" Id. Zdrojewski said, "I get it" and that he would "stop drinking." Id.

Respondent then asked Zdrojewski: "So you rather take the medicine than to be drinking, is that right?" Id. Zdrojewski said "yup," and Respondent said: "let me look at your chart to see what we can do to help you." Id. Respondent then asked Zdrojewski what he was "taking the Xanax for?" Id. Zdrojewski answered: "they just gave them to me." Id. Respondent then said: "You don't really need them," to which Zdrojewski replied: "I'll take them." Id. Respondent then said that if "you're not . . . riddled with anxiety and you're not having a . . . large amount of sleep problems, then we don't want to give you medicine you don't need." Id. Zdrojewski replied: That'll work with me doc," and Respondent stated "I just don't give you medicine just to write a prescription. So . . . so let me look at this." Id. After Respondent told Zdrojewski to lock up his medicine in a safe place, the latter thanked him and the visit concluded. Id. Respondent then issued Zdrojewski a prescription for 150 tablets of Roxicodone 30mg. GX 28, at 19.

On the history and physical examination form documenting the visit, Respondent wrote that on a zero to ten scale, Zdrojewski's pain was an "8 throughout the day," with "flare-ups of . . . 9-10." Id. at 2. Respondent also wrote that Zdrojewski "was confused by pain scale on assessment form" and indicated that his pain was "aggravated by" lifting, bending and twisting. Id. Respondent also wrote that Zdrowjeski had "severe pain in neck" and that "at times pain [is] so severe he is unable to do his work" and that his pain was "sharp." Id. Respondent also documented that he noted a muscle spasm in Zdrojewski's cervical area; however, Zdrowjeski testified that Respondent never touched his neck. Tr. Vol. 3, at 107.

Under his treatment plan, Respondent wrote:

When pt returns pt will need to have seen NSG who will need to have concurred that pain meds are justified. During this visit pt expresses that pain was severe, so I Rx'ed meds sufficient to control his pain. He previously was on a much higher dose including OC. But in light of the MRI findings, I would not expect that pt would have such severe . . . therefore, must obtain referral [with] NSG and probably refer to bd cert pain mgmt before continuing care. Most likely will be D/C if . . . he doesn't follow above plan.

Id. at 6.

In his testimony, Respondent explained that his plan was that "when patient returns, patient will need to have seen or will need to have seen neurosurgery who will need to have concurred that pain medicines are justified. So my plan was to send him to neurosurgery." There is, however, no evidence that Respondent even discussed with Agent Zdrojewski that he needed to be evaluated by a neurosurgeon, let alone referred him to one. See GX 8; see also Tr. Vol. 3, at 102.

The Government's Expert observed that it was significant that Agent Zdrojewski represented that he smoked marijuana and engaged in "excessive alcohol use" and "was bipolar." The Expert further testified that prescribing Roxicodone 30mg to someone who admitted to

¹⁸ Based on Respondent's testimony, I conclude that the abbreviation "NSG" refers to Neurosurgeon.

marijuana use was not an appropriate "first-line treatment" and was not within the standard of care in Florida. Tr. Vol. 7, at 176.

Notwithstanding that Respondent did not prescribe Xanax to Agent Zdrojewski, I conclude that the evidence as a whole supports a finding that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Roxicodone to him. 21 CFR 1306.04(a). More specifically, Zdrojewski presented with vague complaints, completely altered his pain rating from one end of the scale to the other and yet at no point related other symptoms which would be consistent with severe pain, and represented that he abused both marijuana and alcohol. Moreover, Respondent acknowledged that Zdrojewski's MRI was not significant, and while he conducted a physical examination (which lasted all of 38 seconds), Respondent proceeded to falsify the medical record by documenting findings for which he clearly had no basis, as well as a referral which never occurred. Finally, the Expert gave unrebutted testimony (which the ALJ credited) that prescribing Roxicodone 30mg was not within the appropriate first-line treatment under the standard of care. I also adopt the ALJ finding that Respondent failed to maintain accurate records as required by Florida's regulation.

See ALJ at 84.

Agent Ryckeley was another member of the "crew" which visited CCHM on July 23, 2010. Ryckeley likewise testified as to the monetary payments that were made for the office

¹⁹ The ALJ also found that "Respondent's failure to refer SA Zdrojewski to rehabilitation for his use of recreational and illicit controlled substances, and what may well have been his excessive use of licit controlled substances, is also inconsistent with Florida standards." ALJ at 84-85 (citing Fla. Admin. Code Ann. R. 64B8-9.013(e) (prior to Nov. 28, 2010 amendment) ("The physician should be willing to refer the patient as necessary for additional evaluation and treatment Special attention should be given to those patients who are at risk for misusing their medications [or] . . . 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.").

At its text make plain, this version of the rule – which was in effect at the time of the events at issue here - did not make such referrals mandatory. Most significantly, there is no evidence in this record establishing that the standard of care required that a patient presenting in the same manner as did SA Zdrojewski be referred at the first visit. Accordingly, I do not adopt the ALJ's finding.

visit and to receive expedited service, and that he was given several forms to complete. Tr. Vol. 3, at 201.

On his pain assessment form, Agent Ryckeley wrote "back discomfort" as the location of his pain, put a question mark in the entry for the pain's duration. GX 27, at 9. Ryckeley also indicated that his pain was "occasional" and not "continuous," and circled "2" on the numeric pain scale. <u>Id</u>. Finally, Ryckeley wrote that he was currently on 180 oxycodone 30mg, that he had no side effects, and that "fishing" made his pain worse. <u>Id</u>.

On the medical history form, Agent Ryckeley did not indicate that he had any of the listed conditions or diseases. <u>Id</u>. at 7. However, in the "location of pain" block, he wrote "Back Discomfort"; he also indicated that he was not under the care of a physician for the condition, and that he drank alcohol. <u>Id</u>. at 7-8._Moreover, he then listed his current medications as "None." Id. at 8.

Upon entering Respondent's office and exchanging pleasantries, Respondent asked Agent Ryckeley if it was his first visit (it was) and where his pain was. GX 7, at 18. Ryckeley said "back discomfort" and added: "I came in with . . . David Hays and all those guys." GX 7, at 18. Respondent said "right," and asked: "How long have you been having back pain?" Id. Ryckeley responded: "Uh, started in, uh, I got an MRI in May." Id. Respondent again asked when the pain started; Ryckeley replied: "Mid May is when the . . . discomfort started" and added that "it was just before the date on the MRI." Id.

Respondent then asked: "And what have you done to yourself?" <u>Id</u>. Agent Ryckeley stated that he had been on a sport fishing charter and "caught a decent size albacore" which he "was trying to land." <u>Id</u>. Respondent then asked: "And after that things started?" <u>Id</u>. Ryckeley stated that "what would happen after that" is that his girlfriend danced and "was taking some

thirties," and that he "took some of her thirties and . . . it put me in a state where, where I liked it, it made me feel better." <u>Id</u>. Continuing, Ryckeley stated: "so I experimented with that, I know I probably shouldn't have done that . . . but . . . I liked how it made me feel and I said, 'You know, best thing to do is come in and get evaluated by a doctor,' and . . . get your recommendation." <u>Id</u>. at 20.

Respondent then asked Ryckeley how he would "describe the pain" and noted that he needed Ryckeley to fill out the Pain Assessment Form, saying the words "sharp, shooting, stabbing, throbbing, aching." <u>Id</u>. Ryckeley stated: "It aches, I guess," and when Respondent asked: "Anything else?," answered: "I'm not good with words." <u>Id</u>.

Respondent then told Ryckeley to "stand up, turn around, and show where the pain is."

Id. Ryckeley said "okay," and apparently did not initially comply, as Respondent then said:
"No, show it, I mean can you touch where it hurts?" Id. Ryckeley asked: "Oh, point?";

Respondent said "yeah," and Ryckeley stated "it's in . . . my lower back area." Id. Respondent then asked if "the pain is there all the time?" Id. Ryckeley replied: "[I]t comes and goes, mostly comes when I fish." Id. Respondent then asked if the pain "stay[s] there or does it travel anywhere?" Id. Ryckeley answered: "Nope, it stays . . . in my back. Every, occasionally I get . . . headaches and stuff like that." Id. at 21. Upon a further question by Respondent, Ryckeley stated that the pain did not go into his buttocks and legs.

Respondent then asked Ryckeley "how bad" his pain was, apparently noting that the latter had circled the number 2 "on a scale of one to ten." <u>Id</u>. Ryckeley said: "probably around two." <u>Id</u>. Respondent asked: "A two?," and Ryckeley said "Uh-huh." <u>Id</u>. Respondent then asked Ryckeley if he had "ever tried anything else other than all of this fancy medicine?"; Ryckeley said "Oh, I really," but did not complete his answer before Respondent noted, "A two

here, here's the pain scale, I'm not sure, you maybe don't understand the pain scale." Id.

Ryckeley said "okay," and Respondent stated: "a one and two is . . . just sort of . . . a very mild kind . . . of a problem, ten is where you're screaming." Id. Ryckely replied "okay," and Respondent asked "would you characterize it as mild? Which is about one or two, or moderate? You know, five or six, or is it pretty severe, like eight or nine or ten." Id. Ryckeley stated: "Well, I guess it, it could be moderate, I would imagine . . . middle of the road." Id. Respondent stated "see," and Ryckeley explained: "like I said, I took my girl's pills and it made me feel good . . . so I never, I've really never thought about it after that." Id. at 22. Ryckeley added that he was no longer taking the pills because he was applying for a new job and had to take a urinalysis and that if he was "taking something, [and] didn't have a prescription," he "might not get the job." Id. Ryckeley then told Respondent that he had been taking the pills "about six times a day." Id.

Respondent asked Ryckeley: "How's [the pain] affected your life, your work, your home, has it?" <u>Id</u>. Ryckeley stated: "not, not really no. Especially now since I've been on . . . my girl's medication." <u>Id</u>. Respondent then asked Ryckeley about when he was not "on medication." <u>Id</u>. Ryckeley answered: "it makes it more difficult to fish." <u>Id</u>. Respondent laughed and said: "You're underwhelming me," and added "you're sort of telling me, you I do okay." <u>Id</u>. at 22-23. Respondent then told Ryckeley to "just listen" and added:

If I came to you and I wanted pain medicine right? Cause I have pain. And I told you that, 'Um, it's just like a one or a two and it only bothers me when I fish and it hasn't affected my life.' You think that would be an appropriate patient for pain medicine?

<u>Id.</u> at 23. Ryckeley replied: "[W]ell, it bothers me." <u>Id.</u>

Respondent then stated: "You're, you're like telling me that's there's nothing going on."

Id. Ryckeley attempted to interject, but Respondent continued, stating: "I'm writing you the

strongest medicine available. So I'm like, I'm thinking . . . what are we doing here?" <u>Id</u>.

Ryckeley stated "yea, I think I missed," and Respondent replied: "You're, I think, either I'm missing the point or you're missing the point." <u>Id</u>.

Ryckeley said: "I think I'm missing the point." <u>Id</u>. Respondent then added: "[B]ut you [are] telling me that the pain is a two and it doesn't affect you very often and you're doing fine." <u>Id</u>. After Ryckeley interjected that he was "talking on medication," Respondent asked: "it means to me . . . you know what that means to me?" <u>Id</u>. at 24. Ryckeley replied "No," and Respondent said: "You should just take Tylenol . . . Because. . . You don't have anything wrong, I don't get it." <u>Id</u>. Respondent asked: "What are you doing here?" and Ryckeley again insisted his pain level was "a two on the medication." <u>Id</u>.

Respondent and Ryckeley then discussed the latter's employment as a charter boat captain, followed by how long he had taken his girlfriend's medicine. <u>Id</u>. at 24-25. Ryckeley mentioned that he had broken up with his girlfriend and added that "sometimes people gave me two at the club and stuff like that." <u>Id</u>. at 25.

Respondent then asked Ryckeley if the pain depleted his energy, with the latter stating that it made him "less willing to do what I like to do" because he was "in discomfort." <u>Id</u>. Next, Respondent asked Ryckeley if he was "irritable or moody because of the pain?" Ryckeley answered: "Yeah, I guess I would cause I feel a lot better on the pills than I'm at, a lot better mood when I'm not in a discomfort. <u>Id</u>. Respondent followed this by asking if it affected his relationship in "any way." <u>Id</u>. Ryckeley answered: "I think it makes it better, the medicine." <u>Id</u>.

Respondent then asked Ryckeley: "[D]o they cause you problems at work?" <u>Id</u>.

Ryckeley said "Nope," prompting Respondent to ask: "I mean, you're able to work with the

pain?" <u>Id</u>. at 26. Ryckeley replied: "with the medicine, I misunderstood that question. I'm able to work with, . . . with the medicine." <u>Id</u>. Respondent then asked: "But you're now without the medicine, are you able to work without the medicine now?" <u>Id</u>. Ryckeley replied: "It makes it more difficult. Significantly more difficult." <u>Id</u>.

Respondent then asked Ryckeley whether he was allergic to any medicine (Ryckeley answering that he was not aware of any), whether he smoked (answering "no"), and whether he drank, with Ryckeley stating he was a social drinker. <u>Id</u>. Respondent then discussed with Ryckeley the danger of mixing alcohol with oxycodone, with the former saying "I'm not sure you yet have . . . an appreciation of how strong this medicine is, but medicine and alcohol, this medicine and alcohol is not to be mixed." <u>Id</u>. at 27.

Next, Respondent asked Ryckeley if he had any medical problems or surgeries; Ryckeley answered in the negative except for his having broken his nose three times. <u>Id</u>. Respondent then asked if he had ever "seen a doctor for this?" Id. Ryckeley said "no."

Respondent then asked: "But the thirties seem to work good for you?" <u>Id</u>. at 28.

Ryckeley answered: "Yeah, I like them," leading Respondent to ask: "You like them?" <u>Id</u>.

Ryckeley stated: "Well, which I mean, I think they, they work good." <u>Id</u>.

Respondent replied: "You know, you're killing me, I can't even believe I'm having this conversation." <u>Id</u>. Ryckeley maintained that he had "never been [an] educated man," prompting Respondent to state: "killing me." <u>Id</u>.

Respondent then proceeded to perform a physical examination, telling Ryckeley to perform various movements including raising his arms and legs, standing up, and walking across the room. <u>Id</u>. at 28. He also told Ryckeley to have a seat and to show him where he was sore. Id. In total, the exam took less than one minute. Id.; see also GX 7 (audio recording).

Respondent again asked Ryckeley whether he was on any medicines "right now" and how bad his pain was "right now." GX 7, at 29. Ryckeley now claimed that it was "a five or seven . . . after you explained the chart to me" and asserted that there were "a lot [of] words" on the forms that he "didn't understand." Id. Respondent expressed his understanding, and asked "[w]hat makes you hurt the most?" Id. Ryckeley replied that in charter fishing there was "running lines" and "a lot of standing out there." Id.

After a short discussion of sport fishing, Respondent said: "Alright . . . let's . . . get you started on some medicine, we'll see how you do." <u>Id</u>. at 30. Respondent then proceeded to discuss Ryckeley's MRI, which showed a bulging disc with "some inflammation" at L-3, and another bulging disc between L-5 and S-1. <u>Id</u>. at 30-31. Respondent then told Ryckeley not to take the medication other than as it said on the bottle; not to buy, sell or share them; and to keep his medicine locked up. <u>Id</u>. at 31. Respondent also said that it was serious medicine, and that "if you don't need it[,] I don't want you to take it but if your pain is such that . . . you can't function without it then . . . that's a reasonable indication." <u>Id</u>. at 32. Respondent then asked Ryckeley if his work was slow, and the visit ended. <u>Id</u>. at 32-33.

Regarding the discussion with Respondent as to his pain level, Agent Ryckeley testified that he believed Respondent was coaching him to increase his pain level to justify prescribing oxycodone 30mg. Tr. Vol. 3, at 209, 269. Agent Ryckeley also testified that Respondent "was a box-checker . . . and he was going through and checking the boxes and making sure [there was] every element to justify writing me . . . one of the strongest pain level – pain medicines available. He wanted to make sure all his Is were dotted and his Ts were crossed." Id. at 209-10. Respondent maintained, however, that Ryckeley presented as a person who "was not very educated" and "had difficulty in . . . grasping his description of his pain, his degree [of] pain."

Tr. Vol. 10, at 229. Respondent further testified that he "spent the time to try to explain to him the pain scale and . . . give[] him an opportunity to express himself fully so that . . . we were communicating." <u>Id</u>. Respondent further maintained that he "had every indication he was a real patient with pain." <u>Id</u>.

Although it is not entirely clear, the ALJ apparently credited Agent Ryckeley's testimony. See ALJ at 87. In any event, as ultimate factfinder, I find that the transcript of the visit – in particular Respondent's statements to Ryckeley that the latter was "underwhelming him," his asking Ryckeley "if I came to you and I wanted pain medicine" and "it's just like a one or a two . . . You think that would be an appropriate patient for pain medicine?," and his further statements that "you're like telling me that there's nothing going on" and "I think either I'm missing the point or you're missing the point" – fully support Ryckeley's interpretation of the conversation and demonstrates the utter implausibility of Respondent's testimony.

I therefore find that Respondent coached Agent Ryckeley to provide a pain level sufficient to justify prescribing oxycodone. This finding provides reason alone to conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he prescribed oxycodone to Agent Ryckeley.²⁰ 21 CFR 1306.04(a).

SA Brigantty also visited CCHM on July 23, 2010. However, in contrast to the other undercover patients, Agent Brigantty's complaint was generally neither vague nor inconsistent

²⁰ As the Government's Expert also testified, Agent Ryckeley "had stated he had received these drugs from a girlfriend, so he was not receiving them appropriately," Tr. Vol. 7, at 166, and told Respondent that the drugs "put me in a state were, were I liked it, it made me feel better" and he liked how the drugs made him feel. GX 7, at 19-20. Agent Ryckeley clearly presented as a drug-seeking patient, as Respondent himself recognized in his note for the visit in which he wrote: "I want to make sure pt is legitimate pain patient with chance of diversion." GX 27, at 6.

Moreover, in light of the clear evidence that Respondent coached Ryckeley to justify his prescribing, and the latter's presentation of as a substance abuser, I do not find that Respondent's discussion of the risks of combining alcohol and oxycodone mitigates his misconduct. I do, however, adopt the ALJ's finding that Respondent failed to maintain accurate records as required by State regulations. See ALJ at 90.

and he presented an MRI which reported that he had three bulging disks in his lumbar spine. GX 26, at 22.

Respondent asked Agent Brigantty where his pain was (Brigantty answering "his lower back"), how long it had been going on (Brigantty answering "about fifteen years"), how he hurt his back ("lifting heavy objects"), and whether he had been in an accident or fallen off a scaffold ("No"). GX 9, at 35-36. When asked to describe his pain, Brigantty initially complained that his back was "very stiff," but then added that "right now, it's going down . . . my leg, sometimes in on my [U/I], but for the most part, the left side hurts." GX 9, at 36. Upon questioning by Respondent as to whether his pain was "sharp," "shooting," "aching," "throbbing," or stabbing," Brigantty answered: "it depends on what's happening. Most of the time it's sharp." <u>Id</u>. at 36-37.

Moreover, when asked to rate his pain on the numeric scale, Brigantty stated that with the shooting it was "about six," and that "[i]f it's the other pain, it's going to debilitate for a little while, it's pretty f---ing bad." Id. at 37. After being told by Respondent that he would have to figure out what number corresponded to that, Brigantty again related that it could be "pretty f---ing bad" and that the pain went down his left leg although it was more like "on the lower back but towards" his buttocks. Id._Brigantty then related that he felt the pain "sometimes even in the middle back, [and] you feel like someone just punched you in the stomach and you can't breath for a little while." Id. After being interrupted by an unidentified female, Respondent then asked Brigantty what the pain felt like when it went down his leg. Id. at 38._Brigantty replied "it feels like electricity, I guess." Id.

Respondent then asked how the pain interfered with his work and life; Brigantty explained that he did odd jobs and that the pain interfered with his work ("Yeah, of course it does") and with the kids. <u>Id.</u> at 38-39. Respondent then explained that Brigantty had several

bulging disks and that "when the disk is bulging, it means it's pushed back here, pushed back into the nerve," and "[t]hat's what gives you the pain." <u>Id</u>. at 39.

Agent Brigantty asked Respondent if there was "anything you can do for that?" Id.

Respondent replied that other than surgery, "there's nothing you can do to push the disk back."

Id. at 40. Brigantty then asked how successful the surgeries are; Respondent answered that "if you have severe disease that . . . you know, [is] affecting you or giving you severe numbness or not letting you perform your work . . . then they can do the surgery," but "[n]obody will give you a guarantee." Id. Next, Respondent asked Brigantty if he smoked (with Brigantty answering "No"), drank ("occasionally"), was using either IV drugs ("No") or recreational drugs ("No"), as well as whether he had "any medical problems." Id. Brigantty said that the "girl told me my blood pressure was high today." Id. Respondent then stated that Brigantty's blood pressure was "very high" and asked if this was the first time he had been told this. Id. at 41. Brigantty answered: "They mentioned it in the past, but, I feel fine." Id.

Respondent then asked Brigantty where he had gone previously for pain medicine;
Brigantty replied that he went to Jacksonville, but "didn't like that experience" and "for the most part," he purchased them on the street. <u>Id</u>. When asked what he had been taking and how often, Brigantty said that he took Oxy thirties, but not often because "they are pretty expensive" and that someone had given him "a Xanie bar." <u>Id</u>. Respondent then asked how long Brigantty had been taking the medicine; Brigantty said for about two to three years. <u>Id</u>. at 42. Respondent then asked if the oxycodone seemed to help him; Brigantty replied: "Yeah, I was feeling good." <u>Id</u>.

Respondent then told Brigantty that his blood pressure was high and that he needed to get himself re-evaluated. <u>Id.</u> Respondent further explained: "Meaning you need to find a regular medical doctor as soon as possible and have that re-checked." Id. Brigantty asked, "Is that

bad?"; Respondent said "yes." <u>Id.</u> Brigantty then asked if the condition was "life threatening bad?" <u>Id.</u> Respondent answered: "It could be if this persists, it can give you a stroke, heart attack, so it must be re-checked, if it remains at this level you probably need to be on medication." <u>Id</u>. Respondent added that "[i]t sounds like other people have mentioned it to you but you haven't taken it too seriously." <u>Id</u>. Brigantty answered "yeah" and Respondent added that "it's very serious. It's a serious problem." <u>Id</u>. at 43.

After a further discussion of Agent Brigantty's blood pressure, Respondent performed a physical examination during which he had Brigantty breathe in and out and perform various exercises. <u>Id</u>. During the course of the examination, Respondent asked: "[a]nd the pain . . . just goes down that. . . that left leg?" <u>Id</u>. Brigantty answered: "Yeap." <u>Id</u>.

Brigantty then asked if "[t]his can get worse?" <u>Id</u>. Respondent said it could, and when asked if there were "things you could do," replied that Brigantty "could do some stretching exercises to try to . . . increase your muscle strength." <u>Id</u>. at 44. He then added that there was no "medicine to like move those discs back in place." <u>Id</u>.

Respondent then asked Brigantty what he had been given in Jacksonville; the latter again said "Oxy Thirties, a while ago," but that the "place was . . . disgusting." <u>Id</u>. Respondent asked if Brigantty "use[sic] to go to American?" <u>Id</u>. Brigantty stated:

Well they wanted me to . . . they wanted . . . the girls outside told me they want a physician that I was seeing, and I'm like, "I'm not seeing a physician." Then they went, "You need to write something." Someone said American, I was like, "F---it, I'll put American." But I don't see doctors, doc. I can't afford constantly going to the doctor. I barely could come in here today.

<u>Id</u>. Respondent acknowledged this statement, and Brigantty added that "that's the only reason I put that down, cause . . . I didn't even know that I had high blood pressures. You know?" <u>Id</u>. at 45. _Respondent replied that he "want[ed] to make sure that you get that under control," and

asked if Brigantty was "sleeping ok?" <u>Id</u>. Once again, Brigantty represented that he had pain, stating, "It hurts, you know what I mean?" <u>Id</u>. Respondent replied, "Right, but if the pain is under control you'd sleep better." <u>Id</u>. Brigantty said that he thought so and "absolutely." <u>Id</u>. Respondent then stated: "Well, we'll get you started on some medicine and we'll see how you do? You're not on anything now?" <u>Id</u>. Brigantty said he was not. <u>Id</u>. Respondent then prepared a prescription for 150 Roxicodone 30mg, which he gave to Brigantty, telling him to take the medicine as it was prescribed and adding: "Don't buy it, sell it, share it, keep it locked up in a safe place." Id. at 46; GX 26, at 19.

Citing "numerous violations of applicable standards and regulations," the ALJ concluded that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescription to Agent Brigantty. ALJ at 72-73. More specifically, the ALJ noted that "[g]iven SA Brigantty's confessed illicit use of controlled substances, Respondent failed to 'refer the patient as necessary for additional evaluation and treatment,' notwithstanding the Florida regulations provided that '[s]pecial attention should be given to those pain patients who are at risk for misusing their medication' or who 'pose a risk for medication misuse or diversion" ALJ at 68 (quoting Fla. Admin Code Ann. R. 64B8-9.013(3)(e)).

The ALJ further noted that "[t]he record reveals interactions between Respondent and SA Brigantty that reflect poorly both as to Respondent's standard of care as a physician and as to Respondent's knowledge of operations at CCHM." <u>Id</u>. at 68-69. Among other things, the ALJ faulted Respondent because he "did not offer to prescribe blood pressure medication or perform any diagnostic testing for blood pressure," <u>id</u>. at 68-69; and "did not refer SA Brigantty to any particular 'regular doctor," which the ALJ concluded "is inconsistent with the referral standard

contained in Fla. Admin Code Ann. R64B8-.013(3)." <u>Id.</u> at 70._The ALJ further found that Respondent gave inconsistent testimony as to why he did not prescribe blood pressure medication, noting that Respondent initially testified he "didn't want to prescribe medication for people I was only going to see one time," ALJ at 69 (citing Tr. Vol. 2, at 169, 214-15), yet later testified that his goal was to put Brigantty "on a therapeutic trial of" pain medication, and that "I was going to see him back in a month" and see how he did. Tr. Vol. 2, at 177-78; 215 (cited at ALJ 69-70).

As for the ALJ's various criticisms of Respondent's handling of Brigantty's high blood pressure, there is no evidence in this record establishing that prescribing oxycodone is contraindicated for a patient with this condition. Moreover, even if Respondent's failure to treat Brigantty's blood pressure²¹ constitutes civil negligence - and there is no evidence that it does - this alone does not establish a violation of the CSA's prescription requirement. See Laurence T. McKinney, 73 FR 43260, 43266 (2008) (citing cases). Nor is the ALJ's conclusion that Respondent's failure to refer Brigantty "to any particular 'regular doctor' . . . is inconsistent with the referral standard" of the Florida pain regulation, ALJ at 70 (citing Fla. Admin. Code Ann. R.64B8-9.013(3)), supported by either the Expert's testimony or citation to any decision of the Florida courts or Board of Medicine.

To be sure, Respondent's prescribing of oxycodone to a patient who told him he had obtained the drug on the street and whom he did not expect to see again, raises the issue of how he would effectively monitor his patient. However, while the Government's Expert acknowledged on cross-examination that controlled substances can be prescribed to a patient

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²¹ As for the ALJ's criticism that Respondent did not "perform any diagnostic testing for blood pressure," ALJ at 69, here again, the record is devoid of any evidence establishing what tests are required under the standard of care, and in any event, the issue of the adequacy of Respondent's evaluation and treatment of Agent Brigantty's blood pressure is for the state medical board and not this Agency.

who presents with a history of drug abuse if it is done "very carefully with proper monitoring in place," Tr. Vol. 8, at 68; the Expert did not further explain what measures are required to properly monitor a patient under the standard of professional practice nor testify that it exceeds the bounds of professional practice to a prescribe to a person under these circumstances.

Indeed, with respect to Agent Brigantty (as opposed to the other patients), the testimony of the Government's Expert was not particularly illuminating on the ultimate issue of whether Respondent complied with 21 CFR 1306.04(a) in prescribing Roxicodone to him. See Tr. Vol. 7, at 157-162. When asked by Government counsel what information "was significant in considering whether controlled substances should have been . . . prescribed," the Expert noted that Brigantty "saw [Respondent] complaining of sharp, shooting pain in his lower back with radiation into his left leg and buttock. Pain is severe." Id. at 157. While the Expert observed that "the physical exam portion . . . is a lot of check marks involving various portions of the fill-in places for the physical exam," the Expert offered no further testimony to the effect that the Respondent's physical exam did not support the findings and diagnosis that were documented. Likewise, the Expert testified that Respondent noted "bony tenderness being present from L1 to L5 over the entire lumbar spine into the buttock," yet offered no testimony that this finding could not have been made based on the physical exam that was performed. Id. at 158. _Moreover, Agent Brigantty did not remember if Respondent had palpated his back. Tr. Vol. 2, at 41.

Later, Government Counsel asked the Expert "what, if any, information did [Agent] Brigantty give to [Respondent] that's of significant importance?" Tr. Vol. 7, at 159-60. The Expert replied:

Well, he stated he had low back pain for 15 years duration. He wasn't sure of the cause. It may have occurred lifting at work. He noted it shooting down into his leg, into the left leg and buttock, and stated it was severe. He rated the pain as six

throughout the day and with flare-ups a ten, aggravated by lifting, bending, twisting, relieved by resting.

Id. at 160.

Subsequently, the Government asked the Expert if he saw in Agent Brigantty's Patient File "any significant medical information that justifies the issuance of controlled substances prescriptions?" Id. at 162._The Expert answered, "I do not" and provided no further explanation as to why the information he had previously related regarding Brigantty's complaint, history and physical exam did not support Respondent's diagnosis and the prescription. Id. Indeed, the Expert did not even acknowledge the MRI report Brigantty presented, let alone explain why the MRI's findings combined with the other information, did not justify the diagnosis and the issuance of the prescription. In short, substantial evidence does not support a finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing to Agent Brigantty.

²² The ALJ also cited the Government's Expert testimony "that a patient who is illegally buying drugs on the street, and who requests that the same drug be prescribed, should be precluded from receiving prescriptions for controlled substances." ALJ at 72 (citing Tr. Vol. 7, at 161). However, even assuming that the Expert's testimony reflects the accepted standards of professional practice, neither the transcript, nor the DVD of Agent Brigantty's visit, provide evidence that the Agent requested that Respondent prescribe Roxicodone 30mg to him.

The Government and the ALJ also noted that there was no evidence that Respondent discussed the risks and benefits of controlled substances notwithstanding that he documented in the medical record that he did so. While this may constitute a violation of the State's regulations (which require both that he do so and document having done so), as well as some evidence that a practitioner exceeded the bounds of professional practice, by itself it is not conclusive proof that a prescription was issued as part of a drug deal.

Finally, the ALJ found it significant that Respondent prescribed to Agent Brigantty notwithstanding that he had told Respondent that he had falsified his medical record by listing on his history that he had gone to a clinic to which he had not gone. See ALJ at 71. According to the ALJ, "[a]pplicable Florida regulations are clear about the mandatory weight of the recordkeeping guideline: 'The physician is required to keep accurate and complete records' before prescribing controlled substances." Id. (citing Fla. Admin. Code Ann. r. 64B8-9.013(f)). The ALJ then reasoned that "Respondent's acquiescence in recordkeeping inaccuracies weighs heavily against [his] continued registration." Id.

While I agree that there are numerous other apparent violation of the State's regulations (including with respect to Agency Brigantty by documenting having discussed various items which he did not do), see ALJ at 71-72, I do not rely on the above discussion. As the evidence shows, on the history and physical examination form, Respondent documented that Brigantty's "Past history of Pain Management" included "Jacksonville and then the street." This was an accurate statement of what Agent Brigantty had told Respondent.

Accordingly, with the exception of the visit of Agent Brigantty, I reject Respondent's Exceptions to the ALJ's findings that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to Agents Marshall, O'Neill, Doklean, Priymak, Zdrojewski and Ryckeley and thus violated both federal and state law. 21 CFR 1306.04(a), 21 U.S.C. § 841(a)(1); Fla. Stat. Ann. § 458.331(1)(q). I further find that substantial evidence supports a finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to Agent Saenz. See id; see also 5 U.S.C. § 557(b) ("On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision. . . . "). I also adopt the ALJ's findings and legal conclusions with respect to each of the Agents who saw Respondent at Commercial Medical Group, including his finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed Xanax to Agent Bazile. See ALJ at 92 (citing 21 CFR 1306.04(a)). In addition, substantial evidence also supports the ALJ's numerous findings that Respondent failed to maintain accurate records in violation of Florida's regulations, see ALJ at 93 (citing Fla. Admin. Code r.64B8-9.013(3)(f)), and that he falsified numerous patient records to support the prescribing of controlled substances.²³

In his Exceptions, Respondent further contends that he "was denied the opportunity to review and produce files of patients that he had discharged from the clinic" which "had been

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²³ In his Exceptions, Respondent argues that "[t]he Government successfully prevented Dr. Wolff from inquiring whether undercover patients had made subsequent visits to the clinic and whether [they] had been unsuccessful in acquiring controlled substances from Dr. Wolff." <u>Id</u>. at 12. In his Exceptions, Respondent does not identify which of the Agents the ALJ precluded him from asking whether they had returned to the clinic. Upon reviewing the record, it is noted that while the ALJ sustained the Government's objection to Respondent's asking this question on cross-examination of two of the Agents, he did so on the ground that the question was beyond the scope of the direct examination. <u>See</u> Tr. Vol. 3, at 183, 276-77. Respondent does not contend, however, that he sought to subpoena the Agents to ask this question of them. In addition, the patient files contain no evidence that any of the eight Agents made undercover visits after the dates to which they testified as having obtained controlled substances on from Respondent. I thus reject this Exception.

seized by [the Agency] pursuant to a federal search warrant." Exceptions at 9-10. Respondent contends that "[t]he discharge files evidence [his] compliance with Florida Standards of Care, Florida Medical Regulations, as well as state and federal law." Id. at 10. He further contends that the files "would also permit [him] to [show his] methodology in determining whether or not to write prescriptions for persons claiming to have pain" and "that he would not automatically write prescriptions merely because individuals claimed to be suffering from pain." Id.

As for the contention that these files would permit him to show his methodology in determining whether to write prescriptions and that he would not automatically write prescriptions merely because a person complained of pain, these files are not relevant in assessing Respondent's compliance with federal and state standards in prescribing to the undercover CCHM patients. With respect to these patients, Respondent had ample opportunity to testify as to his methodology in determining whether to prescribe to the Agents as he was provided with the files of each of the Agents whose prescriptions form the bulk of the Government's case against him.²⁴

As for the contention that the discharged patient files would show his compliance with applicable standards, I will credit his testimony that he has discharged hundreds of patients. Tr. Vol. 9, at 272. Accordingly, the files were not necessary to prove his assertion and Respondent cannot claim prejudice. <u>Cf.</u> 5 U.S.C. § 706 ("due account shall be taken of the rule of prejudicial error").

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²⁴ It is acknowledged that the Government did not turn over the patient file for Agent Bazile, who saw Respondent at CMG. However, the ALJ's finding that Respondent violated 21 CFR 1306.04(a) when he prescribed Xanax to her was based on Agent Bazile's credited testimony. More specifically, Agent Bazile testified that she asked Respondent for something to help her sleep. Tr. Vol. 6, at 23. Respondent then asked if she had trouble sleeping, and Agent Bazile replied "sometimes," prompting Respondent to remark that she was "not very convincing." <u>Id.</u> at 23-24. At the hearing, Respondent testified that he could not provide the reason he prescribed Xanax to Agent Bazile without having the opportunity to see her patient file. Tr. Vol. 10, at 53. I adopt the ALJ's finding noting that Respondent had ample opportunity to cross-examine her regarding the circumstances surrounding her obtaining of the Xanax prescription and yet did not ask her a single question about this prescription. <u>See Tr. Vol. 6</u>, at 30-61. I thus find her testimony credible as did the ALJ. ALJ at 9.

However, that Respondent discharged hundreds of other patients does not render the prescriptions he issued to Agents Marshall, O'Neill, Doklean, Priymak, Zdrojewski, Ryckeley, Saenz and Bazile any less unlawful. <u>See Dewey C. MacKay</u>, 75 FR 49956, 49977 (2010) (quoting <u>Jayam Krishna-Iyer</u>, 74 FR 459, 463 (2009) (holding that a physician's lawful "prescribings to thousands of other patients [does] not ... render [his] prescribings to undercover officers any less unlawful, or any less acts which 'are inconsistent with the public interest'")). Indeed, with respect to these patients, the evidence is clear that Respondent was not duped and that he intentionally diverted controlled substances. <u>See</u> ALJ at 95. Thus, the

Under the CSA, a practitioner is not entitled to a registration unless [he] "is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(f). Because under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [his] professional career.

Jayam Krishna-Iyer, 74 FR 459, 463 (2009).

In <u>Krishna-Iyer</u>, I further explained that in past cases, this Agency has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion. <u>Id. See also MacKay</u>, 75 FR at 49977; <u>Paul J. Caragine</u>, 63 FR 51592, 51599 (1998) ("[T]he Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients."); <u>id.</u> at 51600 ("[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.").

While in <u>Caragine</u>, my predecessor did consider "that the patients at issue ma[de] up a very small percentage of Respondent's total patient population," he also noted – in contrast to most of the prescriptions at issue here – "that [those] patients had legitimate medical problems that warranted some form of treatment." <u>Id</u>. at 51601. Moreover, in contrast to this case, in <u>Caragine</u>, there was no evidence that the practitioner had intentionally diverted. <u>Id</u>. <u>See also Medicine Shoppe – Jonesborough</u>, 73 FR 364, 386 & n.56 (2008) (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render . . . flagrant violations [acts which are] 'consistent with the public interest.'"), <u>aff'd</u>, <u>Medicine Shoppe-Jonesborough v. DEA</u>, 300 Fed. Appx. 409 (6th Cir. 2008).

Indeed, DEA has revoked other practitioners' registrations for committing as few as two acts of diversion, and "can revoke based on a single act of diversion" absent a credible showing by the registrant that he accepts responsibility for his misconduct. MacKay, 75 FR at 49977. See also Alan H. Olefsky, 57 FR 928, 928-29 (1992) (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacy and noting that the respondent "refuses to accept responsibility for his actions and does not even acknowledge the criminality of his behavior"); Sokoloff v. Saxbe, 501 F.2d 571, 576 (2d Cir. 1974) (upholding revocation of practitioner's registration based on nolo contendere plea to three counts of unlawful distribution).

²⁵ As I have previously explained,

Government has made out a <u>prima facie</u> case that Respondent "has committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4).

As the ALJ explained, under longstanding Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration." Medicine Shoppe, 73 FR at 387 (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." Medicine Shoppe, 73 FR at 387; see also Jackson, 72 FR at 23853; John H. Kennedy, 71 FR 35705, 35709 (2006); Prince George Daniels, 60 FR 62884, 62887 (1995). See also Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir. 2008) ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination). In

Accordingly, evidence that a practitioner has treated thousands of patients does not negate a <u>prima facie</u> showing that the practitioner has committed acts inconsistent with the public interest. While such evidence may be of some weight in assessing whether a practitioner has credibly shown that he has reformed his practices, where a practitioner commits intentional acts of diversion and insists he did nothing wrong, such evidence is entitled to no weight. <u>Krishna-Iyer</u>, 74 FR at 463.

²⁶ As the ALJ explained, the public interest factors are "considered in the disjunctive. [I] may properly rely on any one or a combination of those factors, and give each factor the weight [I] deem appropriate, in determining whether a registration should be revoked or an application for registration should be denied." ALJ at 43 (citing cases); see also Hoxie v. DEA, 419 F.3d, 477, 482 (6th Cir. 2005). Nor am I required to make findings as to all of the factors. Hoxie, 419 F.3d at 482. Moreover, whether conduct is considered under factor two – the experience factor, or factor four – the compliance factor, or both factors, is of no legal consequence because the fundamental question is whether the registrant "has committed such acts as would render [his] registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Thus, as both the Agency and various courts of appeals have recognized, findings under a single factor are sufficient to support the revocation of a registration, especially where the proven misconduct involves egregious acts. See Hoxie, 419 F.3d at 482; Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005); Krishna-Iyer, 74 FR at 462.

That said, I have considered the ALJ's findings with respect to each of the factors and adopt them except as noted herein.

addition, DEA has held that a registrant's candor is an important factor in the public interest determination. <u>See Satinder Dang</u>, 76 FR 51424 (2011); <u>Alan H. Olefsky</u>, 76 FR 20025 (2011); <u>The Lawsons</u>, <u>Inc.</u>, 72 FR 74334 (2007). <u>See also Hoxie</u>, 419 F.3d at 483.

It is acknowledged that Respondent testified that he had fired several clinic employees after he purchased CCHM and that he brought in a risk manager to assess the clinic's procedures and to create a policy and procedures manual. However, as the ALJ found, "Respondent's testimony . . . repeatedly demonstrated [his] belief that he had engaged in no past misconduct and was in full compliance with existing laws and regulations," as well as "a remarkable lack of acknowledgment and recognition of the risks of diversion." ALJ at 97-98. In addition, the ALJ found that "Respondent's testimony in numerous instances was not credible and reflected an overall lack of admission of past misconduct, let alone acceptance of responsibility." Id. at 98. Indeed, much of his testimony regarding the CCHM patients was patently disingenuous. Accordingly, I adopt the ALJ's conclusion that Respondent has "fail[ed] to accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct," ALJ at 98, and therefore hold that he has not rebutted the Government's prima facie case. Given the egregiousness of his misconduct, I further adopt the ALJ's recommendation that Respondent's registrations be revoked and that any pending application for renewal or modification of his registrations be denied.

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 Certificates of Registration FW1453757, BW3918440, BW4448571, AW2065058, FW1338690, BW4362935, AW2654639, AW8594233, and BW0601446, issued to Randall L. Wolff, M.D., be, and they hereby are, revoked. I also order that any pending application of Randall L. Wolff, M.D., to renew or modify these registrations, as well as any pending application for a new registration, be, and they hereby are denied. This order is effective immediately.²⁷

Dated: January 19, 2012 Michele M. Leonhart Administrator

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²⁷ For the same reasons that I ordered the immediate suspension of Respondent's registrations, I conclude that the public interest requires that his order be effective immediately. 21 CFR 1316.67.

RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

I. Introduction

A. The Order to Show Cause and Immediate Suspension of Registration

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 or Government) should revoke a physician's DEA Certificates of Registration (CORs) as a practitioner pursuant to 21 U.S.C. § 824(a)(4) and deny, pursuant to 21 U.S.C. § 823(f), any pending applications for renewal or modification thereof and any application for a new COR. Without these registrations, Respondent Randall L. Wolff, 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.

On December 16, 2010,¹ the Deputy Administrator, DEA, served an Order to Show Cause and Immediate Suspension of Registration (OSC/IS) upon Respondent, dated December 14, 2010. The OSC/IS immediately suspended Respondent's nine (9) DEA CORs as a practitioner, and also provided notice to Respondent of an opportunity to show cause as to why the DEA should not revoke Respondent's CORs, pursuant to 21 U.S.C. § 824(a)(4), and deny, pursuant to 21 U.S.C. § 823(f), any pending applications for renewal or modification thereof and any applications for a new COR, alleging that Respondent's continued registration is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f).

¹ The Government's Notice of Service of Order to Show Cause and Immediate Suspension of Registration states that "Service was completed on December 16, 2010." (Notice of Service at 1.) In his hearing request, Respondent states that "Dr. Wolff was served on December 17, 2010...." (Hg. Req. at 2.) Respondent subsequently stipulated that service occurred on December 16, 2010.

The OSC/IS alleges that Respondent is registered as a practitioner in Schedules II through V under DEA registration numbers FW1453757, BW3918440, BW4448571, AW2065058, FW1338690, BW4362935, AW2654639, AW8594233 and BW0601446, and that on or about August 12, 2010, Respondent submitted an application for registration, assigned Control Number W10053115C, as a practitioner in Schedules II through V. (Administrative Law Judge (ALJ) Ex. 1 at 1-2.)

The OSC/IS further alleges that between approximately March 5, 2010, and July 23, 2010, Respondent distributed controlled substances (to include oxycodone and alprazolam) by issuing prescriptions to at least eleven undercover law enforcement officers for other than a legitimate medical purpose or outside the usual course of professional practice. In particular, the OSC/IS alleges that on March 5, 2010, Respondent distributed to three undercover law enforcement officers various quantities of controlled substances after conducting little or no physical examination, among other deficiencies.

In addition, the OSC/IS alleges that from April 7, 2010, through July 23, 2010, Respondent distributed oxycodone and alprazolam tablets to at least eight undercover law enforcement officers under circumstances similar to those noted above, to include little or no physical examination, no diagnosis warranting the prescription for controlled substances and under circumstances which Respondent knew or should have known that prescribing controlled substances was for other than a legitimate medical purpose.

Finally, the OSC/IS alleges that Respondent's registered location associated with DEA COR FW1453757 is the location of Coast to Coast Healthcare Management Pain Clinic (CCHM) and the location where the vast majority of the undercover activity occurred; that from approximately July 30, 2009, through December 29, 2009, Respondent ordered approximately 249,000 dosage units of oxycodone that were delivered to this location; and that from approximately January 4, 2010, through September 1, 2010, Respondent ordered approximately 267,000 dosage units of oxycodone that were delivered to this location.

In addition to the OSC/IS, the Government also noticed and alleged additional information in its initial and supplemental prehearing statements to include Automation of Reports and Consolidated Orders System (ARCOS) data pertaining to Respondent, along with medical expert opinion regarding Respondent's prescribing and recordkeeping practices.

Following prehearing procedures, a hearing was held in Ft. Lauderdale, Florida between February 15, 2011, and February 18, 2011, and in Miami, Florida between March 8, 2011, and March 17, 2011, with the Government represented by counsel and Respondent 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 of fact have been adopted, they are substantively incorporated into those set forth below.

II. ISSUE

Whether the record establishes that Respondent's DEA CORs FW1453757, BW3918440, BW4448571, AW2065058, FW1338690, BW4362935, AW2654639, AW8594233 and BW0601446 as a practitioner should be revoked and any pending applications for renewal or modification thereof and any applications for a new COR, to include application WI0053115C, 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 FACT³

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

² Hearing was recessed over the weekend of March 12-13, 2011.

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³ In addition to the evidence discussed in this Section, additional evidence and findings of fact are discussed in later Sections of this Recommended Decision.

A. Stipulated Facts⁴

- 1. Respondent is registered with DEA as a practitioner in Schedules II through V under DEA registration numbers FW1453757, BW3918440, BW4448571, AW2065058, FW1338690, BW4362935, AW2654639, AW8594233 and BW0601446 at 328 East Hillsboro Blvd., Deerfield Beach, Florida 33441; Delray Beach Fire Dept., 501 W. Atlantic Avenue, Delray Beach Florida 33444; Palm Beach Fire Rescue, 300 N. County Road, Palm Beach, Florida 33480; West Palm Beach Fire Dept., 500 North Dixie, West Palm Beach, Florida 33401; Wycliffe Golf & Country Club, 4160 Wycliffe Country Club Drive, Wellington, Florida 33449; Public Safety Fire Department, 560 US Highway 1, North Palm Beach, Florida 33408-4902; Greenacres City Public Safety, 2995 Jog Road, Greenacres City, Florida 33467; 10985 Blue Palm Street, Plantation, Florida 33324-8234 and Lake Worth Fire Dept., 1020 Lucerne Ave., Lake Worth, Florida 33460, respectively.
- Respondent's DEA registration numbers FW1453757, BW3918440, BW4448571, AW2065058,
 FW1338690, BW4362935, AW2654639, AW8594233 and BW0601446 expire by their terms on May 31,
 May 31, 2012, May 31, 2013, May 31, 2012, May 31, 2012, May 31, 2013, May 31, 2012, May 31,
 and May 31, 2011, respectively.
- 3. On or about August 12, 2010, Respondent filed an application with DEA for a DEA COR as a practitioner to handle controlled substances in Schedules II through V at 8609 Forest City Road, Orlando, Florida 32809; this application was assigned DEA Control Number W10053115C. Respondent's application is pending.
- 4. On December 16, 2010, a federal criminal search warrant was executed at 328 East Hillsboro Blvd., Deerfield Beach, Florida 33441, one of Respondent's registered locations. Respondent was simultaneously served with the DEA OSC/IS.
 - 5. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii).

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⁴ (<u>See ALJ Ex. 8; see also</u> Tr. vol. 5, at 4-5.)

- 6. OxyContin is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii).
- 7. Roxicodone is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii).
 - 8. Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).
- 9. Xanax is a brand of alprazolam, a Schedule IV narcotic controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).
- 10. Vicodin is a brand of hydrocodone combination product, a Schedule III narcotic controlled substance pursuant to 21 C.F.R. § 1308.13(e)(1)(iv).
 - 11. Soma is a brand of carisoprodol, a non-controlled⁵ muscle relaxant.

B. Introduction

Respondent completed his internship and residency in the field of internal medicine in 1980, subsequently working in emergency medicine as well as completing a fellowship in pulmonary/critical care. (Tr. vol. 9, at 211.) Respondent worked in Florida as an emergency department physician at JFK Medical Center beginning in 1982, later becoming Deputy Medical Director, and eventually Medical Director from 1995 to 2001. (Tr. vol. 9, at 214.) Respondent next worked as a regional medical director for three hospitals in California for a little more than a year, before returning to Florida to work in several different emergency departments. (Tr. vol. 9, at 216-17.) Respondent began a clinic in Delray Beach, Florida, and also worked as medical director for various municipal and community fire and emergency departments. (Tr. vol. 9, at 217.)

In July 2009 Respondent accepted a position at Commercial Medical Group (CMG),⁶ a pain management clinic in Fort Lauderdale, Florida. Respondent's employment at CMG ended in February or

⁵ Although not pertinent to the instant proceeding, I note that because of its potential for abuse, DEA has initiated a proceeding to place carisoprodol into Schedule IV under the Controlled Substances Act. <u>See</u> 74 Fed. Reg. 59,108, 59,109 (DEA 2009).

March 2010 due to a conflict between Respondent and the owner, Mr. Vincent Colangelo. (Tr. vol. 9, at 220.)

Respondent next worked for another clinic known as American Pain for approximately one week, before the clinic was closed down.⁷ (Tr. vol. 9, at 235.) In April 2010, Respondent began working for another pain clinic, CCHM, initially working there with three or four other doctors until October 2010, when Respondent's role changed from independent contractor to owner of the clinic. (Tr. vol. 9, at 221.) Respondent remained at CCHM as owner and practicing doctor from October 2010 until mid-December, 2010, when the clinic was closed by DEA. (Tr. vol. 9, at 222.)

C. Evidence

1. Background

The Government's evidence included testimony from seventeen witnesses, including

Respondent and a pain management expert, Dr. Scott A. Berger, M.D. Three witnesses were undercover law enforcement officers who posed as patients and received treatment from Respondent at CMG: DEA Special Agent (SA) Mark McClarie (SA McClarie); SA Rochelle E. Burnett Bazile (SA Bazile); and SA Kirk

Miller (SA Miller). Eight witnesses were undercover law enforcement officers who posed as patients and received treatment from Respondent at CCHM: SA Nicholas Priymak (SA Priymak); SA Jeffrey K. O'Neil (SA O'Neil); SA Julia Saenz de Viteri (SA Saenz); SA Marc A. Marshall (SA Marshall); DEA Task Force

Officer (TFO) Dana G. Doklean (TFO Doklean); SA Louis J. Ryckeley (SA Ryckeley); SA Brian M. Zdrojewski (SA Zdrojewski); and SA Edwin Brigantty (SA Brigantty). Mr. Kyle J. Wright, Unit Chief, DEA Office of Diversion Control, testified regarding ARCOS data pertaining to Respondent. DEA Diversion Investigator

⁶ Respondent testified that CMG had previously been called Seaside Pain Management Clinic, but that the name was changed in or about August or September 2009. (Tr. vol. 11, at 95.)

⁷ Respondent testified on cross-examination that the only pain clinics he worked at were CMG and CCHM, except that he also worked "for a brief time in Orlando" but did not remember the name of the clinic. (Tr. vol. 11, at 76.)
⁸ The ARCOS evidence shows trends in Respondent's prescribing of controlled substances over time as well as absolute numbers of dosage units prescribed. (See Tr. vol. 1, at 100-169; see also Gov't Exs. 13 & 30.) Mr. Wright could not testify as to the causes of the trends other than to identify that the trends existed. (E.g., Tr. vol. 1, at

(DI) Barbara Boggess (DI Boggess) testified regarding Respondent's DEA certificates of registration. Finally, the evidence included testimony from DEA TFO Robbie R. Weir (TFO Weir), "case agent" for the investigation of CCHM, and SA Joseph Gill (SA Gill), "case agent" for the investigation of CMG.

The Government's evidence also included various audio and video recordings of undercover meetings that occurred at CMG and CCHM, along with transcripts of portions of the various recordings. Additionally, the evidence included eight patient files associated with undercover visits to CCHM. No patient files were offered with regard to undercover visits to CMG.

Respondent's evidence included testimony from four witnesses, including Respondent. Three witnesses provided testimony related to three of Respondent's registered locations: Phil Webb, Fire Chief, West Palm Beach Fire Department; Mark Pure, EMS Chief, Greenacres City Department of Public Safety; and David Dyal, Assistant Fire Chief, Stuart, Florida. Respondent testified regarding his education and professional background, as well as his prescribing practices. Respondent's evidence also included eight patient files associated with undercover visits to CCHM, ¹⁰ along with six other patient files reflecting prior treatment by Respondent. (Resp't Exs. 1-8; 11, 13, 15-17 & 19.)

With the exception of Respondent and Dr. Berger, 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

^{148.)} The Government concedes, correctly, that "[s]tanding alone this ARCOS data is not persuasive" (Gov't Br. at 8.) The Government argues, however, that in conjunction with evidence of Respondent's prescribing practices, the "ARCOS data . . . reveals . . . the impact that the Respondent's illegal conduct had on the health and safety of the public." (Gov't Br. at 8.) To the contrary, in the form it was offered, the ARCOS evidence provides little insight into whether Respondent's conduct was consistent or inconsistent with the public interest. See Gregg & Son Distribs., 74 Fed. Reg. 17,517, 17,517 n.1 (DEA 2009) ("To make clear, it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding.")

⁹ No recording was made of the meeting between SA Bazile and Respondent at CMG, or SA Saenz and Respondent at CCHM, due to recording failures.

¹⁰ Respondent argued at hearing that use of separate copies of patient files for the eight undercover visits to CCHM was necessary because the source of the files, and arguably content, varied from those presented by the Government. In the absence of an objection by the Government, the patient files, which are substantially identical to those offered by the Government, were admitted. (Tr. vol. 10, at 86-88; Tr. vol. 11, at 46.)

of memory for past events. Each witness presented testimony in a professional manner and the material portions of the testimony was consistent with other credible evidence of record. Respondent's testimony was presented in a professional and serious manner, but as more fully explained in the discussion section below, I find it to be only partially credible. Dr. Berger's testimony was generally credible, but was diminished in several respects by various factual errors, as more fully explained below.

2. Expert Testimony and Report

The Government presented the testimony of Dr. Scott A. Berger, M.D., along with a written report prepared by Dr. Berger (Gov't Ex. 32), pertaining to his review of various DEA reports of investigation and eight patient files related to DEA undercover visits to CCHM between April 7, 2010, and July 23, 2010. Dr. Berger did not review or offer any testimony related to three undercover patient visits to CMG.

The Government offered Dr. Berger as an expert in the legitimate and illegitimate use of narcotic controlled substances related to pain management. (Tr. vol. 7, at 38.) Dr. Berger testified that he has over twenty years of experience in treating chronic pain patients and is certified by the American Board of Anesthesiology, as well as the American Academy of Pain Management. (Tr. vol. 7, at 11; see Gov't Ex. 20 at 3.) Dr. Berger further testified that the American Academy of Pain Management is not a board, but rather a peer review organization, which predated the American Board of Pain Management. Dr. Berger testified that he is not board certified by the American Board of Pain Management. (Tr. vol. at 7, at 26.) Based on his experience, education, and training, I accepted Dr. Berger as an expert within the field of pain medicine.

Consistent with his testimony, Dr. Berger stated in his report that the patient files for undercover special agents Brigantty, Zdrojewski and Ryckeley reflected "extremely superficial physical examinations, which were essentially memorialized in the record as a series of checkboxes, which did not truly indicate what was done." (Gov't Ex. 32 at 113.) Dr. Berger's report further indicated that the

three patient files reflected referrals to a neurosurgeon in two instances, and an interventional anesthesiologist in the third, but "these were just words, and never actually occurred." (Gov't Ex. 32 at 114.)

Dr. Berger opined that with regard to his review of eight undercover patient files, and related information, Respondent "fell well below the standard of care in many if not all the standards as they relate to the prescribing of controlled substances in the State of Florida." (Tr. vol. 7, at 177.) Dr. Berger explained the basis for his opinion to include the fact that evaluations of patients were incomplete, lacked review of prior patient records, and Respondent was "essentially taking [patients] at their word for a lot of their stories." (Tr. vol. 7, at 178.) Dr. Berger further explained that Respondent's treatment plans were just checked boxes, and Respondent had not made actual referrals to other healthcare providers. Dr. Berger also testified that it is very dangerous to treat people with depression or bipolar disorder with a combination of opioids and benzodiazepine. (Tr. vol. 7, at 180.)

3. Commercial Medical Group (CMG)

SA Gill testified in substance to having approximately seven years of law enforcement experience with DEA. SA Gill testified that he was primarily involved in the investigation of CMG, which began in September of 2009. (Tr. vol. 5, at 203.) SA Gill testified that he was the "case agent" and learned from a confidential source that a Mr. Vincent Colangelo was the owner of several pain clinics, including CMG. (Tr. vol. 5, at 203.) CMG was determined to be a cash-only business open usually six days per week, with lines of patients outside the door. (Tr. vol. 5, at 205.) SA Gill was also aware that Respondent worked as a physician at CMG. (Tr. vol. 5, at 204.) SA Gill further testified that weekly surveillance which revealed vehicles from the states of Kentucky, Tennessee, the Carolinas and Ohio, among others, raised DEA agents' suspicions. (Tr. vol. 5, at 205.)

SA Gill further testified that based on information from various confidential sources, CMG saw approximately forty to one hundred patients a day. (Tr. vol. 5, at 207-08.) SA Gill testified that

Mr. Colangelo had a well-known formula that would generate the most amount of money for the clinic, keep patients happy and generate a lot of money for the pharmacy. (Tr. vol. 5, at 214.) The formula was "240 oxycodone 30-milligram tablets, 90 oxycodone 15-milligram tablets, and, then, 90 Xanax, 2-milligram bars." (Tr. vol. 5, at 214.)

SA Gill testified that as part of the investigation of CMG, three undercover law enforcement officers posing as patients visited CMG in early 2010¹¹ with the goal of meeting one-on-one with a doctor to determine if there was any level of criminal behavior or if inappropriate prescriptions were being written. (Tr. vol. 5, at 206.) SA Gill further testified on direct examination that in January 2011, he instructed that law enforcement officers go to CMG with release forms and attempt to recover patient files related to three undercover law enforcement visits to CMG in 2010.¹² (Tr. vol. 5, at 215.) SA Gill testified on direct examination that he was unsuccessful in obtaining the undercover patient files from CMG.

On cross-examination, over Government counsel's objection, ¹³ SA Gill testified that he had recovered the patient files for at least two of the three undercover officers that met with Respondent at CMG. (Tr. vol. 5, at 218.) The files were recovered at a storage warehouse. (Tr. vol. 5, at 219.) SA Gill also testified the "Colangelo formula" had been reduced due to law enforcement and media attention, and the formula was not consistent with every patient. (Tr. vol. 5, at 227.) SA Gill further testified on cross-examination that he was aware Respondent had quit CMG, but did not know the reason. (Tr. vol. 5, at 237-38.)

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¹¹ The witness did not recall the exact date, but thought it was "January or so." (Tr. vol. 5, at 205.) The testimony of the undercover officers and other uncontroverted evidence of record places the date at March 5, 2010.

¹² Special Agents Miller, Bazile and McClarie.

¹³ As a cautionary note, although Agency precedent relieves the Government of a duty to disclose "potentially exculpatory information" to a respondent, there remains, of course, an ongoing duty to ensure that material evidence and argument made to a fact-finder is not knowingly contradicted by other material evidence in the Government's possession, but not otherwise disclosed. <u>See, e.g., Richard A. Cole, M.D.</u>, 57 Fed. Reg. 8677, 8677 (DEA 1992) (after hearing, Government filed Request for <u>In Camera</u> Inspection of Information advising that one of Government's witnesses at hearing failed to disclose information in response to certain questions asked during cross-examination).

(a) SA Miller, March 5, 2010 Undercover Visit to CMG

experience, including an assignment to a DEA Tactical Diversion Squad for the past three years.

SA Miller testified that he met Respondent on March 5, 2010, at CMG while working in an undercover capacity and posing as a patient. Upon arriving at CMG he observed the waiting area to be very crowded and disorganized, with a long line of people. (Tr. vol. 5, at 13.) After waiting in line, SA Miller was handed a clipboard with paperwork and told the cost of the visit was \$250, for which he gave the receptionist \$300.¹⁴ (Tr. vol. 5, at 14.) SA Miller completed the paperwork, noting left knee discomfort and nothing on the pain scale, among other information. (E.g., Tr. vol. 5, at 16.) SA Miller also provided CMG staff a copy of an MRI report which was an actual report of SA Miller's knee using his undercover name. (Tr. vol. 5, at 29; see Gov't Ex. 12 at 13.) After returning the forms to the receptionist, SA Miller waited approximately two hours, noticing that other patients arriving after him had already been seen by a doctor. (Tr. vol. 5, at 17.) SA Miller approached the receptionist and gave her a \$100 tip to speed things along, and waited another two hours before being called to triage. (Tr. vol. 5, at 17.) In triage, SA Miller's blood pressure was taken and he was asked the purpose of the visit. SA Miller also submitted to a urinalysis test. (Tr. vol. 5, at 18.)

SA Miller next testified that before he went to the triage area, Mr. Vincent Colangelo arrived and appeared agitated, questioning why so many people were waiting, and indicated that the doctor was not then seeing anyone. (Tr. vol. 5, at 20.) After triage, SA Miller overheard Mr. Colangelo speaking on the phone about prices charged for out-of-state patients. (Tr. vol. 5, at 20.)

SA Miller continued to wait, and eventually Respondent called SA Miller to come back and see him. (Tr. vol. 5, at 23.) SA Miller met with Respondent in an examination room, with the visit lasting a total of approximately five minutes. (Tr. vol. 5, at 23.) SA Miller explained his knee issue, noting that he

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¹⁴ The receptionist indicated she did not have any change and SA Miller told her to keep the difference, which she did. (Tr. vol. 5, at 14.)

had seen a family practice doctor in Colorado, but had not seen a doctor in approximately one month. (Tr. vol. 5, at 24.) SA Miller also told Respondent he was taking Vicodin. (Tr. vol. 5, at 26.) Upon questioning by Respondent, SA Miller stated his pain was a five on a one-to-ten scale. (Tr. vol. 5, at 24.) Respondent next asked SA Miller to stand, raise his arms, touch his toes, and Respondent also placed a stethoscope on SA Miller's chest and back. (Tr. vol. 5, at 25.) Respondent next issued SA Miller a prescription for 60 Roxicodone 15 mg tablets. (Tr. vol. 5, at 26; Gov't Ex. 12 at 14.)

Respondent testified in substance that review of the patient file for SA Miller, including the MRI report, was critical to his ability to respond to the Government's allegations, and would have assisted him with testimony. (Tr. vol. 10, at 13-16.) Respondent understood SA Miller's representation of pain to be a five located in the knee, with pain lasting for eighteen months. (Tr. vol. 10, at 18.) Respondent further testified to the importance he places on listening to patients with regard to prescribing medication. (Tr. vol. 10, at 22.) Having patients perform range-of-motion exercises included checking for track marks. (Tr. vol. 10, at 23.) Respondent testified he believed SA Miller was being honest, expressing reports of pain that were real and significant. (Tr. vol. 10, at 26-27.)

Respondent also testified that part of his plan in treating SA Miller was to assess in a follow-up appointment whether the medication had relieved the pain. (Tr. vol. 10, at 29.) Respondent testified that he "would not have prescribed medication unless a patient presents a convincing story of pain and has a legitimate medical purpose for receiving medication." (Tr. vol. 10, at 30.)

(b) SA McClarie, March 5, 2010 Undercover Visit to CMG

SA McClarie testified in substance to having approximately thirteen years of law enforcement experience, including an assignment to a DEA Tactical Diversion Group for the past few years. (Tr. vol. 5, at 94-95.) SA McClarie testified to meeting Respondent on March 5, 2010, at CMG while working in an undercover capacity and posing as a patient. (Tr. vol. 5, at 95-96.) SA McClarie testified that upon

¹⁵ The evidence also included a partial transcript of the undercover meeting. Neither party produced a patient file.

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arriving at approximately 1:30 p.m. he observed approximately fifty people inside the clinic. (Tr. vol. 5, at 97.) While waiting in line, SA McClarie overheard one person state that he was from New York and "was down here to get prescription medication." (Tr. vol. 5, at 98.) SA McClarie further testified to observing a male who appeared to be in the company of four or five people, and the male went to the front desk, paid cash for all of the people with him and obtained clipboards and forms for the group to fill out. (Tr. vol. 5, at 99.)

SA McClarie next testified that when he reached the front counter he was charged \$350 for the visit and another \$100 for "VIP" expedited service, all paid in cash. (Tr. vol. 5, at 111-12.) The receptionist gave SA McClarie forms to fill out including a pain scale, on which he circled all the numbers with one large circle. (Tr. vol. 5, at 112-13.) SA McClarie also informed CMG staff that he had an MRI done but did not have the MRI report with him, to which the staff indicated they would have it faxed over. (Tr. vol. 5, at 113-14.) SA McClarie next completed a triage procedure and after an additional wait, met with Respondent.

SA McClarie testified that Respondent told him that the MRI of his knee was not very impressive. (Tr. vol. 5, at 117 & 119.) SA McClarie also informed Respondent he was having issues with his back. (Tr. vol. 5, at 117.) Respondent asked SA McClarie about his blood pressure and whether he was allergic to anything, listened to SA McClarie's heart with a stethoscope and had SA McClarie perform a series of basic movements such as standing and bending, among others. (Tr. vol. 5, at 121.) SA McClarie completed the range-of-motion test without difficulty. (Tr. vol. 5, at 121.) Respondent asked SA McClarie how the over-the-counter medications were working, to which SA McClarie said they were doing nothing. (Tr. vol. 5, at 122.) Respondent indicated there was no way he could prescribe strong pain medication and SA McClarie said he did not want the strongest and just wanted some help.

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¹⁶ The triage procedure at CMG generally consisted of an inquiry regarding the purpose of the visit, medications, and the measurement of biometric data such as height, weight, blood pressure and urinalysis testing.

(Tr. vol. 5, at 122.) Respondent then prescribed 120 Roxicodone 15 mg tablets, noting that this was a "compromise." (Tr. vol. 5, at 122 & 172.)¹⁷

Respondent testified in substance that as with SA Miller, his inability to review the patient file for SA McClarie significantly impaired his ability to respond to the Government's allegations. (Tr. vol. 10, at 32.) Respondent testified that he recalls SA McClarie complaining of knee and back pain, but only had an MRI report of the knee. (Tr. vol. 10, at 35.) Respondent further testified that in his experience MRI reports reflecting abnormalities do not always correlate to pain, explaining that there may be patients with significant abnormalities on an MRI report with little or no pain, and other patients with no abnormal findings and significant pain. (Tr. vol. 10, at 36.) Respondent testified that "[w]e required them to have an MRI" to provide some basis to support a diagnosis. (Tr. vol. 10, at 37.)

Respondent testified that in prescribing Roxicodone to SA McClarie, his treatment plan was recorded in the patient chart, and believed the treatment plan would have been to lower pain, increase function and improve ability to work, among other goals. (Tr. vol. 10, at 48.) Respondent further testified that it is sometimes more appropriate to address other items in a treatment plan on subsequent visits, because the doctor/patient relationship is more mature, and the patient has already been in the office a long time on the first visit. (Tr. vol. 10, at 49.)

(c) SA Bazile, March 5, 2010 Undercover Visit to CMG

SA Bazile testified in substance that she had approximately ten years of law enforcement experience, having previously worked as a DEA diversion investigator for approximately six years and most recently as a special agent. (Tr. vol. 6, at 10.) SA Bazile testified to meeting Respondent on March 5, 2010, at CMG while working in an undercover capacity and posing as a patient. (Tr. vol. 6, at 11-12.)

testified that he last listened to the audio recording over a year ago. (Tr. vol. 5, at 133.) SA McClarie further testified that he was certain that portions of the transcript marked as inaudible were in fact audible. (Tr. vol. 5, at 146.) SA McClarie further testified that he was not certain if other portions of the transcript were inaccurate. (Tr. vol. 5, at 147.) The extraction of the transcript were inaccurate.

vol. 5, at 147.) The patient file for SA McClarie was not produced at hearing by either party.

¹⁷ The Government offered a transcript of the audio recording of SA McClarie's undercover meeting at CMG (Gov't Ex. 10), but I excluded the transcript for lack of foundation and reliability. (Tr. vol. 5, at 199.) SA McClarie credibly

SA Bazile was in possession of a recording device to record conversations, but it failed to operate during the entire visit including SA Bazile's meeting with Respondent. (Tr. vol. 6, at 28.) SA Bazile noted approximately twenty persons in the waiting room upon arrival. (Tr. vol. 6, at 12.) SA Bazile testified to overhearing a conversation in the waiting area between a CMG employee and a patient. SA Bazile had noticed the patient because he was falling asleep and had slurred speech. (Tr. vol. 6, at 13.) SA Bazile also overheard the patient complain about not being seen by a doctor because of a staff error. (Tr. vol. 6, at 14.) The patient stated to a CMG employee that he had paid the staff member "\$40 to pass a dirty urine" and the staff member acknowledged that but was explaining to the patient that the reason he could not be seen was due to his appointment being too early. (Tr. vol. 6, at 14.) SA Bazile noted the patient remained in the waiting room for some time, but was unsure if he had been seen by a doctor. (Tr. vol. 6, at 15.)

SA Bazile next testified that upon contact with the CMG receptionist, she was charged \$350 for the office visit and was told by the receptionist that for an additional \$100 she could be placed on the "VIP" list. (Tr. vol. 6, at 15.) SA Bazile agreed and paid a total of \$450 cash. (Tr. vol. 6, at 16.) SA Bazile filled out various forms including a pain scale of one to ten, on which she circled five. (Tr. vol. 6, at 17.) SA Bazile testified that in advance of the office visit she had obtained an actual MRI of her shoulder using her undercover name, which she believed was faxed to CMG from the MRI facility. (Tr. vol. 6, at 26.) After completion of the paperwork, and a short triage procedure, SA Bazile waited approximately one hour before seeing Respondent. (Tr. vol. 6, at 19-20.) Respondent asked SA Bazile questions about her pain and when the injury to her left shoulder occurred, to which SA Bazile stated "about a year ago," referring to the pain as "stiffness." Respondent also reviewed SA Bazile's MRI during the visit, noting that there were no particular findings. Respondent had SA Bazile stand, lift her arms up, and touch her toes, remarking that she had good range of motion. (Tr. vol. 6, at 21.)

SA Bazile testified that after completing the range-of-motion exam she sat down and asked Respondent what he would prescribe, stating in substance that she likes "blues" and shares them with a friend. Respondent did not directly respond to the statement about sharing "blues" but asked why SA Bazile wanted them, noting they are for patients with debilitating illnesses. (Tr. vol. 6, at 22-23.) Respondent also indicated in substance that he was aware from news stories that DEA was "targeting doctors like him." (Tr. vol. 6, at 23.) Respondent then prescribed SA Bazile 90 Roxicodone 15 mg tablets. SA Bazile then asked Respondent for something to help her sleep to which Respondent inquired if she had trouble sleeping. SA Bazile stated "sometimes" and Respondent replied that she was not very convincing, but prescribed 30 Xanax 1 mg tablets. (Tr. vol. 6, at 23-24.)

Respondent testified in substance that he believed SA Bazile had been a patient truthfully seeking relief from pain, and relied on the MRI report and SA Bazile's statements in issuing a prescription for Roxicodone. (Tr. vol. 10, at 52.) Respondent testified that Xanax is used to assist patients with sleep problems, which some people taking Roxicodone may experience, but could not provide the reasons for prescribing Xanax to SA Bazile without having the opportunity to see her patient file. (Tr. vol. 10, at 53.)

4. Coast to Coast Healthcare Management (CCHM)

TFO Weir testified in substance to having approximately ten years of law enforcement experience, and to becoming involved in the investigation of CCHM as case agent. TFO Weir testified that he was involved in redacting information from various patient files, and explained the substance of the information redacted from Government

Exhibits 21-28. (Tr. vol. 5, at 266-305.)

(a) SA Marshall, April 7 and May 4, 2010 Undercover Visits to CCHM

¹⁸ SA Bazile further explained that "Blues" are the street name for oxycodone 30 mg tablets. (Tr. vol. 6, at 22.)

SA Marshall testified in substance to having seven years of law enforcement experience, of which the last five were with DEA. (Tr. vol. 4, at 6.) SA Marshall participated in an investigation of Respondent on April 7 and May 4, 2010. (Tr. vol. 4, at 10 & 11.) SA Marshall had visited CCHM in an undercover role as a first-time patient on March 3, 2010, but had seen a doctor other than Respondent. (Tr. vol. 4, at 9.) SA Marshall testified that as he filled out paperwork in the waiting area during the March 3, 2010 visit a person unknown to him, but who appeared friendly with CCHM staff, provided him advice on filling out the paperwork. (Tr. vol. 4, at 14.) SA Marshall informed the person that he was concerned that his urinalysis would not be "dirty" and the person informed SA Marshall that SA Marshall could give the "girl" some money and she could "dirty" up the urine. (Tr. vol. 4, at 14.) SA Marshall further testified that during the triage process, he informed the female staff member about the conversation in the waiting area, and gave the staff member \$50 in cash, which she accepted. (Tr. vol. 4, at 15.) SA Marshall then observed the staff member indicate on the urinalysis paperwork the presence of opiates, but had never tested his urine. (Tr. vol. 4, at 15.)

SA Marshall testified that on April 7, 2010, he again travelled to CCHM acting in the undercover role of a patient, carrying a concealed recorder, and met with Respondent. (Tr. vol. 4, at 11.) After completing a triage procedure, and a short wait, SA Marshall met with Respondent in a patient examination room. During the encounter SA Marshall stated in substance to Respondent that he was homeless and needed oxycodone, and upon questioning by Respondent provided information on the street value of the medication. (Gov't Ex. 6 at 18-19, 21-22.) SA Marshall further testified that Respondent then informed him that "we don't participate in such folly" and walked him to a nurse's station. (Tr. vol. 4, at 25.) SA Marshall testified that Respondent walked up to a nurse but "that was in a back room, and I couldn't hear what they were saying" and waited. (Tr. vol. 4, at 25.) SA Marshall waited and observed Respondent call another patient.

SA Marshall testified that he then met privately with a staff member named Cindy Mesa, who chastised SA Marshall for informing Respondent that he was living on the street and selling the "stuff," because she would have to erase the information and call him back the next day to see a different doctor. (Tr. vol. 4, at 26; Gov't Ex. 6 at 9.) SA Marshall further testified that Ms. Mesa stated that Respondent thought SA Marshall was an "undercover" and trying to "bust" Respondent. (Tr. vol. 4, at 26.) SA Marshall further testified that he returned the next day, April 8, 2010, was seen by a different doctor and was prescribed the following controlled substances: 120 oxycodone 30 mg and 30 Xanax 2 mg tablets. (Tr. vol. 4, at 27; Gov't Ex. 21 at 24.)

SA Marshall next testified that he returned to CCHM on May 4, 2010, for a follow-up visit, and met with Respondent. (Tr. vol. 4, at 29.) SA Marshall understood from other agents posing as patients that they had already established a "relationship" with staff and had front-of-the-line privileges. (Tr. vol. 4, at 29.) SA Marshall testified that he paid \$200 cash for the visit and met with a female staff member in triage who was the same person he had met on his three previous visits to CCHM. (Tr. vol. 4, at 29.) SA Marshall informed the staff member that he had been kicked out by Respondent on a prior visit because he had told Respondent he was living on the street and selling the drugs, at which point both SA Marshall and the staff member laughed. (Tr. vol. 4, at 30.) Following the triage encounter,

SA Marshall further testified that he met with Respondent for a brief visit lasting approximately three minutes, with questions relating to how he was doing and if the medications were working.

Respondent checked SA Marshall with a stethoscope and had him perform some body movements, and then issued prescriptions. (Tr. vol. 4, at 31.) Respondent prescribed SA Marshall 120 oxycodone 30 mg and 30 Xanax 2 mg tablets. (Gov't Ex. 6 at 45.)

Respondent testified in substance that information relating to the April 7, 2010 meeting with SA Marshall was missing from the patient file. (Tr. vol. 10, at 59; Resp't Ex. 1.) Respondent further

testified that he recalled how SA Marshall looked on April 7, 2010, noting some type of gel in his hair, which was pointing up. Respondent testified that he became concerned during the visit with SA Marshall on April 7, 2010, concluding that SA Marshall was not in need of medication, "but instead was diverting." (Tr. vol. 10, at 61.) Respondent testified that after he discharged SA Marshall, he did not know that SA Marshall had returned the next day and was seen by a different doctor, or that the patient file had been destroyed by CCHM staff. (Tr. vol. 10, at 66.)

With regard to the May 4, 2010 follow-up visit, Respondent testified that he recalls SA Marshall's appearance as being different in that he was wearing a hat, but did not recognize him to be the same person he had discharged on April 7, 2010. (Tr. vol. 10, at 69.) Respondent testified that in making his medical assessment of SA Marshall on May 4, 2010, he reviewed the notes of two other CCHM doctors in the patient file. (Tr. vol. 10, at 75-76.) Respondent testified that in issuing the May 4, 2010 prescription he believed SA Marshall had real pain and the medication was helping. (Tr. vol. 10, at 85-86.)

Dr. Berger testified in substance that the medical file for SA Marshall contained numerous inconsistencies, to include no obvious physical examination on the first visit, an MRI report issued two days before the first visit with no prescribing or ordering physician noted on the MRI report. (Tr. vol. 10, at 63-64; Gov't Ex. 21 at 8.) Dr. Berger further testified that he found the patient file was "very unusual" in that it reflected prescriptions in a "polypharmacy fashion," meaning the use of both benzodiazepines with an opiate, for a patient who had a bipolar disorder with expressions of "severe recent depression," yet no psychiatric consultation in the chart. (Tr. vol. 10, at 64-65.)

(b) SA Saenz May 4, 2010 Undercover Visit to CCHM

SA Saenz testified in substance to having eight years of law enforcement experience with DEA and to participating in an investigation of Respondent on May 4, 2010. (Tr. vol. 2, at 229-31.) SA Saenz testified that on the morning of May 4, 2010, she travelled to CCHM, acting in the undercover role of a

patient, with a concealed recorder,¹⁹ and met with Respondent. (Tr. vol. 2, at 231.) This was SA Saenz's first time meeting with Respondent at CCHM but she had been there on two prior occasions in an undercover patient role, and met with different doctors on each visit.²⁰ (Tr. vol. 2, at 231.) SA Saenz also testified that on a March 10, 2010 visit to CCHM she had listed her pain level as nine, further describing it as sharp, shooting and unbearable. (Tr. vol. 2, at 271.) SA Saenz testified that in filling out the pain assessment forms on March 10, 2010, she was coached by a CCHM employee. (Tr. vol. 2, at 271.) SA Saenz testified that her undercover role was that of a patient in pain that needed medication, but during the March 10, 2010 visit told the doctor that her pain was a level three or four on a pain scale of one to ten. (See generally Tr. vol. 2, at 272-73.)

SA Saenz further testified that during the May 4, 2010 visit to CCHM she was in the company of two other DEA undercover agents, and understood that "one of the undercovers" had negotiated the cost of the visit with CCHM staff. (Tr. vol. 2, 233.) The cost of the office visit was \$150 and SA Saenz paid \$200 but was not given any change. SA Saenz completed one form and after completing a triage procedure²¹ met with Respondent.

SA Saenz testified that upon meeting Respondent, Respondent asked her about current medications, work and whether the medications were helping. (Tr. vol. 2, at 242, 275.) SA Saenz indicated she worked in daycare and needed one more pill per day to increase her current prescription from ninety to 120 pills, and Respondent indicated that he could give her an extra pill a day. (Tr. vol. 2, at 242-43.) SA Saenz testified her medication from a previous visit to CCHM was Roxicodone 30 milligrams. (Tr. vol. 2, at 243.) Respondent checked SA Saenz's heart rate with a stethoscope and asked where the pain was located. Respondent printed the prescriptions and advised SA Saenz not to share or

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¹⁹ The recording equipment failed to record the meeting. (Tr. vol. 2, at 231.)

²⁰ March and April of 2010. (Tr. vol. 2, at 238.) A different CCHM doctor issued SA Saenz's prescriptions for 90 oxycodone 30 mg and 30 Xanax 2mg tablets on April 8, 2010. (Resp't Ex. 4 at 24.)

²¹At triage, staff measured her blood pressure, height, weight and temperature. (Tr. vol. 2, at 241.)

sell the medication. Respondent did not discuss prior CCHM visits with SA Saenz, nor did he discuss a treatment plan, objectives, goals, risks, benefits or alternative medications. (Tr. vol. 2, at 249-51.)

Respondent issued SA Saenz prescriptions for 120 Roxicodone 30 mg and 30 Xanax 2 mg tablets on May 4, 2010. (Tr. vol. 2, at 245; Gov't Ex. 15 at 1-2.)

Respondent testified in substance that when he met with SA Saenz on May 4, 2010, he was aware from the patient file that she had two prior visits to CCHM, and was seen by two different physicians with initial complaints of back pain. (Tr. vol. 10, at 173-75.) Respondent testified that the initial treatment regimen was Motrin, a Medrol dose pack and Vicodin, which was changed on the second visit to oxycodone 30 mg three times per day, as well as Xanax for sleep. (Tr. vol. 10, at 175; Resp't Ex. 4 at 24-25.) Respondent further testified that his thought process on the May 4, 2010 visit was to try and "dial in the right dose" based in part on information contained in the file, and information learned from the patient. (Tr. vol. 10, at 176-80.) Respondent also testified that SA Saenz had convinced him that her pain was still significant, and he relied upon the truthfulness of the information provided by SA Saenz to increase the dose by one tablet per day. (Tr. vol. 10, at 177 & 180.)

Dr. Berger testified in substance and in error that Respondent had treated SA Saenz on April 8, 2010. 22 (Tr. vol. 7, at 129, 135 & 137; Tr. vol. 8, at 206.) Dr. Berger also erroneously stated in his report: "On 4-8-10. Dr. Wolff sees the patient for a second time" (Gov't Ex. 32 at 78; Tr. vol. 8, at 207.) Dr. Berger further stated in his report the belief that the April 8, 2010 patient chart had a signature that appeared to belong to Respondent, which was also erroneous. (Gov't Ex. 32 at 80; Tr. vol. 8, at 199-207.) Dr. Berger also erroneously concluded in his written report that a urinalysis report dated March 10, 2010, was "positive for Phencylidine, [a]nti-depressants, amphetamine, clearly making her a potential dangerous patient to prescribe narcotics to." (Gov't Ex. 32 at 82; Tr. vol. 8, at 190-202.)

²² This error was compounded by Government counsel's questions on direct examination, which misstated the evidence, given that SA Saenz had previously testified during the hearing that she first met Respondent at CCHM on May 4, 2010. (Compare Tr. vol. 7, at 137, with Tr. vol. 2, at 231.)

(c) SA O'Neil, May 4, 2010 Undercover Visit to CCHM

SA O'Neil testified in substance that he had five years of law enforcement experience with DEA and participated in an investigation of Respondent on May 4, 2010. (Tr. vol. 3, at 301.) SA O'Neil testified that on May 4, 2010, he travelled to CCHM acting in the undercover role of a patient, with a concealed recorder, and met with Respondent. (Tr. vol. 3, at 302, 308.) This was SA O'Neil's first time meeting with Respondent at CCHM but he had been there on two prior occasions in an undercover patient role. SA O'Neil further testified that he was in the company of other undercover DEA agents. He paid \$200 cash for the visit costing \$150, letting a CCHM staff member "keep the change." (Tr. vol. 3, at 305.) SA O'Neil informed a female staff member that he was with three other "patients," two with him and one on the way, but they "were all together," and asked her to put their charts in a stack, which she did. (Tr. vol. 3, at 305.)

SA O'Neil next testified that when called to the triage area, he stated to a female staff member "the fact that there was going to be four of us and I'd be quadrupling my money." (Tr. vol. 3, at 306.) In response, the staff member shook her head. SA O'Neil later stated to the same staff member during triage that he did not take the medication, to which the staff member indicated: "I know you don't take them," implying that she was not "stupid." (Gov't Ex. 14 at 25.)

SA O'Neil testified that after waiting for a period of time following triage he was called and met with Respondent. During the meeting SA O'Neil requested an increase in medication, noting at one point that he had run out of the previous prescription and needed more. (Tr. vol. 3, at 340.) SA O'Neil specifically asked if Respondent could increase the Roxicodone dosage from 120 to 210 tablets, to which Respondent replied: "I mean maybe, maybe eventually, but" and concluded by stating he absolutely could not double the medication now. (Tr. vol. 3, at 312; Gov't Ex. 14 at 30.) SA O'Neil also informed Respondent that he had taken liquid oxycodone from a friend, prompting Respondent to reply:

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²³ March and April, 2010. (Tr. vol. 3, at 301-02.)

"Don't even tell me that." (Gov't Ex. 14 at 30.) Respondent counseled SA O'Neil about the dangers of taking liquid oxycodone and informed SA O'Neil that talking about using another patient's medication in a pain clinic could result in getting discharged. (Tr. vol. 3, at 313, 354; Gov't Ex. 14 at 31-32.)

Respondent asked SA O'Neil to lift his upper and lower extremities and had him breathe in and out.

SA O'Neil testified that Respondent discussed how he was doing on the medication and counseled him on stretching exercises. (Tr. vol. 3, at 313-14, 361.) Respondent counseled SA O'Neil on safekeeping and use of medication. (Tr. vol. 3, at 351.)

On May 4, 2010, Respondent issued SA O'Neil prescriptions for 150 Roxicodone 30 mg, 90 Roxicodone 15 mg and 30 Xanax 2 mg tablets. (Gov't Ex. 14 at 53-54.) On April 7, 2010, Dr. [L.C.] issued SA O'Neil prescriptions for 120 oxycodone 30 mg, 90 oxycodone 15 mg, 30 Xanax 2 mg and 30 Lisinopril²⁴ 20 mg tablets. (Tr. vol. 10, at 151; Resp't Ex. 3 at 24.) On March 10, 2010, Dr. [L.C.] issued SA O'Neil prescriptions for 120 oxycodone 15 mg and 30 Xanax 2 mg tablets. (Tr. vol. 10, at 150-51; Resp't Ex. 3 at 24-25.)

Respondent testified in substance that another CCHM doctor had treated and prescribed medication to SA O'Neil on the April 7 and March 10, 2010 visits. Upon inquiry, Respondent learned from SA O'Neil that SA O'Neil had not filled the blood pressure medication prescription. (Tr. vol. 10, at 152.) Respondent further testified that in talking with SA O'Neil Respondent understood most of the pain to be in the lower back, and the present dose was insufficient. (Tr. vol. 10, at 152-53.) With regard to SA O'Neil's statement that he had used liquid oxycodone, Respondent testified that his statement "Don't even tell me that," was not meant to ignore the issue but rather indicated Respondent's being "disturbed" and "hurt" to hear of patients using a dangerous product. (Tr. vol. 10, at 155.) Respondent testified that he explained at length the dangers of using liquid oxycodone, to include death, and believed at the end of his comments that SA O'Neil accepted the rules and guidelines. (Tr. vol. 10, at

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²⁴ Lisinopril is a blood pressure medication. (Tr. vol. 10, at 151.)

159.) Respondent also testified that he told SA O'Neil about Williams stretching exercises, and to look them up on the computer.²⁵

Dr. Berger testified in substance that the medical file for SA O'Neil had several blank pages, including the history and physical examination forms, as well as several forms that had dates inconsistent with the office visit in March 2010. (Gov't Ex. 23, at 10, 12-13; Tr. vol. 7, at 108-09.)

Dr. Berger testified that the existence of blank forms in a medical file is significant because it goes to the "degree of caution in the practice." (Tr. vol. 7, at 117.) Not having a history and physical in the chart is "absolutely below the standard of care." (Tr. vol. 7, at 117.)

Dr. Berger further testified that the patient file reflected a drug screen dated March 10, 2010, which was positive for benzodiazepines only, but contained no indication of a test for alcohol. (Tr. vol. 7, at 113; Gov't Ex. 23 at 27.) Dr. Berger testified that in his opinion, there was no legitimate basis to treat SA O'Neil with "such large doses of narcotics without going through other channels first," to mean such things as a review of prior medical records, other diagnostic tests, medications, x-rays, nerve conduction studies and an orthopedist consultation. (Tr. vol. 7, at 116.) Dr. Berger further testified that SA O'Neil's mention of using liquid oxycodone shows the patient has a tendency to receive medications illegally through diversion, which makes them "a very unlikely candidate to receive further narcotic prescriptions " (Tr. vol. 7, at 125-26.)

(d) TFO Doklean, July 23, 2010 Undercover Visit to CCHM

TFO Doklean testified in substance that she had approximately fourteen years of law enforcement experience, most recently working in a Tactical Diversion Squad, and participated in an

UC1: [LAUGHS] WOLFF: Oxy [U/I] UC1: Yeah

WOLFF: let you use the computer, in light [PH] of the fact that they're trying to murder you.

UC1: [LAUGHS]

WOLF: [PAUSE] Google that. William's stretching exercises.

²⁵ The undercover transcript (Gov't Ex. 14 at 34) reflects in relevant part:

WOLFF: Maybe the person that gave you the, uh . . .

investigation of Respondent on July 23, 2010. (Tr. vol. 1, at 176, 178-79.) TFO Doklean testified that on July 23, 2010, she travelled to CCHM acting in the undercover role of a patient, ²⁶ with a concealed audio and video recorder, ²⁷ and met with Respondent for approximately ten minutes. (Tr. vol. 1, at 177, 178, 181 & 268; Gov't Ex. 4.) The patient file indicates this was TFO Doklean's first visit to CCHM in her undercover role. (See Gov't Ex. 25.) TFO Doklean was in the company of several other DEA agents acting in undercover roles as patients, and the group was represented by an undercover agent posing in the role of "crew leader or ringleader" who was bringing all of the undercover patients to the clinic. (Tr. vol. 1, at 186.) TFO Doklean testified that she paid \$300 for the office visit and another \$200 to a CCHM staff member named Linda for "VIP treatment," meaning expedited service. (Tr. vol. 1, at 186, 187.)

TFO Doklean further testified that the portion of the clinic she observed during her visit to CCHM included examination rooms, waiting areas, a pharmacy dispensary, triage area, front desk and a restroom. (Tr. vol. 1, at 179, 180.) TFO Doklean testified that while waiting for her appointment she engaged in a brief conversation with a male seated next to her regarding levels of prescribing at CCHM, and he told her that even if she was started on low levels of medication "they will bump you up." (Tr. vol. 1, at 185.) TFO Doklean also testified that she observed a sign in the waiting room that stated: "Please be aware that outside pharmacies are reporting prescription transactions to law enforcement agencies. Feel free to discuss this with your physician." (Tr. vol. 1, at 193.)

TFO Doklean testified that following a triage process she met with Respondent. Upon inquiry, TFO Doklean informed Respondent of issues for the prior six months with neck pain of unknown origin. (Gov't Ex. 4 at 31.) Respondent indicated in substance confusion because TFO Doklean had provided an MRI report of her back, not her neck. (Tr. vol. 1, at 201.) TFO Doklean further testified that she

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²⁶ The undercover role included identification information and an actual MRI report of the undercover officer's back taken in advance of the appointment. The MRI was provided to the clinic. (Tr. vol. 1, at 215; Gov't Ex. 4 at 60, 61.)

²⁷ TFO Doklean testified that she had a concealed recording device in her possession throughout her visit to CCHM, with the exception of a few minutes when the recorder was in possession of another undercover agent. (Tr. vol. 1, at 239.)

informed Respondent that the pain fluctuates from a two or three upwards, depending on the day, and impacts her daily activities, including child care. (Tr. vol. 1, at 202.) Later, when Respondent inquired whether TFO Doklean drank alcohol, TFO Doklean stated to Respondent that she had been in rehab last year in November, but was "clean and sober." (Tr. vol. 1, at 203; Gov't Ex. 4 at 34.) TFO Doklean testified that Respondent made no further inquiry regarding where, why or how long she had been in rehabilitation. (Tr. vol. 1, at 203; Gov't Ex. 4 at 34-36.) Upon inquiry about taking medication, TFO Doklean stated to Respondent that in addition to Advils she has been taking some "blues" obtained from a friend on and off for about six months, representing that they seemed to help. (Gov't Ex. 4 at 34.) TFO Doklean testified that the term "blues" is street terminology for oxycodone 30 milligram tablets. (Tr. vol. 1, at 204.)

TFO Doklean next testified that Respondent examined her breathing with a stethoscope and requested that she perform range-of-motion exercises, including turning her head, which she successfully completed without display or complaint of pain. (Tr. vol. 1, at 205 & 206.) Respondent inquired and confirmed that TFO Doklean was not currently taking medications, and stated that he would get TFO Doklean started on some medication, cautioning her on the use and safe storage of the medication. (Tr. vol. 1, at 286; Gov't Ex. 4 at 36.) TFO Doklean then asked if she was going to get some "blues" and Respondent stated in substance that he would look at the chart and "see what we can do for you." (Id.)

Respondent issued TFO Doklean a prescription for 120 Roxicodone 30 mg tablets, which CCHM filled for a cost of \$600 cash. (Tr. vol. 1, 189, 190; Gov't Ex. 4 at 54.) TFO Doklean testified that in addition to requesting but not receiving a prescription for Xanax from Respondent, she also did not know what kind of prescription would be provided until after her meeting with Respondent had already concluded.

TFO Doklean also testified that she had been unsuccessful in persuading a CCHM office manager named Richard to increase the amount of the Roxicodone prescription, noting to Richard that "[i]t's not enough to finance what I need to pay," which Richard acknowledged he understood. (Tr. vol. 1, at 290; Gov't Ex. 4 at 40.) TFO Doklean further testified that following her meeting with Respondent, Richard provided instruction and direction about concerns that Respondent had about patients "not putting the proper things in the paperwork," and that the patients needed to say that they were in pain on the paperwork, and to tell the doctors they were in pain. This information was also directed to the undercover patients who had not yet been seen by a doctor. (Tr. vol. 1, at 188; Gov't Ex. 4 at 39-40.)

Richard further stated to TFO Doklean (referring to Respondent): "This guy is a little . . . this guy is a little . . . partly because he's been in a clinic that's been shut down before, so, it's very hard for him. He knows . . . you guys are cool." (Tr. vol. 1, at 290; id. at 40.)

Respondent testified in substance that based on TFO Doklean's statements, he believed she had both neck and back pain, and the pain was significant enough at times to impact her ability to provide care for her children. (Tr. vol. 10, at 186, 189 & 190-91.) Respondent further testified that he was concerned with her drinking, but understood from TFO Doklean that she had been out of "rehab" and sober for eight or nine months. (Tr. vol. 10, at 192.) Respondent testified that with regard to the term "blues" and whether it constituted a "red flag" for prescribing, he did not "want to make a value judgment upon her as to why she used that term" rather than Roxicodone 30 mg. (Tr. vol. 10, at 193.) Respondent further explained that use of the term "blues" and previously buying or receiving a controlled substance outside of a prescription is not a disqualifier to his prescribing controlled substances to such a patient.

Respondent also testified that he gave TFO Doklean a prescription for an MRI of her neck and expected to review an MRI report on the next follow-up visit. (Tr. vol. 10, at 197.) Respondent further

testified that he prescribed Roxicodone 30 mg tablets because of the severity of the unrelieved pain, and planned to reevaluate the patient in one month. (Tr. vol. 10, at 198.) Respondent testified with regard to the patient file, explaining that he documented various statements by TFO Doklean, including past history of alcohol use. (Tr. vol. 10, at 202.)

Dr. Berger testified in substance that the patient file reflected that TFO Doklean had a prior history of alcohol rehabilitation, but did not list her treating physician, type of treatment or that TFO Doklean had mentioned that she had obtained narcotics on the street. (Tr. vol. 7, at 146.) Dr. Berger testified that this information, taken together, "preclude her from being a good candidate for receiving controlled drugs" on her first visit, and that such a prescription would not be in compliance with "the established care in Florida." (Tr. vol. 7, at 147.) Dr. Berger testified that Respondent was not in compliance with the established standard of care for TFO Doklean, based on Respondent's failure to conduct a complete physical examination, inquire further about past drug use and rehabilitation, or engage in appropriate consultations, among other deficiencies. (Tr. vol. 7, at 153-55.)

Dr. Berger's report similarly concluded that Respondent's treatment of TFO Doklean fell below the standard of care in the areas of patient evaluation, informed consent and agreement for treatment, periodic review, consultation, medical records and compliance with controlled substances laws and regulations. (Gov't Ex. 32 at 32-35.)

(e) SA Brigantty, July 23, 2010 Undercover Visit to CCHM

SA Brigantty testified in substance that he had nine years of law enforcement experience with DEA and participated in an investigation of Respondent on July 23, 2010. (Tr. vol. 2, at 13-16.)

SA Brigantty testified that on July 23, 2010, he travelled to CCHM acting in the undercover role of a patient, ²⁸ with a concealed audio and video recorder, and met with Respondent. (Tr. vol. 2, at 16, 22 &

back taken in advance of the appointment. The MRI was provided to the clinic prior to the appointment. (Tr. vol. 2, at 29-30; Gov't Ex. 9 at 55; Gov't Ex. 26 at 22.)

²⁸ The undercover role included identification information and an actual MRI report of the undercover officer's

26.) This was SA Brigantty's first time visiting CCHM as an undercover patient. (Tr. vol. 2, at 17.)

SA Brigantty was in the company of several other DEA agents acting in undercover roles as patients, and the group was represented by a DEA agent acting in the undercover role of ringleader and patient. (Tr. vol. 2, at 17-19.) CCHM staff members also understood this role, and treated the undercover agents as a group. (Tr. vol. 2, at 17 & 18.) SA Brigantty paid \$200 for the office visit, which was the same for each member of the group and included an expediting fee, and SA Brigantty later paid \$750 for medication prescribed and another \$50 tip to a female CCHM staff member during the clinic visit. (Tr. vol. 2, at 19, 42.)

SA Brigantty further testified that prior to meeting with Respondent he filled out various clinic forms, with assistance from CCHM staff. (Tr. vol. 2, at 2, 60-80.) Following a triage procedure, SA Brigantty testified that he met with Respondent. During the meeting, which lasted approximately fifteen minutes (see Gov't Ex. 9 at 35-46), SA Brigantty informed Respondent about lower back pain which SA Brigantty stated had been present for fifteen years, and was caused by heavy lifting. (Tr. vol. 2, at 22, 59 & 89; Gov't Ex. 9 at 36.) SA Brigantty testified that he informed Respondent that he had been taking pain medicine in the form of "Oxys, 30 milligrams" and a "Zany bar" referring to Xanax, which he purchased "off the street." (Tr. vol. 2, at 37; Gov't Ex. 9 at 41.) SA Brigantty also represented to Respondent that the pain at times was a six or greater, and at times could be debilitating. (Tr. vol. 2, at 92, 96; Gov't Ex. 9 at 37.)

SA Brigantty testified that prior to being seen by Respondent he was standing outside

Respondent's office and noted that Respondent was "walking around, nervous like, trying to figure out

what was going on," and before seeing SA Brigantty went to see another doctor for approximately

twenty minutes. (Tr. vol. 2, at 97.) SA Brigantty further testified that he had then heard from other

undercover officers present at CCHM that "you need to say you are in pain" in order for Respondent and

the rest of the doctors to prescribe pain. (Tr. vol. 2, at 97-98.)

SA Brigantty further testified that during the office visit, Respondent performed a brief examination in the form of having him push, pull and lift his upper and lower extremities, and also showed SA Brigantty a chart. (Tr. vol. 2, at 40-43.) During the examination Respondent asked SA Brigantty a series of questions about past medical issues, including blood pressure, to which SA Brigantty responded that he had been informed earlier that it was high. (Gov't Ex. 9 at 40.) Respondent then acknowledged it was very high and counseled SA Brigantty on the need for reevaluation, meaning the "need to find a regular medical doctor as soon as possible" to be rechecked. (Gov't Ex. 9 at 42.) Respondent inquired of SA Brigantty what he had previously been prescribed, and SA Brigantty stated "Oxy Thirties," further explaining when asked by Respondent whether he "use to go to American Pain" that he put that on the form because the "girls outside" told him he had to write something. (Gov't Ex. 9 at 44.) SA Brigantty explained to Respondent that he was not seeing a physician and could barely afford to come to CCHM. Respondent made no inquiry regarding SA Brigantty's statement of falsely listing American Pain as a current or former treatment provider. (Gov't Ex. 9 at 44-46; 60-V-0010.)

Respondent issued SA Brigantty a prescription for 150 Roxicodone 30 mg tablets. (Tr. vol. 2, at 45; Gov't Ex. 9 at 53-54.)

Respondent testified in substance that he believed SA Brigantty had described significant pain, and even though SA Brigantty had previously been on a lot of medication, Respondent felt it reasonable to start him on a lower dose of 150 Roxicodone 30 mg tablets, to be taken up to five times per day. (Tr. vol. 10, at 265.) Respondent further testified that he did not believe it necessary to prescribe Xanax because the patient stated that if his pain were under control he would sleep better. (Tr. vol. 10, at 265.) Respondent also testified that the MRI report reflected significant disc disease, with disc bulging and "evidence of boney abnormality compressing the spinal cord as well as both areas where the nerve comes out" which correlated with SA Brigantty's complaint of pain. (Tr. vol. 10, at 267.)

Dr. Berger testified in substance that a patient who represents that he is illegally buying drugs on the street, and is requesting the same drug to be prescribed, would be precluded from receiving prescriptions for controlled substances. (Tr. vol. 7, at 161.) Dr. Berger further testified that based on his review of the medical file, he did not see anything that justified the issuance of controlled substances. (Tr. vol. 7, at 162; Gov't Ex. 26.)

(f) SA Priymak, April 7 and May 4, 2010 Undercover Visits to CCHM

SA Priymak testified in substance to having worked for DEA since 2004 and to participating in an investigation of Respondent on April 7 and May 4, 2011. (Tr. vol. 2, at 314-15.) On April 7, 2011, SA Priymak travelled to CCHM acting in the undercover role of a patient, carrying a concealed audio recorder. SA Priymak testified to seeing several dozen people in the waiting room, and to paying \$175 cash to the receptionist. (Tr. vol. 2, at 318-19.) After completing a series of forms and a triage procedure, ²⁹ SA Priymak met with Respondent. (Tr. vol. 2, at 320-21.) SA Priymak further testified that he informed Respondent that he had a little bit of pain in his neck with a pain level of two and three, which Respondent stated was low for him to write a prescription. (Tr. vol. 2, at 322-23.) SA Priymak also testified that upon questioning by Respondent, SA Priymak increased the level to five. (Tr. vol. 3, at 15.) SA Priymak informed Respondent that he was taking 160 milligrams of OxyContin per day along with a quantity of Xanax and Soma, stating he was buying them "off the street." (Tr. vol. 2, at 323, 376.) SA Priymak also indicated a history of intravenous drug use which ended five years prior and current use of alcohol. (Gov't Ex. 5 at 38 & 41.)

SA Priymak next testified that Respondent informed him he would not write a prescription for thirty milligram "oxi's" so SA Priymak inquired about fifteen milligrams, to which Respondent shook his head and said yes. (Tr. vol. 2, at 324.) SA Priymak further testified that Respondent asked him if he wanted Xanax, to which SA Priymak said yes. (Tr. vol. 2, at 325.) Respondent also suggest to SA Priymak

²⁹ The triage procedure at CCHM generally consisted of a collection of biometric information such as height, weight and blood pressure, and sometimes included urinalysis testing.

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that he go to a rehabilitation facility. (Tr. vol. 2, at 325.) Respondent wrote a prescription to SA Priymak for 150 Roxicodone 15 mg and 30 Xanax 2 mg tablets. (Gov't Ex. 5 at 63-64.)

SA Priymak further testified that he returned to CCHM on May 4, 2010, for a follow-up appointment with Respondent. (Tr. vol. 2, at 327.) The cost of the appointment was \$150, for which SA Priymak paid \$200 in cash to CCHM staff but was not given change back. (Tr. vol. 2, at 328.) After a wait and triage procedures, SA Priymak met with Respondent for a very short visit lasting approximately less than four minutes. (Tr. vol. 2, at 328; Gov't Ex. 5 at 2-5.) SA Priymak testified that Respondent checked his breathing and again issued prescriptions for 150 Roxicodone 15 mg and 30 Xanax 2 mg tablets. (Tr. vol. 2, at 328-29; Gov't Ex. 5 at 65-66.) Respondent did not raise the issue of rehabilitation or the use of alcohol during the patient encounter on May 4, 2010. (Gov't Ex. 5 at 54-58.)

Respondent testified in substance that the MRI report associated with the April 7, 2010 visit had been verified. (Resp't Ex. 1 at 25; Tr. vol. 10, at 91.) Respondent further testified that he believed SA Priymak's reference to pain as a one, two and zero to be confusion on the part of the patient, and Respondent attempted to "clarify" but not coach the patient in arriving at a pain number. (Tr. vol. 10, at 94-95.) Respondent testified that during the course of his meeting with SA Priymak, Respondent came to believe that SA Priymak was from "another country" and was not communicating properly. (Tr. vol. 10, at 99.) Respondent explained that he asked a series of questions, including history of past treatment, alcohol and drug use. (Tr. vol. 10, at 102-03.) Respondent testified that he declined to write a prescription for the type and quantity of medication requested by SA Priymak; rather he used his medical judgment based on his interpretation and assessment of the degree of pain, but was convinced that SA Priymak had significant pain. (Tr. vol. 10, at 108.)

Respondent also testified that he does not believe a doctor is precluded from prescribing controlled substances to a patient who has previously taken or is currently taking illegal drugs or drugs without a prescription. (Tr. vol. 10, at 111.) With regard to the prescription for Xanax, Respondent

testified that he prescribed it because SA Priymak stated he had problems sleeping, and Respondent felt it was medically appropriate. (Tr. vol. 10, at 116.) Respondent declined to prescribe Viagra, which SA Priymak had requested, because he saw no medical indication to support SA Priymak's request. (Tr. vol. 10, at 117.) Respondent testified that he diagnosed SA Priymak with neck pain, chronic pain and cervical disc disorder. (Tr. vol. 10, at 125.)

With regard to the May 4, 2010 follow-up visit, Respondent testified that he would have had the prior file information available to him, and relied on the truthfulness of what patients represent, including patient forms with attestations of truthfulness. (Tr. vol. 10, at 131; Resp't Ex. 2 at 15.)

Respondent further testified that people may try to deceive him but he is "always on the lookout to catch that," noting he is not perfect. (Tr. vol. 10, at 132.) Respondent testified that his interpretation of the March 10, 2010 MRI report was "consistent with a patient having significant neck pain." (Tr. vol. 10, at 138; Resp't Ex. 2 at 25.) Respondent testified that based on the patient's representations that he was doing well, Respondent prescribed SA Priymak the same dose of medications.

Dr. Berger testified in substance that after a review of the patient file, among other information, he was of the opinion that prescriptions for Roxicodone and Xanax on April 7, 2010, were unwarranted, particularly given the patient's history of being an intravenous drug user and having purchased drugs illicitly on the street. (Tr. vol. 7, at 92.) Dr. Berger further testified that his review of the patient file noted a discrepancy between the chart, which referenced Roxicodone 30 mg, and the actual prescription, which Respondent issued for Roxicodone 15 mg. (Tr. vol. 7, at 97; Gov't Ex. 22 at 22-24.) Dr. Berger also testified that from April 7, 2010 to May 4, 2010, there was no significant information to legitimize the reissuance of a prescription for controlled substances, explaining that the patient had not gone for another opinion, to include other therapies to reduce narcotic requirements. (Tr. vol. 7, at 98.)

Consistent with his testimony, Dr. Berger opined in his written report that Respondent "fell below the standard of care and treatment of this particular UC patient." (Gov't Ex. 32 at 73.) In support

of this opinion, Dr. Berger noted that Respondent's evaluation lacked a complete history of pain, prior treatments, effects, physicians and records, among other deficiencies. (Gov't Ex. 32 at 73.)

(g) SA Zdrojewski, July 23, 2010 Undercover Visit to CCHM

SA Zdrojewski testified in substance that he had nine years of law enforcement experience with DEA, most recently working in a Tactical Diversion Squad, and participated in an investigation of Respondent on July 23, 2010. (Tr. vol. 3, at 68-69.) SA Zdrojewski testified that on July 23, 2010, he travelled to CCHM, acting in the undercover role of a patient, ³⁰ with a concealed audio recorder, and met with Respondent. (Tr. vol. 3, at 69 & 71.) SA Zdrojewski was in the company of several other DEA agents acting in undercover roles as patients, and the group was represented by a DEA agent, SA Jack Lundsford, acting in the undercover role of "ringleader" for the undercover patients. (Tr. vol. 3, at 69-72.) SA Zdrojewski testified that he paid \$300 for the office visit and another \$200 to SA Lundsford to be given to CCHM staff for "VIP treatment." (Tr. vol. 3, at 72.)

SA Zdrojewski next testified that following completion of "paperwork" he waited and was eventually called to a triage room, where two female CCHM staff members recorded his height, weight and blood pressure. (Tr. vol. 3, at 73 & 76.) SA Zdrojewski was asked to provide a urine sample and noted during the process that other than directions from staff, the urinalysis process was unsupervised. (Tr. vol. 3, at 78.) After providing the urine sample to staff, SA Zdrojewski testified that he told staff members that he had "fooled around with the test" but no one said anything to him. (Tr. vol. 3, at 79.)

SA Zdrojewski further testified that he eventually was called and met with Respondent for approximately ten minutes.³¹ (Tr. vol. 3, at 83.) Upon inquiry by Respondent, SA Zdrojewski stated in substance that he had been having intermittent neck pain for approximately one and one-half years, but did not know the cause. (Tr. vol. 3, at 86, 87 & 126.) SA Zdrojewski further testified that with regard to

³⁰ The undercover role included identification information and an actual MRI report of the undercover officer's neck taken in advance of the appointment. The MRI was provided to the clinic. (Tr. vol. 3, at 81; Gov't Ex. 8 at 24.) ³¹ SA Zdrojewski represented to Respondent that this was his first visit to CCHM and that he had previously been

treated at "Tampa Bay Wellness before they were closed down." (Tr. vol. 3, at 97; Gov't Ex. 8 at 11.)

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a history and physical examination form, Respondent had not discussed with him various items checked on the form, to include: anti-inflammatories and diet, yoga/stretching exercises, and use of omega-3 fish oil, three to six grams per day, among others.³² (Tr. vol. 3, at 88, 89; Gov't Ex. 28 at 5; Gov't Ex. 8 at 11-18.) Upon inquiry by Respondent, SA Zdrojewski stated that he smoked marijuana and was self-medicating for pain. (Tr. vol. 3, at 89 & 90.) SA Zdrojewski had originally written on the pain scale that his pain was a zero or a one but upon explanation by Respondent that zero to one meant no pain, SA Zdrojewski told him to "top it," meaning all the way to the high end of the pain scale. (Tr. vol. 3, at 97, 141-42.) SA Zdrojewski stated to Respondent that other treating sources had given him very large amounts of pain medications, which he further indicated was more than he needed. (Gov't Ex. 8 at 12.)

SA Zdrojewski next testified that upon inquiry by Respondent about alcohol use, SA Zdrojewski stated he drank a lot, further explaining that he considered a "case of beer" to be "a lot" and drank no hard liquor when working. (Tr. vol. 3, at 88, 147; Gov't Ex. 8 at 14.) Respondent had SA Zdrojewski take some breaths and perform some physical maneuvers including bending and touching his toes. ³³ (Gov't Ex. 8 at 16.) Respondent then explained to SA Zdrojewski the results of his MRI, noting that the "MRI doesn't show much of anything and secondly, drinking a case of beer is not compatible with taking strong medicine like this" (Tr. vol. 3, at 153; Gov't Ex. 8 at 17.) Respondent inquired of SA Zdrojewski about the alcohol consumption, to which SA Zdrojewski stated he would stop drinking. (Gov't Ex. 8 at 17-18; Tr. vol. 3, at 163.) Respondent noted the chart contained self-reported use of Xanax, and SA Zdrojewski said that Xanax had been given to him previously and that he would accept an additional Xanax prescription if one were offered to him. (See Gov't Ex. 8 at 18.) Respondent stated in substance that he does not give medication simply in order to write a prescription. (Gov't Ex. 8 at 18.)

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³² This was consistent with testimony from the other witnesses who had posed as patients and seen Respondent.

³³ SA Zdrojewski testified that he stated to Respondent that he could not bend over and touch his toes at the same time that he was doing so, and in fact was able to complete the maneuver. SA Zdrojewski further testified that he over-exaggerated all of the requested maneuvers. (Tr. vol. 3, at 159, 160 & 185.)

up in a safe place. (Tr. vol. 3, at 167.) SA Zdrojewski further testified that at the end of the meeting with Respondent he did not know what, or even if, he was going to be prescribed medication. (Tr. vol. 3, at 169.)

Respondent issued a prescription to SA Zdrojewski for 150 Roxicodone 30 mg tablets. (Tr. vol. 3, at 184; Gov't Ex. 28 at 19-20.)

Respondent testified in substance that he learned from SA Zdrojewski during the patient visit that SA Zdrojewski had previously been treated at another clinic that was now closed, had tried other treatments, and had been taking 60 Xanax 2 mg, 240 Roxicodone 30 mg and 90 OxyContin 80 mg tablets. (Tr. vol. 10, at 239-41.) Respondent further testified that a patient's use of marijuana is not an automatic disqualifier for prescribing controlled substances. (Tr. vol. 10, at 243-44.) Respondent testified that it appeared SA Zdrojewski had done "okay" on medication but he had resorted to self-medicating with marijuana after the other clinic closed. (Tr. vol. 10, at 245.) Respondent also testified that after his discussion with SA Zdrojewski about use of alcohol, he understood from SA Zdrojewski's answer that he would rather take medication than use alcohol. (Tr. vol. 10, at 248.) Respondent testified that he did not prescribe Xanax because SA Zdrojewski stated he did not need it, and was also concerned that SA Zdrojewski was drinking some, so "it was more cautious to hold off on that without a ... strong indication." (Tr. vol. 10, at 250.)

Respondent further testified that he prescribed medication that Respondent believed was sufficient to cover SA Zdrojewski's pain, but noted in the patient file the need for referral to neurosurgery or a Board Certified pain management specialist before continuing care, because Respondent did not expect the patient to have such severe symptoms given the MRI findings. (Tr. vol. 10, at 254.) Respondent testified that he reviewed the patient chart after SA Zdrojewski left because he had some lingering questions, and made a note to prompt him to have questions answered on the next visit, which never occurred. (Tr. vol. 10, at 254; Resp't Ex. 8 at 5.)

Dr. Berger testified in substance that SA Zdrojewski's admission to Respondent that he was engaged in the illegal use of drugs made him a less suitable candidate for prescribing controlled substances to reduce pain. Dr. Berger also did not note any referral to rehabilitation in the patient file. (Tr. vol. 7 at 175-76.) Dr. Berger testified that issuing 150 dosage units of 30 mg Roxicodone to someone admitting use of marijuana is not within the established standard of care "as a first-line of treatment" in Florida. (Tr. vol. 7, at 176.)

(h) SA Ryckeley, July 23, 2010 Undercover Visit to CCHM

SA Ryckeley testified in substance that he had over ten years of law enforcement experience with DEA, most recently working in a Tactical Diversion Squad, and that he participated in an investigation of Respondent on July 23, 2010. (Tr. vol. 3, at 199, 200 & 233.) SA Ryckeley testified that on July 23, 2010, he travelled to CCHM acting in the undercover role of a patient, ³⁴ with a concealed audio recorder, and met with Respondent. (Tr. vol. 3, at 200 & 206.) SA Ryckeley was in the company of several other DEA agents acting in undercover roles as patients, and the group was represented by a DEA agent, SA Jack Lundsford, acting in the undercover role of "sponsor" for the undercover patients, with the undercover "patients" following his direction, "and he was organizing primarily everything with the clinic staff." (Tr. vol. 3, at 201.) SA Ryckeley testified that he paid \$300 for the office visit and another \$200 to a CCHM staff member for "VIP treatment," meaning accelerated preferential treatment. (Tr. vol. 3, at 201.)

SA Ryckeley further testified that following a triage procedure which included a urinalysis test, he was eventually called to meet with Respondent. (Tr. vol. 3, at 206.) SA Ryckeley informed Respondent initially during the meeting that he was suffering from back discomfort which began in May

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³⁴ The undercover role included identification information and an actual MRI report of the undercover officer's lower back taken in advance of the appointment. The MRI was provided to the clinic. (Tr. vol. 3, at 216; Gov't Ex. 7 at 67.)

2010. 35 SA Ryckeley testified that he informed Respondent that he sustained the injury while fishing and landing a fish, and had been taking his girlfriend's "thirties," referring to 30-milligram oxycodone, which made him feel better. (Tr. vol. 3, at 207; Gov't Ex. 7 at 12-13.) Upon inquiry as to pain level, SA Ryckeley initially reported pain at "around a two," later adjusting the level upward to "moderate" upon Respondent's explanation of the pain scale. (Tr. vol. 3, at 257.) SA Ryckeley testified that in his undercover role he was trying to avoid using the term "pain" to help gauge the willingness and propensity of the physician to prescribe controlled substances or discharge the patient. (Tr. vol. 3, at 236, 237.) Upon further inquiry by Respondent about pain, use of medication and impact on daily activities, Respondent stated in substance that SA Ryckeley was "underwhelming" him, that he should just take Tylenol, stating: "You don't have anything wrong, I don't get it." (Tr. vol. 3, at 209; Gov't Ex. 7 at 23-24.) Upon inquiry, SA Ryckeley informed Respondent that he drinks "socially," elaborating that he drank "two (2), two (2) or, I don't know. Two (2) or three (3) drinks, max . . . a week maybe, I don't know, maybe . . . it depends on the occasion " (Gov't Ex. 7 at 26.) Respondent advised SA Ryckeley that "we don't prescribe medicines for people who drink alcohol" explaining further the incompatibility of drinking and taking medications, which SA Ryckeley acknowledged, stating "yeah" and "Okay, doc." (<u>Id.</u> at 26-27.)

Respondent further inquired of SA Ryckeley whether the "thirties (30s) seem to be working for you," and SA Ryckeley replied that he liked them, further explaining that "they work good," prompting Respondent to state: "You know, you're killing me, I can't even believe I'm having this conversation." (Gov't Ex. 7 at 28.) SA Ryckeley testified that Respondent had him perform a range-of-motion test, including bending and walking across the room, which SA Ryckeley performed with ease. (Tr. vol. 3, at 210; Gov't Ex. 7 at 28.) Upon inquiry by Respondent as to SA Ryckeley's current pain, SA Ryckeley responded that pain was a five or seven without medication. (Gov't Ex. 7 at 29.) SA Ryckeley testified

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³⁵ SA Ryckeley related the date of injury to the date of his MRI. (Gov't Ex. 7 at 18-19.)

that at the completion of the meeting, Respondent told him he would be started on some medication but Respondent "never told me that he was going to issue me oxycodone." (Tr. vol. 3, at 211-12.)

Respondent issued SA Ryckeley a prescription for 150 Roxicodone 30 mg tablets, which CCHM filled for an initial cost of \$900 cash, but CCHM staff refunded SA Ryckeley \$150 because he was a member of a "group." (Tr. vol. 3, at 212; Gov't Ex. 7 at 62-63.)

Respondent testified in substance that he understood SA Ryckeley's pain to have begun approximately three months prior to the appointment, and interpreted references of "discomfort" to mean pain. (Tr. vol. 10, at 209-12.) Respondent also testified that with regard to alcohol use, he had tried to overemphasize and caution SA Ryckeley not to "drink and take medicine." (Tr. vol. 10, at 227.) Respondent further testified that he interpreted various statements by SA Ryckeley to mean that he was somewhat language-challenged, but gave him the benefit of the doubt while finding SA Ryckeley's choice of words "a little unusual." (Tr. vol. 10, at 227.)

Respondent also testified that he prescribed a lower dose of pain medication than what SA Ryckeley had represented he had taken of his girlfriend's medication, explaining to the patient not to take the medication more often than needed. Respondent testified regarding the patient chart, explaining the chart reflected his diagnosis of lumbar disc displacement, chronic low back pain and muscle spasm. (Tr. vol. 10, at 237; Resp't Ex. 7 at 4.) Respondent testified that he made notes regarding reevaluation of the patient on a follow-up visit, including a concern if the patient was "a legitimate pain patient," and intended to perform a urine drug screen test on the next visit with possible referral to a "Board Certified pain management specialist." (Tr. vol. 10, at 238; Resp't Ex. 7 at 5.)

Dr. Berger testified in substance and in error that SA Ryckeley had reported "only a three week history of back pain." (Tr. vol. 7, at 164; Tr. vol. 9, at 49-60.) Dr. Berger also testified that references in

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³⁶ The testimony of SA Ryckeley, which was fully consistent with the medical file, audio recording and transcript, reflected a reported duration of pain of approximately three months. (See Gov't Exs. 7 & 27.) On cross-

the medical file regarding the patient taking controlled substances from his girlfriend makes the patient "a bad candidate for compliance," because the patient may be willing to share or divert medication. (Tr. vol. 7, at 167.)

5. Respondent's Registered Locations

The Government presented the testimony of DI Barbara Boggess, DEA, who testified in substance to having approximately twenty-five years of experience with DEA as a diversion investigator. (Tr. vol. 1, at 67.) DI Boggess identified nine registered locations where Respondent had maintained a DEA COR, along with Respondent's Internet application for a DEA registration in Orlando, Florida. (Tr. vol. 1, at 70; Gov't Exs. 2 & 3.) The evidence also included a "returned" envelope, sent by DEA to Respondent's registered location in Wellington, Florida, bearing a postage date of December 22, 2010.³⁷

DI Boggess further testified that if a registrant discontinues practice at a registered location, there is a process to return a COR to DEA. (Tr. vol. 1, at 83-84.) A registrant that leaves a location with the intent of returning prior to the registration expiration date is not required to notify DEA. (Tr. vol. 1, at 86.)

6. Respondent's Registration History and Prescribing Practices

Respondent offered testimony related to his prescribing experience and practice generally.

Respondent also presented testimony from three witnesses related to his work for public safety departments at three registered locations in Florida. Mark Pure, Division Chief, Green Acres Fire and Rescue Department, testified in substance that he has been employed by the City of Greenacres, Florida for approximately eighteen years, and has known Respondent the entire time. (Tr. vol. 9, at 146-47.)

Mr. Pure testified that Respondent was the Medical Director for the fire department, overseeing

examination, Dr. Berger eventually acknowledged the error, stating: "I felt that [Respondent] wrote three weeks. Frankly, three weeks or three months is not that big a difference." (Tr. vol. 9, at 60.)

³⁷ Contrary to the Government's Prehearing Statement, DI Boggess offered no testimony pertaining to her activities on December 16, 2010, related to collecting unused copies of DEA Form 222, or inventory of controlled substances at Respondent's registered location in Deerfield, Beach, Florida. (See ALJ Ex. 9 at 38.)

emergency medical service issues, to include writing protocols. The written protocols included guidance on handling of controlled substances such as morphine, Dilaudid and others. (Tr. vol. 9, at 149.)

Mr. Pure testified that during his tenure he was unaware of any issues or concerns related to Respondent's ordering, maintenance or distribution of controlled substances.

David Dyal, Assistant Fire Chief, Stuart, Florida, testified in substance to having previously worked for the West Palm Beach Fire Department from 1976 to 2004, where he worked with Respondent. (Tr. vol. 9, at 170-71.) Mr. Dyal testified that he met Respondent in the 1980's after Respondent became Medical Director, and worked with Respondent until 2004, but has not worked with him since. (Tr. vol. 9, at 179.) Mr. Dyal testified to interaction over the years with Respondent related to medical treatment protocols, paramedic training and record keeping, to include Respondent's preparation of copies of DEA Form 222. Mr. Dyal further testified that he was not aware of any issues with controlled substances, such as safety or diversion, during his tenure. (Tr. vol. 9, at 174.) Mr. Dyal testified that he believed Respondent to be an outstanding physician. (Tr. vol. 9, at 177.)

Philip Webb, Fire Chief, City of West Palm Beach, Florida, testified in substance to having previously worked with Respondent since in or about 1985 or 1986, but only professionally. (Tr. vol. 9, at 191 & 196.) Mr. Webb testified that during the entire twenty-six year period, Respondent has been the Medical Director for the fire department, performing functions such as training, quality assurance and protocols, among others. (Tr. vol. 9, at 192-93.) Mr. Webb further testified that he is unaware of any problems or issues regarding controlled substances during the time period that Respondent has been Medical Director. (Tr. vol. 9, at 193-94.) Mr. Webb testified that he has not observed Respondent write prescriptions or treat patients. (Tr. vol. 9, at 198.)

Respondent testified in substance to having a twenty-eight year history as an emergency room physician, prescribing controlled substances to large numbers of patients over the years, in addition to work with emergency medical services. (Tr. vol. 9, at 222.) Respondent testified that he has experience

assessing pain, as well as treating chronic pain. (Tr. vol. 9, at 222-23.) Respondent's experience included patients seeking pain medication, and he would attempt to validate if the pain was real or not. (Tr. vol. 9, at 227.) Respondent further testified that over time he developed a "sixth sense in determining whose pain was real or not." (Tr. vol. 9, at 231.) Respondent further testified that since residency training, he has not had any formal training in pain management, other than a one-hour home study course related to pain. (Tr. vol. 11, at 191-92.)

Respondent next testified that he did not receive any new or additional training before starting work at CMG. (Tr. vol. 9, at 232.) Respondent left CMG because of a disagreement with the owner regarding the owner's unwillingness to fire a staff member that Respondent believed was responsible for the falsification of a patient drug screen. (Tr. vol. 9, at 233.) Respondent was not allowed to take his patient files with him when he left CMG, because Respondent felt under duress, fear and in danger, but did not report the incident to the police. (Tr. vol. 11, at 69-70, 74.) Respondent also worked for another pain clinic for approximately one week before it was closed. (Tr. vol. 9, at 235.)

Respondent testified that he began working at CCHM in April 2010, as one of four or five doctors, along with five or six staff members. (Tr. vol. 9, at 236.) In October 2010, Respondent became the owner of CCHM, as well as practicing physician, and "fired" or "didn't continue" a number of staff members, due to issues of trust and comfort that they were on the "same page." (Tr. vol. 9, at 236-37.) Respondent testified that he began making other changes at the clinic upon becoming owner, in an attempt to implement changes that were being contemplated but not yet enacted by the Florida Board of Medicine. (Tr. vol. 9, at 237-38, 249; Resp't Ex. 22.) As part of that process, Respondent hired a Florida certified risk manager, who worked with Respondent to implement a policy and procedure manual for CCHM. (Tr. vol. 9, at 238; Resp't Ex. 23.)

Respondent testified that after becoming owner of CCHM, he recalled an occasion where he "learned that a triage person had dirtied, if you will, a urine test," explaining that to be "slang that

patients use" where check boxes are made to look like the patient is taking medication. (Tr. vol. 9, at 239.) Respondent further testified that he confronted the employee, who admitted the misconduct, and then Respondent fired the person. (Tr. vol. 9, at 240-41.) Respondent also testified that on six to ten occasions Respondent or his staff contacted the Broward County Sheriff's Office to report illegal or deceptive activity, but found the Sheriff's Office very unresponsive. (Tr. vol. 9, at 241-43.)

Respondent testified that the specific changes to CCHM that he began implementing after becoming owner in October 2010 included changes to patient drug testing, an office policy and procedure manual, and urine drug screening process, and the discharge of hundreds of patients. (Tr. vol. 9, at 260-74; Resp't Ex. 23.)

Respondent next testified that during his tenure at CCHM beginning in April 2010, he had "no knowledge that a staff member or physician filled in a form" on a patient's behalf. (Tr. vol. 9, at 285.)

Respondent testified there were times when notations might be placed on forms based on what a patient told a doctor. (Id.) Respondent testified that with regard to SA Priymak's patient file, an arrow on the pain scale form filled out by the patient that reflects higher pain may have been placed on the form by Respondent, who explained in substance that marking a patient form in that matter is appropriate if it clarifies what the patient meant. (Tr. vol. 11, at 63-64; Gov't Ex. 22 at 10.)

Respondent testified that he did not know how many of his patients lived outside of Florida and "never tracked that," but based on patient files acknowledged three lived in Kentucky, and another had identification listing residence in Virginia. (Tr. vol. 11, at 85-87; Resp't Exs. 13, 15, 17 & 19.) Respondent testified that his staff tried to get medical records, but acknowledged that six of the patient files presented at hearing contained no prior medical records or verification of statements made by the patients. (Tr. vol. 11, at 91-92; Resp't Exs. 11, 13, 15-17 & 19.) Respondent testified that hundreds of

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³⁸ With regard to verifying patient statements, Respondent tautologically explained: "Well, if you can't get medical records, then you know, it can't be verified." (Tr. vol. 11, at 92.)

other patient files contain prior medical records, but acknowledged that none introduced at hearing, including undercover files, contained any. (Tr. vol. 11, at 94.)

Respondent testified that he did not recall how he was paid while working at CMG, but the salary was not tied to dispensing pills, and Respondent received payment from the owner. (Tr. vol. 11, at 97-98.) Respondent testified that while at American Pain he made "maybe \$1000," explaining that he "never actually made any money there, because the checks never cleared." (Tr. vol. 11, at 104.) At CCHM, Respondent testified that he recalls being paid "\$1500 a day" by check, and received "\$250 a week" which was not "directly attached to the distribution of pills" but had to do with time Respondent spent in the CCHM pharmacy, on things such as record-keeping, and work with the "pharmacy tech," among other duties. ³⁹ (Tr. vol. 11, at 106.)

Respondent further testified that he was aware of the term "VIP service" in the context of a pain clinic visit, explaining that staff members didn't ask for money, "but that you know, occasional patient would add some money to their bill, in order to be expedited" at the clinic. (Tr. vol. 11, at 183.)

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. ⁴⁰ "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

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³⁹ Respondent testified that payment for pharmacy duties continued up until he purchased CCHM in October 2010. (Tr. vol. 11, at 108.)

⁴⁰ 21 U.S.C. § 822(a)(2); 21 U.S.C. § 802(10).

a corresponding responsibility on the pharmacist who fills the prescription.⁴¹ 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.⁴² 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).⁴³

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 continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. § 823(f).

Pursuant to 21 U.S.C. § 823(f), the Administrator may deny an application for a DEA COR if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Administrator is required to consider the following factors:

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

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

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⁴¹ 21 C.F.R. § 1306.04(a).

⁴² 21 U.S.C. § 844(a).

⁴³ See Kuen H. Chen, M.D., 58 Fed. Reg. 65,401, 65,402 (DEA 1993).

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 record-keeping practices that are "tethered securely to state law . . . and federal regulations." Volkman v. DEA, 567 F.3d 215, 223 (6th Cir. 2009). Additionally, in an action to deny a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied. The burden of proof shifts to the respondent once the Government has made its prima facie case. The description of the proving that the requirement has made its prima facie case.

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. Moreover, up until the time he was served with the OSC/IS in this case, Respondent held a Florida state dispensing license. (Tr. vol. 11, at 117.) Although not dispositive, Respondent's possession of a valid unrestricted medical license in Florida weighs against a finding that Respondent's registration would be inconsistent with the public interest. See Robert A. Leslie, M.D., 68 Fed. Reg. 15,227, 15,230 (DEA 2003) (state license is a necessary, but not a sufficient condition for registration, and therefore, this factor is not dispositive).

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

⁴⁴ See 21 C.F.R. § 1301.44(e) (2010).

⁴⁵ 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).

⁴⁶ He surrendered that license because "without a DEA license, I could not dispense." (Tr. vol. 11, at 117.)

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

In this case, there is indeed evidence that Respondent has failed to remain in compliance with applicable federal and state law relating to controlled substances, and that his past experience in dispensing controlled substances with regard to several patients was inconsistent with the public interest. The evidence at hearing centered in substantial part on patient files previously seized from Respondent's office on December 16, 2010. (E.g., Tr. vol. 2, at 111.) In addition to the patient files, the Government presented the testimony and written report of a medical expert witness, Dr. Berger, with regard to his review of eight patient files along with his opinion as to whether Respondent issued prescriptions in each instance for a legitimate medical purpose and in the usual course of professional practice. The patient files related to office visits with Respondent occurring at various dates between April and July, 2010. Respondent testified as to his standard of care and treatment for each of the eight patients, along with his past experience, among other testimony. Respondent also testified as to his standard of care and treatment of six additional patients. (See Resp't Exs. 11, 13, 15-17 & 19.)

Evaluation of Respondent's prescribing conduct in this case is governed by applicable federal and state law. The applicable standard under federal law is whether a prescription for a controlled substance is "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). The 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 (DEA 2011) (citing Brown v. Colm, 11 Cal.3d 639, 642-43 (1974)). Although it is recognized that state law is a relevant factor in determining whether a practitioner is acting in the "usual course of professional practice," it is also 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).

The applicable standards under Florida law may be found in FAC 64B8-9.013 ("Standards for the Use of Controlled Substances for the Treatment of Pain"). 47 Prevailing Florida regulation emphasizes 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). It further provides 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. 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. r. 65B8-9.013(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 . . .
- (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:
 - 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);

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⁴⁷ Due to the effective dates of the applicable state regulation, FAC 64B8-9.013 (2003) applies to conduct between October 19, 2003, and October 17, 2010; FAC 64B8-9.013 (2010) applies to conduct thereafter. See generally https://www.flrules.org/gateway/ruleNo.asp?id=64B8-9.013.

- 8. Instructions and agreements; and
- 9. Periodic Reviews

10.

Fla. Admin. Code Ann. r. 65B8-9.013(3) (2003).

Turning to the evidence in the instant case, the record reveals violations of federal and state law relating to Respondent's interactions with undercover agents posing as patients at two clinics: CCHM and CMG.

1. CCHM

(a) SA Marshall

(i) SA Marshall, March 10, 2010 Visit to CCHM

As noted above, the record reflects that SA Marshall visited CCHM on March 10, 2010, and was ultimately treated by Dr. [L.C.]. 48 (See, e.g., Gov't Ex. 6 at 18 & 20; Tr. vol. 4, at 7.) SA Marshall presented the staff with an MRI. (Tr. vol. 4, at 43.) A man in the lobby filled out some of SA Marshall's patient paperwork, to include circling the numbers nine and eight on his pain scale, the descriptions of pain, the times of day that pain became worse, whether pain was continuous and side effects from medication. (Tr. vol. 4, at 22, 38-39.) A patient in the lobby told SA Marshall that to indicate on his patient forms that he was already receiving opiates, he should reference American Pain, a clinic which was then closed, "because they had been closed down and [CCHM] wouldn't be able to pull my prior history there " (Tr. vol. 4, at 41.) SA Marshall told Dr. [L.C.] that "someone in the lobby had . . . circled the 9's, and I told him that I was more like a three or a four." (Tr. vol. 4, at 50.) Dr. [L.C.] ultimately issued SA Marshall a prescription for oxycodone and Xanax. (Gov't Ex. 21 at 25; Tr. vol. 4, at 42-43; see Gov't Ex. 6 at 19, 21-23.)

(ii) SA Marshall, April 7, 2010 Visit to CCHM

⁴⁸ Although there is some ambiguity in the record as to the date, the great weight of references to SA Marshall's March 2010 visit to Coast to Coast places the meeting on March 10, 2010.

SA Marshall returned to CCHM in an undercover capacity on April 7, 2010. (E.g., Gov't Ex. 6, at 1.) A CCHM employee named Cindy Mesa recognized him when he arrived, stating "I know you." (Gov't Ex. 6 at 2.) SA Marshall responded that he was there for a follow-up visit and Ms. Mesa directed him to a window for follow-up patients. (Gov't Ex. 6 at 3.) Respondent later testified that on April 7, 2010, SA Marshall appeared unshaven and his hair stood up in spikes as if there were gel in it. (Tr. vol. 10, at 60.)

Behind closed doors in the triage nurse's office (see Tr. vol. 4, at 20), SA Marshall had a conversation with CCHM triage nurse (Tr. vol. 4, at 13) Chera Kay Davis (e.g., Gov't Ex. 6 at 27), in which SA Marshall recounted that an unknown white male in the lobby (Tr. vol. 4, at 13-14) during his March 10 visit "said . . . to give you some dough and you'd dirty up my urine . . . He told you that . . . he'd slide you fifty dollars . . . and that you'd, you, dirty up my urine." (Gov't Ex. 6 at 10.) Ms. Davis responded that she remembered (Gov't Ex. 6 at 10) and then asked: "Oh, he just gave you fifteen's the last time?" to which SA Marshall responded "Yeah, he didn't give me [anything] . . . I don't have [anything] in my urine, so I hope he'll up, he'll up me . . . You think he will?" (Gov't Ex. 6 at 10.) Ms. Davis replied: "You're seeing another doctor though, so don't . . . worry about him." (Gov't Ex. 6 at 10-11.)

SA Marshall testified that "I slid her \$50. Then she took it and she found the sheet that referenced urinalysis and I noticed that she checked opiates, specifically . . . And she never tested my urine." (Tr. vol. 4, at 15, 18; see Gov't Ex. 21 at 26.) This conversation constitutes evidence that at least one member of Respondent's staff was willing to falsify SA Marshall's patient files in an effort to facilitate the diversion of controlled substances.

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⁴⁹ At hearing, SA Marshall explained that "what I mean by dirty up my urine is to ensure that it showed it had narcotics in my system . . ." (Tr. vol. 4, at 13.)

⁵⁰ SA Marshall later testified that he gave the triage nurse money on March 10, not April 7. (Tr. vol. 4, at 18-19.)

The record further reflects a meeting between Respondent and SA Marshall on April 7, 2010. 51

(Compare Gov't Ex. 6 at 1, with id. at 16; Tr. vol. 4, at 20.) Respondent asked "what have you been treated for here?" to which SA Marshall responded "my neck." (Gov't Ex. 6 at 18.) Respondent asked how SA Marshall hurt himself, to which SA Marshall replied "I'm homeless . . . I live out on the streets . . . [a]nd I can't sleep." (Gov't Ex. 6 at 18.) SA Marshall stated he was taking an unidentified medication to help him sleep and oxycodone to help with his stiff neck. (Gov't Ex. 6 at 19.) Respondent asked how bad his pain was, to which SA Marshall responded that "sometimes it's like a three or four . . . How does it need [to] be?" (Gov't Ex. 6 at 19.) SA Marshall also told Respondent that a person in the lobby had filled out his patient forms. (E.g., Tr. vol. 4, at 62; Gov't Ex. 6 at 20.) Respondent replied: "Is this a test? . . . I think this must be . . . a test for me." (Gov't Ex. 6 at 19-20; Tr. vol. 4, at 24.) Respondent asked what being homeless had to do with pain medicine, confirming with SA Marshall in substance that SA Marshall was selling the prescriptions. (Gov't Ex. 6 at 21-23.) Shortly thereafter, Respondent escorted SA Marshall to the reception area, (Tr. vol. 4, at 25), stating: "we don't, um, participate in such . . . folly." (Gov't Ex. 6 at 23.)

SA Marshall testified that Respondent walked up to a nurse but "that was in a back room, and I couldn't hear what they were saying." (Tr. vol. 4, at 25.) SA Marshall waited and observed Respondent call another patient.

SA Marshall testified that a nurse named Cindy Mesa then took him aside for a conversation (Tr. vol. 4, at 25) in the reception area (Gov't Ex. 6 at 24). Ms. Mesa elaborated:

Mesa: Are you [expletive] crazy? . . . You told him you live on

the street and that you sell the pills?

UC1: Well he wouldn't . . . listen to my story about how I'm

trying to fix my neck.

Mesa: Oh my God! You know, okay, now you know what I have

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⁵¹ SA Marshall testified that his first meeting with Respondent occurred on April 8, 2010, (Tr. vol. 4, at 7), but he later retracted this testimony and stated that his first meeting with Respondent occurred on April 7, 2010. (Tr. vol. 4, at 10.)

to do? I have to change the files and erase this [information] that he put here, and reschedule for [Dr.[R.C.]] tomorrow. Okay?... never, never say that you sell this, that, that on the street, ever. Because they think that you're an undercover, okay? And that you're trying to bust his nuts... Now I'll have to call you tomorrow.

(Gov't Ex. 6 at 25-26.) At hearing, SA Marshall explained that Ms. Mesa told him she would "change your chart, erase the information and call you back tomorrow to see another doctor." (Tr. vol. 4, at 26.) Respondent testified that he was not privy to this conversation, nor was he made aware that records from SA Marshall's April 7, 2010 visit would be destroyed or that SA Marshall returned the next day to see Dr. [N.]. (Tr. vol. 4, at 65-66.) Respondent further testified that there was no basis in the medical record to conclude that Dr. [N.] was aware that SA Marshall had been ejected the previous day. (Tr. vol. 10, at 68.) Although I find that that Respondent did not know in April 2010 that his employee destroyed documents from SA Marshall's original patient chart or arranged for him to be seen again, I find that Respondent believed SA Marshall was an undercover law enforcement officer, which served as his basis for discharging SA Marshall. At hearing, Respondent testified that he discharged SA Marshall because he was concerned about the possibility of diversion, which I do not find credible. (Tr. vol. 10, at 61-62. 64.) In fact, Respondent had a concern about law enforcement activity dating back to at least March 5, 2010, as evidenced by his statement to SA Bazile during an undercover patient visit at CMG that he was aware from news stories that DEA was "targeting doctors like him." (Tr. vol. 6, at 23.)

(iii) SA Marshall, April 8, 2010 Visit to CCHM

On April 8, 2010, one day after his unsuccessful visit with Respondent, SA Marshall returned to CCHM in an undercover capacity (Tr. vol. 4, at 27) and was seen by Dr. [N.] (Gov't Ex. 6 at 38; Tr. vol. 4, at 27-28.) The evidence further reflects that Cindy Mesa had prepared a new chart for SA Marshall and "She had me sign something, which was so quick, I don't know what I signed." (Tr. vol. 4, at 27.)

SA Marshall received prescriptions for OxyContin, Roxicodone and Xanax from Dr. [N] or Dr. [N.]'s physician's assistant. (Tr. vol. 4, at 28, 42; Gov't Ex. 21 at 24.)

(iv) SA Marshall, May 4, 2010 Visit to CCHM

SA Marshall returned to CCHM in an undercover capacity for a fourth visit on May 4, 2010. (E.g., Gov't Ex. 6, at 27; Tr. vol. 4, at 11, 28-29.) SA Marshall had a conversation with triage nurse Chera Kay Davis (Tr. vol. 4, at 29) recounting how Respondent had rejected SA Marshall as a patient on a previous visit and what happened afterward. "[H]e went and he told Cindy and . . . she changed my paper work and brought me back in and I saw . . . [Dr. [N.]]. So I hope he doesn't remember me . . . my paperwork is all different, 52 but he shouldn't . . . recognize it." (Gov't Ex. 6 at 38; see generally Tr. vol. 10, at 59.)

Davis responded: "You go and tell that man, tell him that you are in pain. What the hell!" (Gov't Ex. 6 at 38.) This conversation constitutes evidence that multiple members of Respondent's staff knew, and were not concerned, that CCHM staff member Cindy Mesa had tampered with SA Marshall's patient files in an effort to facilitate the diversion of controlled substances.

SA Marshall then met with Respondent, who did not recognize him. (Gov't Ex. 6 at 39-41; Tr. vol. 4, at 126; Tr. vol. 10, at 69-70.) Nor did SA Marshall call Respondent's attention to the fact that they had met before (see Tr. vol. 4, at 76, 125-26); Respondent testified that SA Marshall's spiked hair was covered with a hat, that SA Marshall presented with a different persona and that Respondent had seen approximately 400 patients since last they met. (Tr. vol. 10, at 69, 73-74, 76.) The meeting lasted under three minutes. (Tr. vol. 4, at 30, 128.) Respondent listened to SA Marshall's breathing and directed him to place his hands out palm up. (Tr. vol. 4, at 31.) Although SA Marshall had indicated in his patient forms that he had emphysema / asthma, bipolar disorder, fractures, insomnia, depression and

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⁵² The record reflects, however, that some of SA Marshall's original paperwork remained. (E.g., Tr. vol. 4, at 38 (paperwork completed on March 10, 2010).) I therefore infer that Cindy Mesa destroyed only the notes relating to SA Marshall's first visit associated with Respondent's decision to terminate SA Marshall as a patient, clearly evidencing Ms. Mesa's disagreement with Respondent's assessment that SA Marshall was an undercover law enforcement officer. (See Tr. vol. 4, at 92.)

headaches (Tr. vol. 4, at 36-37; Gov't Ex. 21 at 10-11), Respondent did not discuss any of these topics with SA Marshall. (Tr. vol. 4, at 36-37.) As noted above, Dr. Berger found notable the absence of psychiatric consultations in the patient chart. (See Tr. vol. 10, at 64-65.)

Respondent then inquired whether SA Marshall had pain in his back, and SA Marshall responded in the negative. (Tr. vol. 4, at 31.) Respondent asked if SA Marshall had pain in his neck, and SA Marshall responded in the affirmative. (Tr. vol. 4, at 31.) Moments later, Respondent issued SA Marshall the same prescription Dr. [N.] had prescribed on April 8, 2010 (Tr. vol. 4, at 86): 120 oxycodone 30 mg and 30 Xanax 3 mg tablets.⁵³ (Tr. vol. 4, at 31; Gov't Ex. 6 at 45; Gov't Ex. 21 at 22.) Respondent did not address alternative medications, treatment plans or physical therapy. (Tr. vol. 4, at 44-45.) Respondent did not ask SA Marshall for prior medical records from previous doctors, which is inconsistent with the requirement and spirit of Fla. Admin. Code Ann. r. 64B8-9.013(3)(f), which provides that a physician must keep accurate medical records.⁵⁴ (Tr. vol. 4, at 45.) He ordered no diagnostic tests, provided no time table for his pain management, discussed no objective goals for pain relief and did not explain how SA Marshall's care would continue or be monitored. (Tr. vol. 4, at 45.) Respondent did, however, ask whether, overall, SA Marshall was doing okay, to which SA Marshall responded in the affirmative. (Tr. vol. 4, at 81.) Dr. Berger testified in substance that the medical file for SA Marshall contained numerous inconsistencies, to include no obvious physical examination on the first visit, an MRI report issued two days before the first visit with no prescribing or ordering physician noted on the MRI report. (Tr. vol. 10, at 63-64; Gov't Ex. 21 at 8.)

The record further reveals evidence that Respondent documented in SA Marshall's patient file discussions that did not actually occur. For instance, despite contrary notations in the patient file (see Gov't Ex. 21 at 8), SA Marshall testified that Respondent never discussed anti-inflammatory medication,

⁵³ As Respondent testified, I find that Dr. Berger's testimony that Respondent had doubled the prescription was inaccurate. (Tr. vol. 10, at 82-83.)

⁵⁴ A copy of SA Marshall's MRI report appears to have been in his case file at the time Respondent viewed it. (<u>E.g.</u>, Gov't Ex. 21 at 27-28; Tr. vol. 4, at 42-45.)

diet, the risks and benefits of the medication, omega-3 fish oil, glucosamine chondroitin sulfate, avoidance of alcohol, soda and illegal drugs or weaning off of medication or the medications SA Marshall was currently taking. (Tr. vol. 4, at 35-36, 39.) Respondent did, however, advise SA Marshall to do some stretching. (Tr. vol. 10, at 85.) Respondent's conduct constitutes a failure to keep accurate records, to include evaluations, consultations and discussion of risks and benefits, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3).

In summary, the record reveals violations attributable to Respondent of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA Marshall's undercover visits to CCHM. I find that Respondent credibly testified that he did not recognize SA Marshall on May 4, 2010, or remember having terminated him as a patient. Nevertheless, substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Marshall lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code Ann. r. 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). Moreover, I find that Respondent knew or should have known that staff members and individuals posing as patients at CCHM diverted or attempt to divert controlled substances.

(b) SA Saenz

SA Saenz visited CCHM in an undercover capacity on March 4, 2010, twice on March 10, 2010, and again on April 8, 2010. (See Tr. vol. 2, at 236-37, 259 & 265.) She was seen by Dr. [L.C.], Dr. [R.C.] and Dr. [N.] and prescribed controlled substances by Dr. [R.C.] and Dr. [N.]⁵⁵ (Tr. vol. 2, at 237, 281-83; Gov't Ex. 24 at 25-26.) May 4, 2010, however, was the first time SA Saenz came into contact with

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⁵⁵ SA Saenz testified that Dr. [L.C.] declined to prescribe medication for her during a previous visit to Coast to Coast. "He told me he didn't want me to be a drug addict, and that is why he wasn't going to prescribe it, because he didn't think I needed it." (Tr. vol. 2, at 300.) SA Saenz did not tell Respondent about her conversation with Dr. [L.C.], but she did tell the clinic staff (Tr. vol. 2, at 301), which tends to show that Respondent's staff facilitated or acquiesced in the prescription of controlled substances for other than a legitimate medical purpose and outside the usual course of professional practice.

Respondent at CCHM, when she visited again in an undercover capacity. (See_Tr. vol. 2, at 231, 238.) SA Saenz testified that at each visit she went to a different doctor at CCHM, "told them I wanted something stronger" and the doctors accommodated her request. (Tr. vol. 2, at 263-64.) She has no legitimate medical condition that would justify taking any of the prescriptions she was ultimately prescribed. (Tr. vol. 2, at 264.)

During SA Saenz's undercover visit to CCHM on May 4, 2010 (Tr. vol. 2, at 231), she was accompanied by two other undercover agents initially and a third who joined them later. (Tr. vol. 2, at 233 & 285.) Upon arriving at the clinic they requested to be moved to the front of the line, paid a receptionist named Carla \$200 for the \$150 office visit and did not receive any change. (Tr. vol. 2, at 233-34.) Carla then instructed SA Saenz to complete paperwork to add to her patient file, which already contained paperwork from previous visits. (Tr. vol. 2, at 235-36.) She was directed to wait in a waiting room, after which she completed triage procedures with staff members. (See Tr. vol. 2, at 241.)

The record reflects that Respondent briefly met with SA Saenz in a patient consultation room and issued her controlled substances prescriptions after limited conversation and a cursory physical examination. SA Saenz testified that she met with Respondent for no more than ten minutes. (Tr. vol. 2, at 242, 244.) He asked her how she was, whether her current prescriptions were helping and whether she had a job; beyond that did not discuss her previous medication. (Tr. vol. 2, at 242, 257.) She said her prescriptions, including oxycodone, were helping and that she had a job at daycare but requested to increase her Roxicodone 30 mg dosage from ninety to 120 pills, and Respondent agreed. (Tr. vol. 2, at 242-43, 275-76.) Using a computer, he printed prescriptions for 120 Roxicodone 30 mg and 30 Xanax 2 mg tablets. (Tr. vol. 2, at 245; Gov't Ex. 15 at 1-2, 5-6; Gov't Ex. 24 at 2 & 24) and advised her not to share or sell her prescriptions. (Tr. vol. 2, at 243-44.) SA Saenz testified that Respondent checked her heart rate with a stethoscope but did not conduct any further testing or direct her to complete any physical exercises. (Tr. vol. 2, at 245.) Respondent asked what was bothering her and she indicated her

lower back. (Tr. vol. 2, at 245.) He did not use his hands to check her spine. (Tr. vol. 2, at 245.) Respondent did not discuss the prior doctors that SA Saenz saw, additional diagnostic tests she might have, a treatment plan, the objective and goals for pain relief, a time table for pain management treatment, the risks and benefits of the pain medication or alternative medication and treatments. (Tr. vol. 2, at 249-50.) Under such circumstances, questions arise as to whether Respondent complied with Florida guidelines regarding treatment plans and informed consent, to include discussion of risks and benefits. See Fla. Admin. Code Ann. r. 65B8-9.013(3)(b) & (c).

The record further reveals evidence that Respondent documented in SA Saenz's patient file discussions that did not actually occur. For instance, despite contrary notations in the patient file (Gov't Ex. 24 at 2 & 9), SA Saenz testified that Respondent never discussed anti-inflammatory medications, diet, the risks and benefits of the medication, yoga and stretching exercises, omega-3 fish oil, recommended at 36 grams per day, glucosamine chondroitin sulfate, avoidance of alcohol and soda, smoking cessation, follow-up visits or weaning off medications, in violation of compulsory language contained in Fla. Admin. Code Ann. r. 65B8-9.013(3)(f) ("The physician is required to keep accurate and complete medical records" (emphasis supplied)). Of additional concern is Respondent's failure to discuss alcohol avoidance while on the controlled substances that he prescribed, in light of the fact that SA Saenz had indicated on patient intake forms in her patient file that she drank alcohol. (Tr. vol. 2, at 255; Gov't Ex. 24 at 12.)

By corollary, the record reveals evidence of discussions that should have occurred, but didn't. SA Saenz testified that in her patient intake form she indicated that she suffered from insomnia and depression (Gov't Ex. 24 at 11, Tr. vol. 2, at 291) but the record supports the inference that Respondent did not inquire about these matters (see Tr. vol. 2, at 226 (SA Saenz's testimony that she did not forget about anything that occurred during her visit with Respondent)) and the patient note from the visit does not reflect that Respondent made such inquiries. (See Gov't Ex. 24 at 2.)

In support of his prescribing practices, Respondent testified as to how SA Saenz presented as a patient on May 4, 2010. He testified that she had been seen previously, had an MRI reflecting abnormalities in her lower lumbar spine and that Dr. [R.C.] and Dr. [N.] prescribed medication that did not afford her much relief. (Tr. vol. 10, at 174-75.) Respondent opined that "trying to dial in the right dose for each patient, sometimes takes some modifications and takes some time to reach that dose." (Tr. vol. 10, at 175.) Moreover, Respondent testified that "She lists back in March that . . . she was taking a large amount of medication [and] . . . was still well below what she represented that she had taken" previously. (Tr. vol. 10, at 176-77; see also id. 179.) Respondent further explained that two drugs that SA Saenz had listed on her pain assessment form, Roxicodone 30 mg and oxycodone 50 mg tablets, might reasonably be prescribed together to address breakthrough pain. (Tr. vo. 10, at 177-78.) Respondent testified that he was relying on the truthfulness of the information contained in her patient file, and that had he been aware of the misrepresentations, he would not have prescribed medications to her. (Tr. vol. 10, at 180.) Respondent further testified that he believed she was using the medication for medical purposes and was not diverting. (Tr. vol. 10, at 180-81.)

As noted above, I give little to no weight to Dr. Berger's testimony with respect to SA Saenz because of material factual errors in his analysis of this patient file.

In sum, the record reveals violations of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA Saenz's May 4, 2010 visit to CCHM. Substantial evidence supports a finding that Respondent kept inaccurate records, in violation of Florida regulations. The Government, however, has failed to sustain its burden of proof to support its allegation that Respondent's issuance of controlled substances prescriptions to SA Saenz were for other than a legitimate medical purpose.

(c) SA O'Neil

SA O'Neil visited CCHM in an undercover capacity in March and April 2010 and met with Dr. [L.C.] (Tr. vol. 3, at 301-02.) Pursuant to those visits, SA O'Neil supplied CCHM with an MRI report. (See Tr. vol. 3, at 304; Gov't Ex. 14 at 55-56.) On May 4, 2010, he returned to CCHM in an undercover capacity and met with Respondent for the first time. (E.g., Tr. vol. 3, at 301.) The circumstances of Respondent's interaction with SA O'Neil make clear that Respondent and Respondent's staff believed SA O'Neil was diverting and abusing controlled substances.

On May 4, 2010, SA O'Neil arrived at CCHM with three other agents and entered the facility through the front door. (Tr. vol. 3, at 301.) Upon arrival, SA O'Neil signed in as a returning patient and requested that he and the other three agents be seen together. (Tr. vol. 3, at 303, 305.) A woman asked whether they were new patients. SA O'Neil responded "No, no, no. They're . . . followers." (Gov't Ex. 14⁵⁶ at 3.) The staff member complied with his request and placed the agents' charts in the same area. (Tr. vol. 3, at 306; see Gov't Ex. 14 at 16-19.) SA O'Neil paid \$200 for a \$150 visit and let the employee keep the change. (Tr. vol. 3, at 305.) He also told the staff member that he would quadruple the money. (Tr. vol. 3, at 306; Gov't Ex. 14 at 16.) Although not dispositive, this evidence indicates that the staff of CCHM interacted with patients in unorthodox ways. For instance, the overpayment by \$50 and discussion of quadrupling provides some evidence of a profit motive for employees to process patients according to the patients' requests instead of according to an established or conventional medical office procedure. Hearing the patients referred to as "followers" provides some basis for the staff member to have suspected, if not actually known, that the patients were together as some sort of a common plan or scheme.

SA O'Neil next proceeded to the triage area where a female staff member named Ms. Wade measured his blood pressure, weight and temperature and asked for his height. (Tr. vol. 3, at 306; see Gov't Ex. 14 at 23-25.) SA O'Neil testified that "I discussed the fact that I don't take the medication . . .

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⁵⁶ SA O'Neil testified that in the context of the first tape (N43.1) of Government Exhibit 23, SA O'Neil is identified as UC1. (Tr. vol. 3, at 363.)

And she said 'I know.' She said something to the extent of 'I know, I'm not stupid.'" (Tr. vol. 3, at 307.)

A transcription of an undercover recording of the conversation confirms SA O'Neil's account:

WADE: [Laughs] Ah ah ah. [Pause] How could he get you on this

s[tuff]?

UC1: Uh-huh.

WADE: You asked him for it?

UC1: Yeah, of course. I'm not gonna waste money . . . for

nothing . . . even more too.

WADE: You take the pills, Sean?

UC1: Nah.

WADE: I know you [unintelligible] . . . Besides, I know you don't

take them.

UC1: How can you tell?

WADE: What you mean how can I tell? I'm stupid?

(Gov't Ex. 14 at 24-25; see generally Tr. vol. 3, at 308.) This conversation constitutes evidence that Respondent's staff in this instance possessed actual knowledge of diversion by patients. The staff's open indifference, if not encouragement, of patients seeking controlled substances for no legitimate medical purpose is inconsistent with Respondent's claim that he was unaware of the problems plaguing CCHM. Episodes such as this, while perhaps not on their own dispositive as to Respondent's specific knowledge of staff misconduct, do in the aggregate weigh in favor of a finding that Respondent was, at a minimum, willfully blind to the flagrant indications of diversion and abuse at the clinic he worked in and later owned.

Following his conversation with Ms. Wade, SA O'Neil waited and was later seen by Respondent. (Tr. vol. 3, at 308-10.) The consultation occurred in an office and lasted approximately fifteen minutes. (Tr. vol. 3, at 310.) Respondent asked SA O'Neil how he was, what his age was and what his current medication was. (Gov't Ex. 14 at 26.) SA O'Neil responded that he was "not bad" and that he took "thirties (30s) . . . two times. And then fifteens (15s) I usually take about one eighty (180), but you wrote

it too low last time . . . And then, Xanax, two (2) milligrams, and sometimes soma."⁵⁷ (Gov't Ex. 14 at 26.) Respondent reviewed the medication SA O'Neil had been prescribed previously by Dr. [L.C.], stating: "well, it's inappropriate . . . your blood pressure. You're taking a blood pressure medicine?" (See Gov't Ex. 14 at 26-27; see generally Tr. vol. 10, at 150-51.) SA O'Neil responded "Uh . . . I just never filled it," to which Respondent replied that SA O'Neil's blood pressure was up again on that day. (Gov't Ex. 14 at 27.)

SA O'Neil next told Respondent what Dr. [L.C.] had told him on a previous visit. "He told me . . . 'start, and you can go up each time.' . . . I found out he only works Wednesdays, but, . . . he said you'd [sic] gonna increase it." (Gov't Ex. 14 at 27.) This statement by SA O'Neil apprised Respondent that SA O'Neil was a drug-seeking individual and that Respondent's colleague, Dr. [L.C.], was also aware of this fact.

Respondent asked how SA O'Neil was doing on the present dosage of medication. (Gov't Ex. 14 at 27.) A transcript of the conversation that followed reveals that SA O'Neil communicated that although he was doing "Fine" (Gov't Ex. 14 at 27), he nevertheless wanted a higher dosage of medication for other than a legitimate medical purpose:

WOLFF: Oh, so you're doing okay?

UC1: No, no. I need more. But I don't need any less. The present dose is not.

. . it would be better if it was more. It's not, you know, not making me

feel worse.

WOLFF: No, no, I understand. You ran out, or it wasn't enough

UC1: Yeah, yeah, I ran out.⁵⁸

(Gov't Ex. 14 at 27-28.) Respondent's comment about SA O'Neil's medication running out represents the first instance that either of them had suggested that SA O'Neil ran out.

⁵⁷ Respondent testified that he did not understand "you" to be referring to himself, because he hadn't seen SA O'Neil before. (Tr. vol. 10, at 151-52.)

⁵⁸ SA O'Neil had not previously indicated that he ran out of medication until Respondent suggested the possibility.

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SA O'Neil later requested that Respondent increase his prescription to 210 pills, to which Respondent replied "maybe eventually, but . . . I can't double your medicine now. Absolutely not." (Gov't Ex. 14 at 30.) The record further reflects that during the meeting, Respondent advised SA O'Neil that "the goal is not to get up to the highest number possible." (Gov't Ex. 14 at 33; Tr. vol. 3, at 338-39.) This statement by Respondent is somewhat consistent with his testimony at hearing that he prescribed controlled substances to SA O'Neil only for a legitimate medical purpose. But other statements and actions by Respondent cut against a finding that Respondent's continued registration would be consistent with the public interest. SA O'Neil provided Respondent with unmistakable evidence of diversion or abuse, stating that he was taking liquid drops of oxycodone that a friend gave him (Gov't Ex. 14 at 30; see id. at 34 ("Oxy"); Tr. vol. 10, at 154-55), to which Respondent replied:

WOLFF: Don't even tell me that.

UC1: Is that still bad? WOLFF: Yeah, high abuse.

(Gov't Ex. 14 at 30.) Incredibly, a follow-up visit sheet in SA O'Neil's patient file dated May 4, 2010, and filled out by Respondent (<u>see Tr. vol. 3</u>, at 321-22), reflects a handwritten check in the box labeled "No indication of substance abuse or diversion." (Gov't Ex. 23 at 2.) Not only did Respondent state that he did not wish to be told about abuse, Respondent filled out paperwork as if he had not been so told. ⁵⁹ Nor did Respondent talk to SA O'Neil about referring him to rehabilitation (Tr. vol. 3, at 371-72), as is contemplated by Fla. Admin. Code Ann. r. 64B8-9.013(3)(e) ("The management of pain in patients with a history of substance abuse . . . requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.").

At hearing, Respondent testified concerning his statement "Don't even tell me that."

Respondent testified that "I was very disturbed that he would do such a thing, and that was what I said meaning that it - - it hurt me to hear that because I don't like to hear patients using that because I think

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⁵⁹ As noted below, I therefore reject Respondent's explanation that his statement "Don't even tell me that" (Gov't Ex. 14 at 30) should be understood as Respondent's emotional reaction to the patient's behavior. (Tr. vol. 10, at 155.)

it's a dangerous product." (Tr. vol. 10, at 155.) Having observed the witness's demeanor at hearing I reject this statement as not credible, particularly in light of contemporaneous records that Respondent filled out as if SA O'Neil had never told him he was taking liquid oxycodone. (See Gov't Ex. 23 at 2.)

In light of the foregoing evidence, it is apparent that Respondent knew or should have known that SA O'Neil presented as a patient who intended to divert or abuse the controlled substances he sought from Respondent. This conclusion is confirmed by statements attributable to Respondent: the record reflects that Respondent directed SA O'Neil not to take anyone else's medication, to only take his own medication as indicated on the bottle, that there was a risk of death and that "you're living on the edge." (Gov't Ex. 14 at 30-31.) Respondent's failure to reject SA O'Neil as a patient and his decision to issue him controlled substances prescriptions is inconsistent with state and federal law. See Fla. Admin. Code Ann. r. 64B8-9.013(1)(d) ("Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes."); see also 21 C.F.R. § 1306.04(a) ("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.")

Additional statements by Respondent demonstrate Respondent's awareness of the impropriety in the medical community about prescribing to a patient known to be diverting or abusing controlled substances:

WOLFF: Most pain clinics, when, uh, they find out that uh . . .

patients taking other people's stuff, [NOISE].⁶⁰

UC1: Really?

WOLFF: Absolutely. Instantly.

UC1: Even if you run out?

WOLFF: Yeah. [Unintelligible.] . . . because then you will have

violated what I just said "

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⁶⁰ The reference to noise on the transcript reflects Respondent's verbal reference to being cut off. <u>See infra</u> note 94.

(Gov't Ex. 14 at 32; Tr. vol. 3, at 312.) Respondent's admission that most clinics would not continue prescribing controlled substances to SA O'Neil under the circumstances (see also Tr. vol. 10, at 159) is strong evidence that Respondent's May 4, 2010 prescriptions to SA O'Neil were outside the usual course of professional practice. Notwithstanding Respondent's admission of the general consensus that further prescribing would be inappropriate, Respondent nevertheless prescribed 150 Roxicodone 30 mg, 90 Roxicodone 15 mg and 30 Xanax 2 mg tablets, constituting an increase of thirty dosage units of oxycodone from what Dr. [L.C.] had prescribed previously. (E.g., Gov't Ex. 14 at 53-54; Tr. vol. 3, at 311, 331 & 356.) And Respondent made clear that SA O'Neil would be welcome again in the future and Respondent would continue to prescribe controlled substances:

UC1: ... So I should probably just make my appointment in

thirty (30) days with you then, right?

WOLFF: I'm here for you.

UC1: All right. Thanks, doc. WOLFF: Yeah. We got a bond now. 61

(Gov't Ex. 14 at 33.) I find that Respondent's issuance of controlled substances to SA O'Neil was outside the usual course of professional practice, in violation of 21 C.F.R. § 1306.04(a); see Fla. Admin. Code Ann. r. 65B8-9.013.

The record further reflects evidence that Respondent documented in SA O'Neil's patient file discussions with the patient that did not actually occur. For instance, contrary to the indications in SA O'Neil's patient file⁶² (see Gov't Ex. 23 at 9), Respondent did not discuss alternative medications, such as anti-inflammatories, a treatment plan for SA O'Neil's pain management, omega-3 fish oil, glucosamine chondroitin sulfate, avoiding alcohol, smoking and soda, any of SA O'Neil's other doctors

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⁶¹ Respondent also instructed SA O'Neil not to see other doctors. (Gov't Ex. 14 at 29.) At hearing, Respondent testified that "I felt he had received the message and given me feedback that he would comply with my direction." (Tr. vol. 10, at 160.)

⁶² Page nine of Government Exhibit 23 is not dated or signed and does not on its face contain express indications that Respondent completed it on May 4, 2010, or that it applies to SA O'Neil. Nevertheless, the document is included in an exhibit that SA O'Neil testified contains his medical records (see Tr. vol. 3, at 367) and the context, including SA O'Neil's testimony that SA O'Neil did not fill it out (Tr. vol. 3, at 323) offers a basis to conclude that Respondent completed the form.

other than Dr. [L.C.], SA O'Neil's MRI report, any diagnostic test, objectives or goals for pain relief, a timetable for treatment, the risks and benefits of his medication or SA O'Neil's continuing care, how he would be monitored on controlled substances or weaning off the medications he was taking. (Tr. vol. 3, at 315-16, 324.) Respondent's conduct constitutes a failure to keep accurate records, to include evaluations, consultations and discussion of risks and benefits, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3).

Explaining why he prescribed controlled substances to SA O'Neil given his indications of drug abuse or diversion, Respondent testified that "I didn't want him to have to use liquid medication to supplement what he was previously on. I wanted him . . . to be in that controlled environment . . . where the amount of medication that he's on is controlled by the physician." (Tr. vol. 10, at 163.) By raising SA O'Neil's dosage, "it was my goal to achieve pain control on . . . a slightly increased dosage that would negate any need on his part to supplement the medication because he may have run out." (Tr. vol. 10, at 164.) Respondent testified that if he had thought SA O'Neil was diverting controlled substances, "I would not have written him anything." (Tr. vol. 10, at 164.) I reject this testimony as not credible, because it is inconsistent with the objective evidence of record. In short, Respondent at hearing attempted to present the impression that Respondent took very seriously the dangers to the patient illuminated by the patient's self-reported drug abuse or diversion. But Respondent's contentions at hearing are not as telling as his own statements to SA O'Neil on May 4, 2010, when Respondent joked about the friend providing oxycodone drops to SA O'Neil, stating "Maybe that person that gave you the, uh, . . . oxy . . . let you use the computer, in light of the fact that they're trying to murder you . . . Google that. William's stretching exercises." (Gov't Ex. 14 at 34.) y

Moreover, as discussed above, Dr. Berger identified numerous problems with Respondent's prescription of controlled substances to SA O'Neil, including, among others, reason to opine that

Respondent's documentation with respect to SA O'Neil was "absolutely below the standard of care." (Tr. vol. 7, at 117.)

In summary, the record reveals numerous violations of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA O'Neil's undercover visit to CCHM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA O'Neil lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code Ann. r. 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) TFO Doklean

The record reflects that TFO Doklean visited CCHM in an undercover capacity on July 23, 2010. (E.g., Gov't Ex. 4, at 1.) TFO Doklean's undercover role was as a patient with a level of neck pain that affected her ability to interact normally with her children. (Tr. vol. 1, at 230, 253, 255-56, 258, 264 & 282.) Upon arriving at the clinic, she wrote on patient intake forms that running and exercise made her pain worse. (Gov't Ex. 25 at 9; Tr. vol. 1, at 316.) She also brought an MRI report that she had acquired for the purpose of her undercover visit using her undercover name. (See Tr. vol. 1, at 215.) At hearing, TFO Doklean testified that she intended to determine whether she could acquire a prescription without filling out patient intake forms in their entirety. (Tr. vol. 1, at 237.) She therefore intentionally left blank the questions inquiring about her pain level. (Tr. vol. 1, at 252-53.) No one else filled out any of her forms for her. (Tr. vol. 1, at 315.) She made cash payments to office staff totaling \$1100. (Tr. vol. 1, at 190.) The payments included: \$300 for an office visit (Tr. vol. 1, at 186; Gov't Ex. 4 at 7-9); \$200 for "expedite service" (Tr. vol. 1, at 187, 314; see Gov't Ex. 4 at 13); and \$600 for medication (Tr. vol. 1, at 189-90 & 213). Respondent ultimately met with TFO Doklean for approximately ten minutes and issued a prescription for oxycodone.

Respondent's prescribing to TFO Doklean was marked by a number of irregularities. First, although she complained of neck pain, the sole MRI report TFO Doklean produced related to her lumbar region and not her neck. (Tr. vol. 1, at 201; Gov't Ex. 4 at 60-61.) Respondent was aware of this discrepancy, and issued a prescription directing TFO Doklean to obtain a cervical spine MRI. (Gov't Ex. 4 at 56; Tr. vol. 10, at 196-97; see Tr. vol. 10, at 196-97; see Tr. vol. 10, at 186.) Notably, however, Respondent did not require that TFO Doklean acquire the MRI report for her neck before prescribing controlled substances. Respondent testified that based on TFO Doklean's statements that "it goes up and down" and that the pain "radiates," and based on gestures she made pointing to her lower back, Respondent believed TFO Doklean had back pain, as well as neck pain. (Tr. vol. 10, at 188.) After TFO Doklean testified that her pain was preventing her from playing with her children, Respondent testified that although she stated that her pain was "two or three" on a pain scale (Gov't Ex. 4 at 33), Respondent interpreted her pain as actually being higher, such as an eight or a ten. (Tr. vol. 10, at 190-91, 201.) Respondent's assertion that the patient's pain was more than twice the level that the patient herself indicated on the pain scale is dubious.

Respondent's medical examination of TFO Doklean raises additional questions regarding whether the controlled substances prescription he provided was pursuant to a legitimate medical purpose. TFO Doklean testified that Respondent's physical examination of TFO Doklean consisted of placing a stethoscope on her back, asking her to breathe in and out; having her perform some range-of-motion exercises: bending down, turning her neck and standing on a foot. She displayed no discomfort and did not complain of pain during the exercises, which she completed successfully in less than one minute. (Tr. vol. 1, at 206-08.) TFO Doklean further testified that Respondent seemed to chuckle at the fact that TFO Doklean could bend down completely and touch the ground in a swift maneuver. (Tr. vol. 1, at 206.) Respondent asked if she had any pain when she did the exercises, and she said "not right now." (Tr. vol. 1, at 206.) Respondent did not touch TFO Doklean's spine or neck, the area of her

professed pain (Tr. vol. 1, at 208); in fact, he only touched her when he put the stethoscope on her. (Tr. vol. 1, at 208.)

Viewed together, the evidence relating to TFO Doklean's lumbar MRI and Respondent's physical examination constitute a lack of objective indicia of neck pain, along with subjective indicia of neck pain that are inconsistent, insomuch as the patient's comments are contradicted by her ease at performing physical exercises in the clinical setting. This disparity further calls into question the extent to which the prescription Respondent issued to TFO Doklean was pursuant to a legitimate medical purpose consistent with 21 C.F.R. § 1306.04(a) and Fla. Admin. Code Ann. r. 64B8-9.013(1)(b) & (3)(f) (2003).

Also of concern is Respondent's acquiescence to TFO Doklean's apparent diversion or misuse of controlled substances. The record reflects that TFO Doklean told Respondent she was getting the "blues," referring to oxycodone 30 mg tablets, from a friend. (See Gov't Ex. 4 at 34; Gov't Ex. 25 at 2; Tr. vol. 1, at 204, 216-17.) In addition, for "Past History of Pain Management," Respondent wrote "Friends & Street." (Gov't Ex. 25 at 2; see Tr. vol. 1, at 216-17.) Respondent then asked TFO Doklean "how long have you been taking the blues" and whether they helped. (Gov't Ex. 4 at 34.) TFO Doklean responded that she took them every couple of days, and they did help. Respondent did not press the matter. Nor did he "refer the patient as necessary for additional evaluation and treatment," notwithstanding the Florida requirement that "[s]pecial attention should be given to those pain patients who are at risk for misusing their medication" or who "pose a risk for medication misuse or diversion . . . " Fla. Admin. Code Ann. r. 65B8-9.013(3)(e). Respondent explained he thought TFO Doklean was getting controlled substances from friends because "she didn't have the money to see a doctor previously." (Tr. vol. 10, at 194.) He intended to "prescribe medication for her in a controlled way . . . [t]hat prevents diversion and prevents her from continuing to have to get medicine in an illegitimate way." (Tr. vol. 10, at 196.) "I don't discriminate against people for their language, for their social status, for how much money they have." (Tr. vol. 10, at 194.)

Respondent's response to TFO Doklean's professed participation in the illicit misuse or diversion of controlled substances is all the more concerning given TFO Doklean's indication that she had undergone rehabilitation for addiction to alcohol. (See Gov't Ex. 4 at 34; see also Gov't Ex. 25 at 8.)

Respondent asked her when she had undergone rehabilitation, TFO Doklean responded "last November," and the conversation moved on to other topics. (Gov't Ex. 4 at 34.) Respondent never asked the name of her rehabilitation clinic, how long she was in rehabilitation or the specific reasons for her treatment. (Tr. vol. 1, at 203.) Even if Respondent believed that TFO Doklean's acquisition from friends of controlled substances was for purely therapeutic purposes, Respondent should have been concerned about her history of addiction. Indeed, although she stated she was sober in her interview with Respondent (Gov't Ex. 4 at 34), TFO Doklean's patient forms indicate that she presently drinks alcohol. (Gov't Ex. 25 at 8.) Respondent was therefore faced with contradictory information but accepted TFO Doklean's representation that she was clean and sober, without securing confirmatory records from any medical facility. Respondent failed to comply with his "require[ment] to keep accurate and complete records to include, but not . . . limited to: . . . 1. The medical history . . . including history of drug abuse and dependence" Fla. Admin. Code Ann. r. 65B8-9.013(3)(f).

The record further contains evidence that Respondent annotated TFO Doklean's patient file to document conversations with TFO Doklean that did not in fact occur. (See, e.g., Tr. vol. 1, at 221-22.)

For instance, despite contrary notations in the patient file (see Gov't Ex. 25 at 5), TFO Doklean testified that Respondent never discussed anti-inflammatory medications, diet, the risks and benefits of the medication Respondent prescribed, the risk of abuse or addiction or physical dependence, yoga/stretching exercises, omega-3 fish oil, strict avoidance of alcohol, smoking cessation, illegal drugs, follow-up in one month or issues or concerns or weaning off medication. (Tr. vol. 1, at 217-20.)

Similarly, TFO Doklean testified that Respondent filled out the Consent for Chronic Opioid Therapy form, which recites that Respondent has discussed alternate options of "acupuncture, m[a]ssage, neurological

evaluation and surgery" (Gov't Ex. 25, at 16), but that Respondent never discussed those options with her. (Tr. vol. 1, at 224-25.) In fact, TFO Doklean signed the form before even being seen by Respondent. (Tr. vol. 1, at 225.) Respondent also did not discuss with TFO Doklean other pain medication options and did not ask for TFO Doklean's prior medical records from another doctor, other than the lumbar MRI noted above. (Tr. vol. 1, at 227-28.) He did not ask about her prior treatment plan or give her a time table for pain management. (Tr. vol. 1, at 228.) He did not suggest alternative medications or treatment options. (Tr. vol. 1, at 228.) These facts demonstrate that Respondent did not keep accurate medical records, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3).

At the end of his meeting with TFO Doklean, Respondent agreed to prescribe medication for TFO Doklean (Gov't Ex. 4 at 36), ultimately prescribing 120 Roxicodone 30 mg tablets. (Gov't Ex. 4 at 53.) Remarkably, TFO Doklean did not know what the medication would be until the consultation with Respondent had already ended.

After her consultation with Respondent, TFO Doklean talked to a manager at the clinic named Richard Mendez. (Tr. vol. 1, at 188.) TFO Doklean testified that Mr. Mendez provided instruction and direction about concerns that Respondent had about patients "not putting the proper things in the paperwork," and that the patients needed to say that they were in pain on the paperwork, and to tell the doctors that they were in pain. (Tr. vol. 1, at 188.) This information was also directed to the undercover patients with TFO Doklean who had not yet been seen by a doctor. (Tr. vol. 1, at 188; Gov't Ex. 4 at 39-40; Gov't Ex. 4, Audio Session #1 10:44-46.) Mr. Mendez further stated to TFO Doklean (referring to Respondent): "This guy is a little . . . this guy is a little . . . you know . . . serious and by the book in making sure . . . uh . . . He does everything . . . partly because he's been in a clinic that's been shut down before, so, it's very hard for him. He knows . . . you guys are cool." (Tr. vol. 1, at 290; id. at 40.) I find that Respondent in this instance subjectively did not believe that TFO Doklean was in pain, which weighs in favor of a finding that Respondent's prescription of controlled substances lacked a

legitimate medical purpose and was outside the usual course of professional practice. Additionally, the fact that Respondent asked Mr. Mendez to inform patients he had not yet seen to say they were in pain contradicts Respondent's testimony that in all instances he believed that the patients to whom he prescribed controlled substances were truly reporting pain.

TFO Doklean testified that she observed a sign in the waiting room that stated: "Please be aware that outside pharmacies are reporting prescription transactions to law enforcement agencies.

Feel free to discuss this with your physician." (Tr. vol. 1, at 193.) This sign in Respondent's waiting room is evidence that Respondent was aware that a meaningful number of his patients diverted or were at risk of diverting controlled substances.

In addition, as noted above, Dr. Berger testified, <u>inter alia</u>, that, in substance, the circumstances "preclude [TFO Doklean] from being a good candidate for receiving controlled drugs" on her first visit, and that such a prescription would not be in compliance with "the established care in Florida." (Tr. vol. 7, at 147.)

Viewed as a whole, although Respondent's prescription of controlled substances to TFO Doklean was not wholly without some indicia of medical purpose, substantial evidence supports a finding that Respondent's prescription of controlled substances to TFO Doklean lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code Ann. r. 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).

(e) SA Brigantty

The record reflects that SA Brigantty visited CCHM in an undercover capacity on July 23, 2010.

(E.g., Gov't Ex. 9 at 3; Tr. vol. 2, at 16.) The evidence regarding this visit reveals a number of departures from the usual course of professional practice that call into question the degree to which the medication that Respondent ultimately prescribed to SA Brigantty was pursuant to a legitimate medical purpose.

As an initial matter, the context of SA Brigantty's arrival at CCHM suggests the existence of an arrangement between undercover agents posing as patients and CCHM's office staff. After being met outside by an individual named Freddy, SA Brigantty entered the clinic through a rear entrance with a group of other undercover agents posing as patients. (Tr. vol. 2, at 17-18.) "The staff understood that we, as a whole, all those people who went in at the same time, were together." (Tr. vol. 2, at 18.) All the undercover officers paid a two hundred dollar expediting fee "to get through the clinic, see the doctors, and get out." (Id. at 19.) Although not dispositive, this arrangement casts suspicion on the legitimacy of Respondent's medical practice at CCHM because it provides circumstantial evidence that Respondent's staff participated in a plan by which groups of individuals, who may or may not have legitimate medical needs, could obtain controlled substances. SA Brigantty's testimony that he paid a fifty dollar tip to a female office staff member in the reception area (Tr. vol. 2, at 43) raises similar concerns because it represents a concrete instance of a staff member receiving cash in exchange for funneling patients to Respondent.⁶³

At his meeting with Respondent, SA Brigantty presented as a patient with pain in his lower back for the past fifteen years, which he attributed to lifting heavy objects at a construction job. (Gov't Ex. 9 at 35-36.) He described his pain as about six on a pain scale of one to ten. (Gov't Ex. 9 at 37.) He further described an additional kind of his pain as "pretty [expletive] bad," to which Respondent replied: "I don't have a number that correlates with that one " (Id.; Tr. vol. 2, at 96.) SA Brigantty testified that he also circled the number ten on the pain scale. (See Tr. vol. 2, at 48.)

SA Brigantty testified that Respondent did not ask him about his past treatments, previous diagnostic tests or the names of his previous doctors over the fifteen-year period. (Tr. vol. 2, at 34-36.) In fact, however, Respondent did ask where SA Brigantty previously received pain treatment, and SA Brigantty replied that he had gone to Jacksonville. (Gov't Ex. 9 at 25.) SA Brigantty also told

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⁶³ The extent and import of Respondent's knowledge of his staff's practices is discussed in numerous locations throughout this Recommended Decision.

Respondent that he had previously purchased "The Oxys. Thirty (30) milligrams" and "a Zanie bar," referring to Xanax, off the street. (Gov't Ex. 9 at 41; see Tr. vol. 2, at 37.) He said he hadn't taken medication for approximately one month, but that the drugs helped him and he had been taking them for two to three years. (Gov't Ex. 9 at 41.) SA Brigantty also wrote on a Pain Assessment Form that he was presently taking oxycodone and Xanax (Gov't Ex. 26, at 9; Tr. vol. 2, at 49), statements which he orally contradicted when he informed Respondent that he was not presently taking medication. (Tr. vol. 2, at 125.) Given SA Brigantty's confessed illicit use of controlled substances, Respondent failed to "refer the patient as necessary for additional evaluation and treatment," notwithstanding the Florida regulations providing that "[s]pecial attention should be given to those pain patients who are at risk for misusing their medications" or who "pose a risk for medication misuse or diversion . . ." Fla. Admin.

Code Ann. r. 6588-9.013(3)(e). Ultimately, Respondent issued a prescription to SA Brigantty for oxycodone, explaining that many patients get their medications from the street because they: "find that that is the only place they can get it, short of coming to a doctor. So by starting them on medication you can stop them . . . from having to get the medication in places that they shouldn't be." (Tr. vol. 2, at 180.)

The record reveals interactions between Respondent and SA Brigantty that reflect poorly both as to Respondent's standard of care as a physician and as to Respondent's knowledge of operations at CCHM. During the patient consultation, Respondent advised SA Brigantty that his blood pressure was high: "You need to get yourself re evaluated. Meaning you need to find a regular medical doctor as soon as possible and have that re checked." (Gov't Ex. 9 at 42.) Respondent, however, did not offer to prescribe blood pressure medication or perform any diagnostic testing for blood pressure, (Tr. vol. 2, at 38), because

⁶⁴ Respondent declined to issue a prescription for Xanax, because SA Brigantty "seemed to indicate that if the pain was under control, he would be sleeping better. So I didn't want to prescription [sic] any Xanax if it wasn't necessary." (Tr. vol. 10, at 265.)

"I didn't want to prescribe medication for people I was only going to see one time . . . giving a patient a strong recommendation . . . was more in the patient's best interest . . . because it prompted them to seek out a regular medical doctor, which would have been a more appropriate place for them to receive medication on a regular basis, and receive the follow-up that they needed."

(Tr. vol. 2, at 169.) Respondent later contradicted himself, testifying that

my best measure of success was in my interaction with the patient, in that we were going to prescribe some medication, we were going to see how he did . . . I would have had to see him back, at a follow-up appointment, and ask him questions as to how he was doing. And then I would have been able to measure

the success of the oxycodone treatment. (Tr. vol. 2, at 214-15.) This second statement by Respondent can be read in two ways: either Respondent thought SA Brigantty would return for another visit, undercutting Respondent's assertion that he did not expect SA Brigantty would return for a follow-up appointment; or it shows that Respondent did not truly expect ever to see SA Brigantty again, calling into question Respondent's ability to monitor the success of his interaction with the patient and tending to show Respondent did not believe he was issuing the prescription in the usual course of a professional practice or pursuant to a legitimate medical purpose.⁶⁵

In any event, even if it can be reconciled with his other statements, Respondent's explanation as to why he failed to prescribe blood pressure medications to SA Brigantty raises more questions than it answers. First, Respondent's assertion that he did not expect to see SA Brigantty again for a follow-up visit is inconsistent with Respondent's testimony that line items on the History and Physical Examination Form in SA Brigantty's medical file "should serve as talking points, over time, with patients" and need not be discussed all at once. (Tr. vol. 2, at 172; see Gov't Ex. 26 at 5.) These two statements are inconsistent because viewing the discussion checklist as the basis of a continuing doctor-patient

⁶⁵ In support of his prescribing practices, Respondent testified that an MRI report for SA Brigantty revealed significant disc disease and evidence of a boney abnormality compressing the spinal cord sac, consistent with pain. (Tr. vol. 10, at 267-68.) On different facts devoid of irregularities in CCHM's office practice and Respondent's conduct with respect to SA Brigantty and SA Brigantty's indications of diversion, such evidence might have been more persuasive.

dialogue over time is incompatible with a view that the patient probably will not return for a follow-up visit.

Moreover, Respondent's opinion that SA Brigantty should seek a "regular doctor," speaks volumes as to Respondent's beliefs about his own practice. Respondent explained that he considers himself "a regular medical doctor. But in this setting, this was a clinic where we treated pain management, or our main role was pain management." (Tr. vol., 2, at 169.) Even if Respondent's testimony concerning the need for SA Brigantty to see a separate "regular doctor" is to be taken at face value, the record unambiguously reflects that Respondent did not refer SA Brigantty to any particular "regular doctor" (Tr. vol. 2, at 170), which is inconsistent with the referral standard contained in Fla. Admin. Code Ann. r. 65B8-9.013(3). Moreover, Respondent did not discuss the risks to a person with high blood pressure of taking oxycodone, the controlled substance he ultimately prescribed to SA Brigantty (Tr. vol. 2, at 39-40), contrary to Fla. Admin. Code Ann. r. 65B8-9.013(3)(c) ("The physician should discuss the risks and benefits of the use of controlled substances with the patient ") and Fla. Admin. Code Ann. r. 65B8-9.013(3)(f) (requiring accurate and complete medical records of "Discussion of risks and benefits"). Additionally, Respondent's contention that the oxycodone he prescribed to SA Brigantty was merely a "therapeutic trial" (Tr. vol. 2, at 177-78) cannot comfortably coexist with Respondent's assertion that he did not believe SA Brigantty would return for a follow up visit (see Tr. vol. 2, at 169).

Also notable is evidence of SA Brigantty's misrepresentation in his undercover role about his own medical history, and Respondent's reaction after learning of the misrepresentation. SA Brigantty testified that when filling out patient intake paperwork, a female member of Respondent's office staff communicated the requirement that "you had to put down . . . a primary doctor, or some other place you have been to she told us you can put anything down, put American Pain, they are closed." (Tr. vol. 2, at 20-21.) On cross-examination, SA Brigantty elaborated that the staff member had instructed:

"I don't care what it is, where you have been, you can write American Pain." (Tr. vol. 2, at 61.) In fact, the staff member's actual statement as reflected in a transcribed recording was: "Your last physician is gonna be . . . We need all the information. If you don't have it you gotta, somehow get it. If it is American Pain, Right [sic] American Pain, if they are no longer there or . . . you gotta put something." (Gov't Ex. 9 at 23; see Tr. vol. 2, at 73.) SA Brigantty testified that he interpreted this as coaching him to write "American Pain" as his previous provider. (Tr. vol. 2, at 21.)

This incident came to light during Respondent's consultation with SA Brigantty, when Respondent inquired if SA Brigantty had been to American Pain. The undercover agent responded that he wasn't seeing a physician, but that the office staff had instructed him "'You need to write something.' Someone said American, I was like '[expletive] it, I'll put American.'" (Gov't Ex. 9 at 44.) Despite knowing that the patient had falsified his medical record, and knowing that SA Brigantty believed Respondent's staff had coached him to make such a falsification, Respondent ultimately issued a prescription for 150 Roxicodone 30 mg tablets to SA Brigantty. (Gov't Ex. 9 at 53-54; Tr. vol. 2, at 29.) SA Brigantty paid \$750 cash. (Tr. vol. 2, at 31.) Applicable Florida regulations are clear about the mandatory weight of the recordkeeping guideline: "The physician is required to keep accurate and complete records" before prescribing controlled substances. Fla. Admin. Code Ann. r. 65B8-9.013(3)(f). Respondent's acquiescence in recordkeeping inaccuracies weighs heavily against Respondent's continued registration under Factors Two and Four of 21 U.S.C. § 823(f).

SA Brigantty's undercover patient file reflects additional irregularities. For instance, a History and Physical Examination form not filled out by SA Brigantty (Tr. vol. 2, at 45) reflects that Respondent prescribed to SA Brigantty Roxicodone 15 mg and Xanax 2 mg tablets. (Gov't Ex. 26, at 5.) SA Brigantty testified, however, that he never received any such prescriptions from Respondent. (Tr. vol. 2, at 45.) Respondent explained that his notation in the file as to the Roxicodone 15 mg and Xanax 2 mg must have been in error. (Tr. vol. 2, at 163-64.) Even crediting Respondent's testimony and finding that the

inaccuracy was an oversight, the error nevertheless constitutes a violation of Florida's recordkeeping regulations. See Fla. Admin. Code Ann. r. 65B8-9.013(3)(f). In addition, the record reflects that SA Brigantty completed a urine test, which Respondent's office staff did not monitor. (Tr. vol. 2, at 133-34.)

The record further reveals evidence that Respondent documented in SA Brigantty's patient file discussions with the patient that did not actually occur. For instance, despite contrary notations in the patient file (Gov't Ex. 26 at 5-6), SA Brigantty testified that Respondent never discussed anti-inflammatory medications, diet or the risks and benefits of medication, including the risk of abuse, addiction and physical dependence; yoga and stretching exercises; omega-3 fish oil, strict avoidance of alcohol, smoking cessation, or the avoidance of illegal or recreational drugs while on pain medication; or the weaning off of medication or the treatment plan objectives of pain relief or improvement, improved physical and psychological function, improving activity of daily living, working at full capacity, rehabilitation programs or interdisciplinary approaches to treatment.⁶⁶ (Tr. vol. 2, at 45-48.)

Respondent attempts to downplay these misrepresentations on the basis that some of the information he failed to discuss with SA Brigantty is contained in the consent form for opioid medications provided to patients at CCHM. (E.g., Tr. vol. 2, at 170.) This attempt is unpersuasive for two reasons. First, Respondent's argument is undercut by his admission in a similar context that "the word discussed should probably be whited out" because "these should serve as talking points, over time, with patients." (Tr. vol. 2, at 172.) Respondent's argument fails because if the items are to be discussed over time, it is logical to check off an item only once it has actually been discussed, and not before, as happened here. Second, Respondent's argument cannot overcome the plain language of the Florida regulation providing that "[t]he physician is required to keep accurate and complete records to

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⁶⁶ Respondent did, however, raise the issue of surgery. (Tr. vol. 2, at 102.)

include . . . [e]valuations and consultations [and] . . . [d]iscussion of risks and benefits " Fla. Admin. Code Ann. r. 65B8-9.013(3) (emphasis supplied).

In addition, as noted above, Dr. Berger testified in substance that a patient who is illegally buying drugs on the street, and who requests that the same drug be prescribed, should be precluded from receiving prescriptions for controlled substances. (Tr. vol. 7, at 161.) Dr. Berger further testified that based on his review of the medical file, he did not see anything that justified the issuance of controlled substances to SA Brigantty. (Tr. vol. 7, at 162; Gov't Ex. 26.)

In summary, the record reveals numerous violations of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA Brigantty's undercover visit to CCHM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Brigantty lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code Ann. r. 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).

(f) SA Priymak

SA Priymak first visited CCHM in an undercover capacity on April 7, 2010, accompanied by two or three other undercover agents. (E.g., Tr. vol. 2, at 315-16; Gov't Ex. 5 at 1.) He approached the front desk, presented as a new patient and obtained patient intake forms, which he filled out as he sat down. (Tr. vol. 2, at 317-20.) He paid \$175 for the visit. (Tr. vol. 2, at 319.) Dozens of people were waiting in the lobby. (Tr. vol. 2, at 318.) After completing all the triage procedures that were requested of him, SA Priymak testified that Respondent called his name, and SA Priymak followed Respondent to an office. (Tr. vol. 2, at 321.) This testimony, consistent with testimony of other agents, tends to show that Respondent did have interaction with the waiting area. Respondent therefore was not completely

isolated from the waiting or triage area and can reasonably be understood to have at least some knowledge of things that occurred there and objects present there, to include a sign on the waiting room wall as of July 23, 2010 stating: "Please be aware that outside pharmacies are reporting prescription transactions to law enforcement agencies. Feel free to discuss this with your physician." (Tr. vol. 1, at 193.)

When SA Priymak entered the consultation room, Respondent asked if it was SA Priymak's first visit, to which SA Priymak responded in the affirmative. (Gov't Ex. 5 at 34.) Respondent's next statement was "Alright. Let['s] see. We gonna help with your pain in your neck," (Gov't Ex. 5 at 34; Tr. vol. 2, at 321) even though SA Priymak had not mentioned having any pain or neck issues. SA Priymak affirmed that he had neck pain, stating also that his shoulder was "kind a . . . tight." (Gov't Ex. 5 at 34.) Respondent asked SA Priymak how long he had had pain, how he had injured his neck, how old he was and whether he was working. (Gov't Ex. 5 at 34-35.) SA Priymak responded that the pain began in 2001 when he tweaked his neck playing basketball, that he was thirty-four years old and that he was between jobs, working in construction. (Gov't Ex. 5 at 34-35.)

SA Priymak further told Respondent that he was not presently taking medication (Gov't Ex. 5 at 35), in direct contrast to his later statements to Respondent and also his pain assessment form dated April 7, 2010, which indicated he was taking medications consistent with OxyContin, Xanax, Soma and Dilaudid, listing side effects from medication as "it feels good." (Gov't Ex. 22 at 9-10; see Tr. vol. 2, at 331, 349-50.) I find that SA Priymak's statement that "it feels good" was evidence of potential diversion that Respondent did not sufficiently weigh in deciding to prescribe controlled substances. Moreover, SA Priymak testified that Respondent never discussed Dilaudid with SA Priymak (Tr. vol. 2, at 349), constituting additional evidence of Respondent's lack of concern for potential drug abuse or diversion.

⁶⁷ In mitigation, SA Priymak testified that he provided Coast to Coast with an MRI report of his neck (Tr. vol. 2, at 331), which Respondent later testified was consistent with a patient having significant neck pain. (Tr. vol. 10, at 138.)

Respondent remarked that SA Priymak's condition didn't sound so bad, to which SA Priymak responded that he had been taking medication on and off for the last ten years "cause it gets tight, especially in my . . . shoulder." (Gov't Ex. 5 at 36.) Respondent stated "So the pain is sort of mild. It's that right?" and asked what medicines SA Priymak had been taking. (Gov't Ex. 5 at 36.) He responded that he was taking four tablets of "Oxy forties" per day, which Respondent confirmed was oxycodone, and "some Somas" that weren't helping him, and agreed that the pain was mild. (Gov't Ex. 5 at 36-37, 40; Tr. vol. 2, at 323.) Respondent confirmed: "you told me that pain is mild . . . and mostly affects you . . . when you play basketball . . . you otherwise do pretty good?" (Gov't Ex. 5 at 37.) SA Priymak responded: "Mm . . .No. I just . . .I need that . . . to get through the day," and stated that sometimes his pain was a five. (Gov't Ex. 5 at 37.) Under the number "5" on SA Priymak's pain assessment form, there appears a handwritten arrow that SA Priymak testified he did not draw (Gov't Ex. 22 at 10; Tr. vol. 2, at 350), leading to the conclusion that Respondent drew the arrow. Respondent asked if SA Priymak was sleeping well, to which SA Priymak responded in the negative and indicated that he had been taking one-half to two bars of Xanax. (Gov't Ex. 5 at 37, 40.)

Upon inquiry from Respondent, SA Priymak stated that he was not allergic to any medications, smoked approximately two cigars per day, had high blood pressure and had used intravenous drugs five or six years ago. (Gov't Ex. 5 at 38.) Respondent then inquired:

WOLFF: Is there any history of drug abuse or drug dependence?

UC1: Mm . . . I've been taking Oxies for, for a while.

WOLFF: Ox[y] codone.

UC1: Yes.

WOLFF: How much [o]xycodone are you taking?

UC1: I mean, it depends. Uhm . . . it's kind of expensive, so . . . I . . . buy

forties....

WOLFF: And have you seen a doctor at all uh lately, or no?

UC1: No, no.

WOLFF: No. So just get them off the street.

UC1: Yeah.

(Gov't Ex. 5 at 39; see also Tr. vol. 2, at 323; Tr. vol. 3, at 33.)

The record reveals evidence that Respondent's staff tampered with SA Priymak's patient file. On cross-examination, SA Priymak admitted that he was not actually taking controlled substances that he claimed he obtained off the street. (Tr. vol. 3, at 33-34.) A urine drug screen for SA Priymak, however, indicates a positive test for opiates/morphine, benzodiazepine and oxycodone. (Gov't Ex. 22 at 25; see Tr. vol. 3, at 34-36.) Further complicating matters is SA Priymak's testimony that he did not recall taking a drug test. (Tr. vol. 3, at 37.) He testified that "when I was seen at the triage room, the staff member indicated playfully that – checked something in my file like 'Yeah, you have drugs in your system.'" (Tr. vol. 3, at 37; see Gov't Ex. 5 at 24.) I find by substantial evidence that a member of Respondent's staff at CCHM falsified SA Priymak's patient file to reflect false positive test results for a urine drug screen. Although there is no indication that Respondent knew of this particular instance of tampering with SA Priymak's medical record, the record as a whole supports the conclusion that such practices were not uncommon at CCHM. Each additional instance of misconduct by Respondent's staff decreases the credibility of Respondent's contention that he was unaware of his staff's actions.

Respondent then inquired about SA Priymak's alcohol consumption, to which he admitted drinking three or four bottles of beer a couple times a week. (Gov't Ex. 5 at 39.) Respondent conducted a brief physical examination of SA Priymak, including motion exercises. (See Tr. vol. 2, at 330.) SA Priymak successfully completed the exercises without showing signs of pain (Tr. vol. 2, at 330), which should have given Respondent pause before prescribing controlled substances. Perhaps it did: Respondent then stated "I think that you're taking a lot of medicine for mild pain." (Gov't Ex. 5 at 40.) He continued that SA Priymak was "on requirements for medication []way out of proportions for the degree of pain you have . . . I don't think I['m] gonna be able to help you" (Gov't Ex. 5, at 41.) SA Priymak then proposed:

UC1: Can you help me with something of less amount?

WOLFF: Like?

UC1: I won't be able to function, like thirties (30s), twenties

(20s).

WOLFF: I mean, thirties (30s) is always right, you know?

UC1: Can be thirties (30s)?

WOLFF: I just don't' see it uh for . . . what you have.

UC1: Can you give me some fifteens (15)s?

WOLFF: You know, maybe I'll give you some fifteens (15s).

UC1: Oh, thank you.

WOLFF: You probably would need to be on . . . medicine to get off

of this. You should go up to some sort of rehab facility . . .

you want some Xanax?

UC1: Yeah.

(Gov't Ex. 5 at 42; see generally Tr. vol. 2, at 347.) SA Priymak next requested Viagra, stating that he was going to a party next week and wanted to try it. (Gov't Ex. 5 at 43.) Respondent asked if he had "some problems . . . that we're gonna give that for you?" to which SA Priymak answered in the negative. (Gov't Ex. 5 at 44.) Respondent confirmed: "Just for the party?" to which SA Priymak responded "yeah." Respondent laughed and said "Good try." (Gov't Ex. 5 at 44.) Respondent wrote SA Priymak a prescription for 150 Roxicodone 15 mg and 30 alprazolam 2 mg tablets on April 7, 2010. (Gov't Ex. 22 at 23; Tr. vol. 2, at 325-36.)

Respondent's failure to refer SA Priymak to a particular rehabilitation center, despite the notation in the patient chart "Rec. pt see MD for Suboxone" (Gov't Ex. 22 at 6) is concerning and raises questions of whether Respondent complied with Fla. Admin. Code Ann. r. 65B8-9.013(3)(f) (requiring a physician to keep accurate medical records) and Fla. Admin. Code Ann. r. 65B8-9.013(3)(e) (stating that a physician "should be willing to refer the patient as necessary for additional evaluation and treatment . . ."). ⁶⁹

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⁶⁸ SA Priymak also testified that a staff member at the reception area said Respondent did not have a DEA license and therefore the prescription could not be filled at Coast to Coast. (Tr. vol. 2, at 326-27.)

⁶⁹ Referring to a later visit by SA Priymak, Respondent testified that he did not urge that SA Priymak get rehabilitation treatment at his second visit to CCHM because SA Priymak said he was not experiencing withdrawal symptoms. (Tr. vol. 10, at 140.) The persuasiveness of Respondent's testimony in this regard is substantially undercut by Respondent's statement that SA Priymak "was no longer having to get his medicine on the street."

Respondent acted correctly in declining to prescribe Viagra to SA Priymak, in light of the patent lack of medical indication. Respondent's prescription of pain medication, however, was another matter. Respondent knew that SA Priymak was a drug-seeking individual who had purchased controlled substances off the street and whom Respondent suspected had used intravenous drugs due to "something on his arm." (Tr. vol. 10, at 100.) As noted above, Dr. Berger opined that prescriptions for Roxicodone and Xanax were unwarranted, particularly given the patient's history of being an intravenous drug user and having purchased drugs illicitly on the street. (Tr. vol. 7, at 92.) Moreover, Respondent acknowledged that SA Priymak's mild pain level did not support the controlled substances SA Priymak said he was currently taking off the street. (Tr. vol. 10, at 105.) Additionally, Respondent did not inquire as to the source of SA Priymak's drugs, nor did he admonish him to stop acquiring off the street.

Under these circumstances, it cannot be concluded that Respondent's controlled substances prescriptions, even at a so-called "reduced" amounts, were pursuant to a legitimate medical purpose or within the usual course of professional practice. To the contrary, they were not. Respondent's testimony that he didn't want SA Priymak to suffer from withdrawal symptoms (Tr. vol. 10, at 128) and the fact that Respondent's prescription of oxycodone was less than half of the dosage that SA Priymak represented he was previously taking (Tr. vol. 3, at 32; Tr. vol. 10, at 109) perhaps mitigate in Respondent's favor, but do not alter the conclusion that the prescriptions themselves were not justified under all the circumstances.

SA Priymak returned to CCHM in an undercover capacity on May 4, 2010. (Tr. vol. 2, at 315.) He paid \$200 for the \$150 visit but did not receive any change back. (Tr. vol. 2, at 327-28.) This evidence is consistent with payments for "VIP service," apparently common at CCHM. As noted elsewhere in this Recommended Decision, overpaying for medical service is indicative of, or at least consistent with, a

⁽Tr. vol. 10, at 141.) Respondent had no way to verify the truth of this statement, nor does a transcript of the May 4, 2010 visit indicate Respondent made such an inquiry. (See Gov't Ex. 5, at 54-58.)

climate where patients and staff members play an improper role in causing controlled substances to reach patients outside the usual course of professional practice. The record as a whole supports a finding that all or substantially all of the undercover agents sought and received VIP treatment as a matter of course. Given the clear prevalence of this practice at CCHM, I reject Respondent's testimony that he had no knowledge of it, especially as the admitted owner of CCHM as of October 2010, daily work history at CCHM beginning in April 2010, and in light of Respondent's admission at hearing that he was familiar with the practice for an "occasional patient." (Tr. vol. 11, at 183.)

After completing triage procedures, SA Priymak met with Respondent. (Tr. vol. 2, at 328.)

Respondent asked whether the medication he had prescribed was working, to which SA Priymak responded in the affirmative. (Tr. vol. 2, at 328; Tr. vol. 3, at 56-58.) After checking SA Priymak's breathing, Respondent asked him to move his hands up and down and his head from left to right. (Tr. vol. 2, at 330.) Respondent prescribed 150 Roxicodone 15 mg and 30 alprazolam 2 mg tablets. (Tr. vol. 2, at 328-29, 338, 348, 352; Tr. vol. 3, at 60-61; Gov't Ex. 22 at 20-21.)

The record reveals evidence that Respondent documented in SA Priymak's patient file discussions that did not actually occur. For instance, despite contrary notations in the patient file (e.g., Gov't Ex. 22 at 6), SA Priymak testified that Respondent did not discuss a treatment plan with SA Priymak on either April 7 or May 4, 2011, alternative medications or treatment options, anti-inflammatories or diet, yoga and stretching exercises or return to functional ability while on pain medication. (Tr. vol. 2, at 331, 333 & 345.) Respondent's conduct constitutes a failure to keep accurate records, to include evaluations, consultations and discussion of risks and benefits, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3).

As noted above, Dr. Berger credibly testified that in his professional medical opinion,
Respondent's April 7, 2010 and May 4, 2010 Roxicodone and Xanax prescriptions were unwarranted and that Respondent's treatment of SA Priymak fell below the standard of care. (E.g., Tr. vol. 7, at 92, 98;

Gov't Ex. 32 at 73.) The record as a whole reveals numerous violations of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA Priymak's undercover visits to CCHM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Priymak lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code Ann. r. 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)

(g) SA Zdrojewski

The record reflects that SA Zdrojewski visited CCHM in an undercover capacity on July 23, 2010, along with nine other undercover agents. (Tr. vol. 3, at 69.) The agents arrived at the back door of the clinic. (Tr. vol. 3, at 69-70.) The back room was bare, containing approximately eleven chairs and "there was really no real interaction with office staff." (Tr. vol. 3, at 70.) After a few minutes, an armed staff member named Fred or Freddie, and a separate staff member named Lina, came to the back room and spoke with the "ringleader" SA Lunsford. (Tr. vol. 3, at 71-72.) The agents paid \$500, including an extra \$200 for "VIP treatment, speeding it up a little bit." (Tr. vol. 3, at 72; Gov't Ex. 8 at 3-4.) SA Zdrojewski also testified that he gave his patient paperwork to SA Lunsford to hand in to the office staff. (Tr. vol. 3, at 73-74.) Although not dispositive, this evidence indicates that the staff of CCHM interacted with patients in unorthodox ways. The existence of a ringleader, the agents' entrance through a back door of the clinic into a back room, and the payment of \$200 for preferential treatment provides clear evidence of a profit motive for employees to process patients according to the patients' requests instead of according to an established and legitimate medical procedure.

SA Zdrojewski also testified that agents made comments within earshot of clinic staff members that "This is costing us too much money. We're not gonna make any money off this." (Tr. vol. 3, at 73.)

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 $^{^{70}}$ SA Zdrojewski also testified that he supplied a true MRI report of his body. (Tr. vol. 3, at 81; see Gov't Ex. 8 at 24.)

Although not dispositive, this testimony provides evidence that CCHM staff members, at least those within earshot of the undercover agents, knew that the "patients" sought to acquire controlled substances for the purpose of diverting and selling them.

SA Zdrojewski proceeded to a triage area where he was weighed and his blood pressure and other vital signs were measured. (See Tr. vol. 3, at 74-76; Gov't Ex. 8 at 8.) SA Zdrojewski's blood pressure reading was high, and SA Zdrojewski informed staff members that he was on the medication Diovan, which he believed they documented in his chart. (Tr. vol. 3, at 77.) Triage staff informed SA Zdrojewski that he couldn't see a doctor without conducting a urinalysis first. (Tr. vol. 3, at 77.) SA Zdrojewski submitted a urine specimen for analysis. (Tr. vol. 3, at 77.) SA Zdrojewski testified that

It was not supervised, and after I came out of [the bathroom], I was kind of joking around that I fooled with the test, like put water in it . . . I just said I fooled around with the test in front of staff members and in front of those nurses to other agents and was kind of laughing about it, but then no one ever said anything.

(Tr. vol. 3, at 78-79.) The cup he used did not contain a label identifying it as his own. (Tr. vol. 3, at 79.) The staff's non-reaction and apparent indifference to SA Zdrojewski's manifestations that he had tampered with his urine drug screen are indicative of a culture at CCHM that is accepting of diversion of controlled substances and prescribing outside the usual course of professional practice. I find that the drug screen process, as applied to SA Zdrojewski and other undercover agents discussed elsewhere in this Recommended Decision, was manifestly inadequate at CCHM, which Respondent knew or should have known. Respondent's testimony that he felt the need to improve the urinalysis process after assuming ownership of CCHM in October 2010 indicates that at some point prior to October 2010 he had actual knowledge of the deficiencies in CCHM's urinalysis process. (See Tr. vol. 9, at 260-74.)

SA Zdrojewski testified to his visit with Respondent. A staff member directed SA Zdrojewski to stand in a dimly lit hallway with no chairs for approximately ten to fifteen minutes. (Tr. vol. 3, at 83.) He

⁷¹ Respondent also asked SA Zdrojewski if he had medical problems such as high blood pressure or diabetes, and SA Zdrojewski responded in the affirmative, stating he was on Diovan. (Gov't Ex. 8 at 14.)

watched an individual named Richard Mendez enter Respondent's office, where SA Zdrojewski saw
Respondent sitting at a desk. (Tr. vol. 3, at 83.) After exiting Respondent's office, Mr. Mendez talked to
an undercover agent who then approached SA Zdrojewski, stating: "You have pain." (Tr. vol. 3, at 84.)
Although not dispositive, this statement is consistent with other evidence of record that Respondent
instructed CCHM staff members to tell patients they needed to indicate pain.⁷²

A couple minutes later, Respondent invited SA Zdrojewski to enter the office, which contained a desk, chairs and an examination table. (Tr. vol. 3, at 85-86.) SA Zdrojewski approached the examination table "and kind of vaulted myself up on it." (Tr. vol. 3, at 86.)

Respondent asked if SA Zdrojewski was visiting for the first time, and SA Zdrojewski responded in the affirmative, stating that he had previously been a patient at Tampa Bay Wellness, which had closed. (Gov't Ex. 8 at 11.) Respondent inquired where SA Zdrojewski's pain was and how long the pain had lasted, to which SA Zdrojewski responded "Neck" and a year and a half. (Gov't Ex. 8 at 11.) SA Zdrojewski further stated that he was self-employed as a charter captain and could not explain how he hurt his neck. (Gov't Ex. 8 at 11-12; see Tr. vol. 3, at 87.) He stated that his previous doctor gave him "crazy amounts but I didn't even fill it all out. Dude was giving me ninety (90) count eighties (80's) . . . [and] sixty (60), two (2) [m]illigrams [X]anax and two hundred forty (240) Thirties (30's) . . . Don't need all that." (Gov't Ex. 8 at 12.) Respondent replied by asking SA Zdrojewski to describe his pain, noting that "You got zero (0) to one (1), is that right?" (Gov't Ex. 8 at 12.) Respondent did not ask what SA Zdrojewski was doing with the excess medication he was not using. (Tr. vol. 3, at 98.)

At hearing, SA Zdrojewski testified that he had circled zero to one on the pain scale. (Tr. vol. 3, at 96.) SA Zdrojewski stated to Respondent that his pain was intermittent, comes and goes, and later in

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⁷² <u>E.g., supra</u> text at notes 26-28 (noting TFO Doklean's testimony that a staff member voiced Respondent's concerns that patients needed to say they were in pain in their paperwork, and needed to tell doctors they were in pain).

⁷³ Respondent asked how long SA Zdrojewski's back had been hurting, and SA Zdrojewski replied that in fact his neck was the issue. (E.g., Tr. vol. 3, at 86-87.)

⁷⁴ Respondent did not inquire about SA Zdrojewski's duties as a charter captain. (Tr. vol. 3, at 99.)

his conversation with Respondent "I just said, 'Well, then top it, then,' meaning just, you know, 'You write it in there," and that's all I said is, "Top it, then,' and he filled that out."⁷⁵ (Tr. vol. 3, at 97.) As viewed at the date of hearing, SA Zdrojewski's pain assessment form indicates that Respondent circled the numbers eight through ten on the pain scale. (Gov't Ex. 28 at 9; see Tr. vol. 3, at 97.) Although SA Zdrojewski stated "It can be" after Respondent inquired whether "the pain's been pretty bad?" (Gov't Ex. 8 at 12), SA Zdrojewski told Respondent that he controls his pain: "you know, I'm just, not gonna sit around." (Gov't Ex. 8 at 13.) The inconsistency in SA Zdrojewski's representations as to the degree of his pain and SA Zdrojewski's ability to vault up onto the examination table should have given Respondent pause before prescribing controlled substances.

SA Zdrojewski also told Respondent that he had previously received traction treatment and treatment from a chiropractor. (Tr. vol. 3, at 87.) Respondent asked when SA Zdrojewski last received treatment from Tampa Bay Wellness, and SA Zdrojewski responded that he had received treatment approximately two months previously. (Gov't Ex. 8 at 15.) Respondent, however, did not ask for these doctors' prior medical records. (Tr. vol. 3, at 95.)

Respondent conducted a physical examination of SA Zdrojewski, lasting approximately one to two minutes. (Tr. vol. 3, at 107.) He directed SA Zdrojewski to complete a variety of range-of-motion exercises (see_Gov't Ex. 8 at 16), which SA Zdrojewski did with "solid, strong movements. I kind of over-exaggerated my movements" (Tr. vol. 3, at 106.) Moreover, SA Zdrojewski testified that he completed all those movements without mentioning pain. (Tr. vol. 3, at 106-07.) As noted elsewhere in this Recommended Decision in the context of other undercover patients, the ease and overtly painless effort with which SA Zdrojewski completed his physical examination contradicted SA Zdrojewski's reports of pain, which varied throughout the course of the meeting. It was an

⁷⁵ To similar effect, Respondent testified that SA Zdrojewski had said "swap it." (Tr. vol. 10, at 242.)

⁷⁶ The only apparent exception was one instance in which Respondent apparently directed SA Zdrojewski to bend over, and the latter replied "I can't bend that far down." (Gov't Ex. 8 at 16.) Even in this case, however, SA Zdrojewski did successfully bend down and touch his toes, even as he said he could not. (Tr. vol. 3, at 160.)

inconsistency that should have alerted Respondent to the possibility that SA Zdrojewski was posing as a patient who was not seeking controlled substances for a legitimate medical purpose. Perhaps Respondent considered this possibility and simply went through the motions in conducting a physical examination: on a patient who complained of neck pain, Respondent never touched SA Zdrojewski's neck. (Tr. vol. 3, at 107.)

Consulting SA Zdrojewski's MRI report, Respondent told SA Zdrojewski he had only trace amounts of inflammation in the joints between SA Zdrojewski's vertebra and neck: "it's very minimal . . . Other than that it's normal. There's no disk herniations, everything else is in place" (Gov't Ex. 8 at 16.) SA Zdrojewski inquired what caused his headaches, in that case. Respondent answered: "Oh, my God, there's nothing. I . . . I don't know. There's nothing around here that, that ah, explains that." (Gov't Ex. 8 at 16; Tr. vol. 3, at 95.) The following colloquy ensued:

WOLFF: Well, uh . . . we have a little issue here. First of all your

MRI doesn't show much of anything and secondly,

drinking a case of beer⁷⁷ is not compatible with taking a

strong medicine like this . . . I'm not sure . . .

UC1: I can pull that off.

WOLFF: I'm not sure how you lived though, all of this Oxy . . .

UC1: I . . . I told you I didn't take, I didn't take all of that.

WOLFF: alcohol . . . coupled with Oxycontin and Oxycodone

and Xanax is being very bad combination, as in you need to

worry about death . . .

UC1: You got to watch your . . . I get it. I'll stop drinking. WOLFF: Watch you! Yeah I . . . I think that . . . um . . . So, you rather

take the medicine than to be drinking, is that right?

UC1: Yeah, yup.

WOLFF: Alright, well let me look at your chart to see what we can do to help you.

(Gov't Ex. 8 at 17-18.) On July 23, 2010, Respondent issued SA Zdrojewski a prescription for 150 Roxicodone 30 mg tablets.⁷⁸ (Gov't Ex. 28 at 19; Gov't Ex. 8 at 22-23; Tr. vol. 3, at 103.) Although

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⁷⁷ SA Zdrojewski had told Respondent he was drinking a lot of alcohol, to include a case of beer on the weekends. (<u>See</u> Tr. vol. 3, at 88; Gov't Ex. 8 at 14.)

Respondent testified that this prescription is much less than what SA Zdrojewski told Respondent he had previously been prescribed (Tr. vol. 10, at 255), the import of the difference is reduced in substantial part by SA Zdrojewski's statement to Respondent that he wasn't even filling all of the prescriptions his previous doctor had provided, because they were "crazy amounts." To be certain, Respondent's lowering of the dosage standing alone cuts somewhat in Respondent's favor; but I find Respondent's reliance on SA Zdrojewski's self-reported past prescriptions of excessive quantities of controlled substances as a baseline for future prescriptions to be facially outside the usual course of professional practice.

The record further reveals evidence that Respondent documented in SA Zdrojewski's patient file discussions that did not actually occur. For instance, despite contrary notations in the patient file (e.g., Gov't Ex. 28 at 5), SA Zdrojewski testified that Respondent never discussed anti-inflammatories and diet, the risk and benefits of medication, including the risk of abuse and addiction and physical dependency, 80 yoga and stretching exercises, omega-3 fish oil, the use of illegal drugs, 81 weaning off medications, treatment plans for pain relief or improvement, 82 improving physical and psychological functions, regaining quality of life, improving SA Zdrojewski's activities of daily living, sleep, improved energy,

⁷⁸ Respondent declined to write SA Zdrojewski a prescription for Xanax because Respondent didn't believe SA Zdrojewski needed it. (Gov't Ex. 8 at 18.)

⁷⁹ Notably, Respondent demonstrated no interest in learning any information to include the doctor's name at Tampa Bay Wellness that had prescribed what SA Zdrojewski represented to be "crazy amounts" of controlled substances.

⁸⁰ Respondent did counsel SA Zdrojewski, however, on the risk of alcohol. (Tr. vol. 3, at 88.)

⁸¹ Strictly speaking, Respondent did ask whether SA Zdrojewski was using recreational drugs or had any drug abuse or dependence problems, to which SA Zdrojewski replied that he was presently self-medicating with marijuana. (Gov't Ex. 8 at 15; see Tr. vol. 3, at 89.) But Respondent's response upon learning of SA Zdrojewski's marijuana use was "Oh, Oh." (Gov't Ex. 8 at 15.) Respondent asked no follow-up questions about his marijuana use. Nor does a transcript of the interview reveal that he asked "How often?", as SA Zdrojewski testified. (See Tr. vol. 3, at 89.) Significantly, Respondent did not counsel SA Zdrojewski against using marijuana while on pain medication. (Tr. vol. 3, at 90; see Gov't Ex. 8.) Respondent's testimony tending to suggest that he believed SA Zdrojewski "was using marijuana to get through the day" now that the Tampa clinic was closed (Tr. vol. 10, at 245) is hard to reconcile with SA Zdrojewski's statements to Respondent that the medication he had been receiving there was wildly

⁸² SA Zdrojewski explained "I didn't even know how many oxycodones I was getting [from Respondent] until I received them." (Tr. vol. 3, at 109.)

mood or motivation, working at full capacity, a rehabilitation program, exercise, diet, lifestyle or habits. (Tr. vol. 3, at 88-92.) He did not discuss alternative medications beside controlled substances or alternative treatments for pain, such as back injections. (Tr. vol. 3, at 109.) Respondent's conduct constitutes a failure to keep accurate records, to include evaluations, consultations and discussion of risks and benefits, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3). Consistent with Dr. Berger's testimony as noted above (e.g., Tr. vol. 7, at 176), Respondent's failure to refer SA Zdrojewski to rehabilitation for his use of recreational and illicit controlled substances, and what may well have been his excessive use of licit controlled substances, is also inconsistent with Florida standards. See Fla. Admin. Code Ann. r. 65B8-9.013(3)(e) ("The physician should be willing to refer the patient as necessary for additional evaluation and treatment . . . Special attention should be given to those patients who are at risk for misusing their medications [or] . . . pose a risk for medication misuse or diversion")

By corollary, the record reveals evidence of discussions that should have occurred, but didn't.

The record reflects that SA Zdrojewski indicated in his patient form that he suffered from bipolar disorder (Gov't Ex. 28 at 7), but SA Zdrojewski testified that Respondent did not discuss bipolar disorder.

(Tr. vol. 3, at 93-94.) SA Zdrojewski further testified that Respondent did not discuss high blood pressure. (Tr. vol. 3, at 93.)

In sum, the record reveals numerous violations of applicable standards and regulations concerning the prescribing of controlled substances in the context of SA Zdrojewski's July 23, 2010 visit to CCHM. Substantial evidence supports a finding that Respondent's prescription of controlled substances to SA Zdrojewski lacked a "legitimate medical purpose . . . that is supported by appropriate documentation establishing a valid medical need and treatment plan," in violation of Fla. Admin. Code

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⁸³ Respondent's testimony that he intended to make referrals to a neurosurgeon at the next visit (Tr. vol. 10, at 254) is not to the contrary. As an initial matter, there was no subsequent visit. Moreover, Respondent's failure to make a referral in the context of SA Zdrojewski is generally consistent with Dr. Berger's testimony that Respondent failed to make a proper referral in the context of SA Priymak, providing some evidence of a trend. (See generally Tr. vol. 8, at 298; Gov't Ex. 5 at 42.)

Ann. r. 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).

(h) SA Ryckeley

The record reflects that SA Ryckeley visited CCHM in an undercover capacity on July 23, 2010. (E.g., Gov't Ex. 7 at 2; Tr. vol. 3, at 200.) He arrived with a group of nine other undercover officers, and the group was "shepherded in through the back door." (Tr. vol. 3, at 200, 203.) SA Ryckeley testified that the group was led by undercover agent Jack Lunsford, who was acting as a sponsor: a person who arranged for a group of people to come in and attempt to seek pain medicine. (Tr. vol. 3, at 201.) A female employee of the clinic greeted the group and requested \$300 for the office visit. (Tr. vol. 3, at 201.) The agents also paid her an additional \$200 for accelerated preferential treatment. (Tr. vol. 3, at 201; Gov't Ex. 7 at 6.)

Record evidence concerning SA Ryckeley's visit with Respondent in Respondent's office (Tr. vol. 3, at 206) reveals a number of departures from the usual course of professional practice. As the visit began, Respondent asked if it was SA Ryckeley's first visit, and SA Ryckeley said yes. (Gov't Ex. 7 at 18.) Respondent asked "where's your pain that we're gonna help you with?" to which SA Ryckeley replied "Uh, back discomfort. I came in with, uh, David Hays and all those guys." (Gov't Ex. 7 at 18.) SA Ryckeley's statement gave Respondent reason to suspect, if not to know, that SA Ryckeley was visiting CCHM with other people as part of a common plan or scheme that may not have been connected to legitimate complaints of pain.

It is also notable that SA Ryckeley's statements regarding the intensity of his pain changed over the course of the interview. Respondent asked SA Ryckeley to describe his pain with reference to the

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⁸⁴ As noted elsewhere in this Recommended Decision, although not dispositive, evidence of "VIP treatment" indicates that the staff of CCHM interacted with patients in unorthodox ways. The existence of a sponsor and the payment of \$200 for preferential treatment provides some evidence of a profit motive for employees to process patients according to the patients' requests instead of according to an established and legitimate medical procedure.

pain descriptions on a Pain Assessment Form, which SA Ryckeley did not complete upon intake but believed that Respondent partially completed for him during the consultation. ⁸⁵ (Gov't Ex. 7, at 20; Gov't Ex. 27 at 9; Tr. vol. 3, at 225-26.) SA Ryckeley replied that his pain ached in his lower back area. (Gov't Ex. 7 at 20.) "[I]t comes and goes, mostly comes when I fish." (Gov't Ex. 7 at 20.) Respondent asked how bad the pain was, on a scale of one to ten, to which SA Ryckeley responded "[u]h, probably around two (2)." (Gov't Ex. 7 at 20.) Respondent replied that maybe SA Ryckeley didn't understand the pain scale, and that "a one (1) and two (2) is . . . just sort of . . . a very mild kinda problem, ten (10) is were your [sic] screaming. So, that sort of the scale . . . So . . . would you characterize it as mild? Which is about (1) or two (2), or, or moderate? You know, five (5) or six (6) or is it pretty severe, like, eight (8) or nine (9) or ten (10)?" (Gov't Ex. 7 at 21.) SA Ryckeley replied: "Well, I guess it, it could be moderate, I would imagine . . . middle of the road." (Gov't Ex. 7 at 21.) SA Ryckeley later characterized his pain as a five or a seven. (Gov't Ex. 7 at 29.) The record does reveal one possible benign explanation for SA Ryckeley's shifting answers: a transcript of the patient meeting shows that SA Ryckeley stated "when I read through that twelve (12) page medical questionnaire it was a lot of words I didn't understand on there." (Gov't Ex. 7 at 29; see also Tr. vol. 3, at 270-71.)

SA Ryckeley viewed the situation less optimistically, and testified at hearing that he interpreted remarks by Respondent as coaching him to state he had greater pain. The record shows that Respondent asked how the pain affected SA Ryckeley's life, work and home. (Gov't Ex. 7 at 22.)

SA Ryckeley replied that it makes it more difficult to fish, to which Respondent laughed and stated: "You're under-whelming me." (Gov't Ex. 7 at 22.) Respondent elaborated, later saying: "[E]ither I'm missing the point or you're missing the point." (Gov't Ex. 7 at 23.) Respondent told SA Ryckeley that he should just take Tylenol. "You don't have anything wrong, I don't get it." (Gov't Ex. 7 at 24.)

SA Ryckeley explained that he believed Respondent was being "a box-checker . . . going through and

⁸⁵ Respondent testified that SA Ryckeley commented that he was not very good with words, which Respondent interpreted as meaning SA Ryckeley was not an educated man and wasn't good with language. (Tr. vol. 10, at 215.)

checking the boxes and making every element to justify writing me" (Tr. vol. 3, at 210.)

SA Ryckeley called Respondent's comments "clear-cut coaching" (Tr. vol. 3, at 210) "that I better say the right things if I wanted to get the prescription, so that's what I did." (Tr. vol. 3, at 224.) "[I]t was apparent that he was coaching me to a higher level to be able to prescribe me narcotics." (Tr. vol. 3, at 269.)

SA Ryckeley presented Respondent with evidence that he had been taking controlled substances that he obtained without a prescription. Respondent asked how long SA Ryckeley had had back pain, to which SA Ryckeley responded that his pain started in May while he was fishing on a sport fishing charter boat. (Gov't Ex. 7 at 18-19.) SA Ryckeley told Respondent that he took some of his girlfriend's "thirties," and "it put me in a state were [sic] I liked it, it made me feel better . . . and so I experimented with that, I know I probably shouldn't of [sic] done that." (Gov't Ex. 7 at 19-20.) "I've never really thought about [my pain] after that." (Gov't Ex. 7 at 22.) SA Ryckeley testified that Respondent wasn't fazed or set back by learning that SA Ryckeley was using his girlfriend's oxycodone. (Tr. vol. 3, at 208.) In spite of, or perhaps because of, the fact that SA Ryckeley indicated on a patient form that no doctor prescribed the oxycodone he had been taking (see Tr. vol. 3, at 228), Respondent did not ask if any doctor prescribed the 180 oxycodone 30 mg tablets that SA Ryckeley indicated on his Pain Assessment Form that he was taking. (Tr. vol. 3, at 226; Gov't Ex. 27 at 9.)

The record contains evidence that Respondent acknowledged the impropriety of SA Ryckeley's illicit use and possible abuse of oxycodone, but decided to issue a prescription for controlled substances anyway. SA Ryckeley told Respondent he was taking oxycodone six times per day but stopped two weeks before the consultation because of an impending drug test for a job application. (Gov't Ex. 7 at 22 & 24.) He said that his girlfriend had been prescribed four pills per day, but "[s]ometimes people gave me two (2) at the club and stuff like that." (Gov't Ex. 7 at 25.) Respondent later asked:

WOLFF: But the, the thirties (30s) seem to work good for you? UC1: Yeah, I like them.

WOLFF: You like them?

UC1: Well, which I mean, I think they, they work good.

WOLFF: You know, you're killing me, I can't even believe I'm having this

conversation. [LAUGHS]

UC1: I've never, I've never been a, uh, educated man doc, you know?

WOLFF: Killing me

(Gov't Ex. 7 at 28.) SA Ryckeley's confession that he had diverted controlled substances from his girlfriend and others at "the club" and his statement that he liked the opioids should have constituted grounds for significant concern by Respondent that the patient was abusing or diverting controlled substances. Indeed, as noted above, Dr. Berger also testified that references in the medical file regarding the patient taking controlled substances from his girlfriend makes "them a bad candidate for compliance," because they may be willing to share or divert their medication. (Tr. vol. 7, at 167.) At hearing, Respondent testified that he found the response "I like them" to be unusual and assumed it was related to SA Ryckeley's difficulty communicating and gave SA Ryckeley the benefit of the doubt. (Tr. vol. 10, at 226-27.) But Respondent's reply that "you're killing me" demonstrates Respondent's recognition that issuing a prescription under such circumstances would raise serious questions whether such a prescription was within the usual course of professional practice or pursuant to a legitimate medical purpose. Moreover, the record reflects that Respondent did not discuss a rehabilitation program to address the fact that SA Ryckeley was taking between four and six oxycodone pills per day without a prescription (Tr. vol. 3, at 225), as contemplated by Fla. Admin. Code Ann. r. 64B8-9.013(3)(e) ("The management of pain in patients with a history of substance abuse . . . requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.").86

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⁸⁶ Respondent did indicate in the patient file that at the next visit he would "consider referral to a Board Certified pain management specialist" (Tr. vol. 10, at 238; Gov't Ex. 27 at 6; Resp't Ex. 7 at 5), but there is no indication regarding referral to a rehabilitation program. In any event, there was no subsequent visit and no such referral ever occurred.

Respondent ultimately agreed to "get you started on some medication, we'll see how you do." (Gov't Ex. 7 at 31.) Respondent issued a prescription for 150 Roxicodone 30 mg tablets, constituting a decrease by thirty pills from the amount that SA Ryckeley had self-reported. (Tr. vol. 3, at 211, 271; Gov't Ex. 7 at 62-66.) SA Ryckeley filled the prescription at CCHM for a cost of \$900. (Tr. vol. 3, at 211.) Because he was a member of a group of patients who had entered the clinic together, the staff determined that SA Ryckeley had overpaid and refunded him \$150. (See Tr. vol. 3, at 212.) Even in the absence of expert testimony, I find that the practice of providing a discount on medication to patients who arrive together in a group bears no rational connection to the legitimate practice of medicine. Moreover, although it is not by itself conclusive proof of diversion of controlled substances, such a practice is nevertheless consistent with diversion.

The record reflects Respondent's own uncertainty as to whether a controlled substances prescription for SA Ryckeley was for a legitimate medical purpose: "I don't know, if, if you don't need it I don't want you to take it but if your pain is such that, you know, you can't function without it, then, uh, then that's a reasonable indication." (Gov't Ex. 7 at 32.) He cautioned SA Ryckeley not to take the medication except as indicated, not to buy, sell or share it, and to keep it locked in a safe place. (Gov't Ex. 7 at 31.) "I know it's out in the street and everything, but we consider it serious stuff..." (Gov't Ex. 7 at 31.) At hearing, Respondent testified that he was merely "trying to give him an appreciation for the fact that I don't want him to take the medication unless he needs it." (Tr. vol. 10, at 231.) Given SA Ryckeley's shifting answers regarding the scope of his pain and the other indications of diversion and abuse, however, I give Respondent's explanation little weight. Indeed, Respondent testified that he wrote in SA Ryckeley's patient file (Gov't Ex. 27 at 6; Resp't Ex. 7 at 5) that "I want to make sure patient is legitimate... without a chance of diversion. Will perform urine drug test next visit...." (Tr. vol. 10, at 238.) Respondent's notation effectively deferring his present concerns of diversion to a future date is

consistent with a pattern of evidence that Respondent repeatedly and deliberately ignored clear indications of diversion while prescribing controlled substances.

The record further reveals evidence that Respondent documented in SA Ryckeley's patient file discussions that did not actually occur. For instance, despite contrary notations in the patient file (e.g., Gov't Ex. 27 at 5), SA Ryckeley testified that Respondent never discussed sleep disturbance, anti-inflammatory medications, diet or alternative forms of treatment, yoga and stretching exercises, omega-3 fish oil, smoking, weaning off medication or a time frame for pain management. (Tr. vol. 3, at 219-21, 231.) Moreover, although SA Ryckeley told Respondent that he occasionally experienced headaches (Gov't Ex. 7 at 21), Respondent did not discuss the possibilities of neurosurgical consultation and surgery. (Tr. vol. 3, at 228.) Respondent's conduct constitutes a failure to keep accurate records, in violation of Fla. Admin. Code Ann. r. 65B8-9.013(3).

In mitigation, Respondent did inquire whether SA Ryckeley drank. SA Ryckeley responded that he drank socially: "Two (2) or three (3) drinks, max . . . a week maybe." (Gov't Ex. 7 at 26.) Respondent replied that "we don't prescribe medicines to people who drink alcohol because the interaction between alcohol and medicine is bad . . . you could die from it." (Gov't Ex. 7 at 26-27.) "[T]his medicine and alcohol is not to be mixed." (Gov't Ex. 7 at 27.)

Moreover, Respondent did ask SA Ryckeley whether he was currently working. (Gov't Ex. 7 at 24.) SA Ryckeley responded: "Uh, I'm between jobs." (Gov't Ex. 7 at 24.) There is no evidence that Respondent asked SA Ryckeley why SA Ryckeley wrote on his patient medical history that he was currently employed. (See Gov't Ex. 27 at 8.) SA Ryckeley did, however, tell Respondent that he occasionally works on weekends. (See Gov't Ex. 7 at 32.) SA Ryckeley also told Respondent that he used to work as a boat captain on a commercial charter. (Gov't Ex. 7 at 24.) Respondent initially thought "if [SA Ryckeley] couldn't go fishing, it wouldn't be the end of the world. But then I realized that this was his job." (Tr. vol. 10, at 222.) Respondent asked if the pain depleted his energy, and SA Ryckeley

responded that the pain "makes me less willing to do what I like to do . . . because . . . I'm in discomfort." (Gov't Ex. 7 at 25.) He elaborated that he is in a better mood when on oxycodone pills, that they improve his relationship with his girlfriend or his sex life, and that it is significantly more difficult to work without medicine. (Gov't Ex. 7 at 25-26.)

In addition, Respondent did conduct a physical examination of SA Ryckeley and also explained that SA Ryckeley's MRI report showed a bulging disk. (Gov't Ex. 7 at 28, 30; see Tr. vol. 3, at 208.)

SA Ryckeley's performance during a physical examination, however, should have raised concerns of diversion: Respondent instructed SA Ryckeley to perform a range-of-motion test and walk across the room (Tr. vol. 3, at 208 & 210; Tr. vol. 10, at 228; see Gov't Ex. 7 at 21), which SA Ryckeley completed with ease and without complaining about pain. (Tr. vol. 3, at 210.) Because SA Ryckeley told

Respondent that he was not currently taking medication (Gov't Ex. 7 at 22 & 24), Respondent could not have believed that SA Ryckeley had pain that was satisfactorily numbed by medication. He therefore should have been concerned that SA Ryckeley's successful and apparently painless completion of the range-of-motion tests contradicted SA Ryckeley's reports of pain, which, as noted above, varied throughout the course of the meeting. It was an inconsistency that should have apprised Respondent that SA Ryckeley may not have been a legitimate patient.

Of still greater concern is that Respondent commenced a physical examination of SA Ryckeley only after deciding to prescribe controlled substances to SA Ryckeley. (See Gov't Ex. 7 at 28 ("You like [oxycodone]?... You know, you're killing me, I can't even believe I'm having this conversation... Alright, hold up your arms up here, like this....").) In requiring that physicians conduct a patient evaluation prior to prescribing controlled substances, see Fla. Admin. Code Ann. r. 64B8-9.013(3)(a), the Florida Board of Medicine intended that the physical examination inform the practitioner's decision of whether to prescribe controlled substances, not vice versa. Where, as here, the physician conducts a physical examination of a first-time patient only after having already decided to prescribe controlled

substances, the physician cannot be considered to have acted within the usual course of professional practice.

After considering the evidence weighing in Respondent's favor with respect to SA Ryckeley, the balance of the evidence shows that Respondent knew or should have known that SA Ryckeley was presenting as a patient who had previously obtained and used controlled substances without a prescription and presently intended to use controlled substances for other than a legitimate medical purpose. Dr. Berger was of the opinion that statements by SA Ryckeley, if known by the physician, "would absolutely preclude a physician practicing medicine within the standard of care" from prescribing controlled substances. (Gov't Ex. 32 at 111.) I further reject as inconsistent with the weight of the evidence Respondent's statements at hearing to the effect that he would not have prescribed controlled substances if he did not believe SA Ryckeley was a real pain patient. (See, e.g., Tr. vol. 10, at 233-34.) Moreover, I find that Respondent's prescription of oxycodone to SA Ryckeley was outside of the usual course of professional practice and lacked a legitimate medical purpose, in violation of Fla. Admin. Code Ann. r. 64B8-9.013 and 21 C.F.R. § 1306.04(a).

2. CMG

As discussed above, the Government presented evidence relating to prescribing practices at CMG and undercover visits to see Respondent at that location by three agents: SA Miller, SA McClarie and SA Bazile. The Government did not produce patient records for these undercover agents or present expert testimony surrounding their visits. Moreover, in light of testimony by Respondent, the treating physician, that he acted appropriately, I give little weight to the evidence relating to CMG except with respect to SA Bazile. The record reflects that after Respondent issued a prescription for 90 Roxicodone 15 mg tablets, SA Bazile testified that she said "can I have something to sleep and he said do you have trouble sleeping? I said sometimes and he said – he seemed a little irritated. He said you're not very convincing." (Tr. vol. 6 at 23.) Ultimately, however, Respondent issued a prescription for Xanax. (Tr.

vol. 6, at 24.) SA Bazile's unrebutted testimony that Respondent did not find SA Bazile's need for Xanax "very convincing," even without the aid of expert testimony, fully supports a finding that Respondent's prescription for Xanax was not pursuant to a legitimate medical purpose under 21 C.F.R. § 1306.04(a). See Cynthia M. Cadet, M.D., 76 Fed. Reg. 19,450, 19,450 (DEA 2011) (explaining that in cases of particularly flagrant conduct by a registrant "expert testimony adds little to the proof necessary to establish a violation of Federal law").

3. Summary of Undercover Patients

For the foregoing reasons, I find by substantial evidence that Respondent issued a substantial number 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. Additionally, Respondent repeatedly failed to comply with the requirement to keep accurate and complete records. In 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.

4. Evaluation of Expert Testimony

The evidence at hearing included opinions from Dr. Berger and Respondent regarding Respondent's prescribing practices. Expert testimony regarding a physician's prescribing practices is an important but not indispensible part of evaluating whether a practitioner is acting for a "legitimate medical purpose" in the "usual course of his professional practice." 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 (DEA 2011).

⁸⁷ E.g., 21 C.F.R. § 1306.04(a); 21 U.S.C. § 841(a)(1); and Fla. Admin. Code Ann. r. 65B8-9.013 (2003).

⁸⁸ Fla. Admin. Code Ann. r. 65B8-9.013(3)(f).

⁸⁹ 21 C.F.R. § 1306.04(a).

As a general matter, the opinion of a treating physician in the context of a DEA administrative hearing 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."

<u>Eastover Mining Co. v. Williams</u>, 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. Accordingly, I have not given Respondent's testimony on the facts of this case greater weight simply because of his status as a treating physician, particularly given the short duration of his treatment of each undercover patient.

Dr. Berger's testimony at hearing, while credible for the most part, was fraught with numerous instances of nonresponsive answers and lapses of memory with regard to the evidence, including his written report. Additionally, Dr. Berger's testimony and report was found to contain substantive errors, including dates of patient treatment, urinalysis results, identity of signatures and patient history. (See, e.g., Tr. vol. 7, at 222-24; Tr. vol. 8, at 5; Tr. vol. 8, at 199.) Notwithstanding the foregoing deficiencies, I have given Dr. Berger's testimony and opinions with regard to seven of eight patient files significant weight, as discussed above, since his opinions were well supported by other objective evidence of record, including the patient file. While I have given weight to Dr. Berger's opinions regarding "medical standards of care" for seven of the eight patient files relating to CCHM, I give no weight to his various opinions and statements regarding the legality of conduct by physicians and staff at CCHM. (Gov't Ex. 23 at 123.)

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⁹⁰ See 20 C.F.R. §§ 404.1527(d)(2) and 416.927(d)(2).

⁹¹ Dr. Berger's written report was as unimpressive as his testimony in various respects, to include factual errors and the lack of a date and signature, among other deficiencies. Upon inquiry as to the basis for Dr. Berger's identification of his written report as the final draft, given the absence of a date or signature, he responded: "It looks familiar to me." (Tr. vol. 9, at 137.)

⁹² I have given Dr. Berger's testimony with regard to SA Saenz little to no weight due to Dr. Berger's material and erroneous belief that Respondent had treated SA Saenz on more than one occasion, and his erroneous interpretation of a urinalysis report, which clearly influenced his opinion regarding Respondent's standard of care.

Respondent's testimony in this case was significantly diminished by his lack of credibility in numerous instances, to include a lack of objective patient record evidence to support his assertions that he always conducted an adequate patient evaluation, and that he reasonably believed each of the undercover patients to which he prescribed controlled substances truthfully reported real pain. The evidence of record is overwhelming that Respondent had actual knowledge of diversion in a number of instances or simply ignored clear warning signs in others, making incredible his assertion that he was effectively duped into prescribing controlled substances during each undercover visit, with the exception of SA Marshall. Respondent's testimony and opinion that he acted in accord with the public interest standard in numerous "other" cases, even if accurate, is unavailing because even a single act of intentional diversion is sufficient grounds upon which to revoke a registration, e.g., Cynthia M. Cadet, M.D., 76 Fed. Reg. 19,450, 19,450 n.3 (DEA 2011), and "evidence that a practitioner has properly treated thousands of patients does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest." Jayam Krishna-lyer, M.D., 74 Fed. Reg. 459, 463 (DEA 2009).

The evidence in this case reflects in numerous instances a willful blindness or deliberate ignorance by Respondent of facts that put him on notice of actual or potential diversion, yet Respondent "deliberately closed his eyes to wrongdoing that should have been obvious to him." <u>U.S. v. Veal</u>, 23 F.3d 985, 988 (6th Cir. 1994). For example, Respondent made no substantive inquiry to SA Bazile's statement that she likes "blues" and shares them with friends. (Tr. vol. 6, at 22-23.) Similarly, Respondent failed to inquire about the details surrounding SA Priymak's statement that he gets oxycodone off the street. (Gov't Ex. 5 at 39.) In response to SA O'Neil's statement that he was illegally taking liquid oxycodone,

⁹³ Even with regard to SA Marshall, Respondent's decision not to prescribe rested on his belief that SA Marshall was an undercover law enforcement officer rather than upon a concern for preventing diversion.

Respondent stated: "Don't even tell me that." (Gov't Ex. 14 at 30.) Respondent later stated in substance that most pain clinics hearing such information would cut the patient off. ⁹⁴ (Gov't Ex. 14.)

I find Respondent's testimony explaining that his comment "[d]on't even tell me that" was simply an expression of being "disturbed" and "hurt" to hear such information to be palpably not credible in light of the totality of the evidence, particularly Respondent's pattern of ignoring similar evidence of diversion and abuse. (See Tr. vol. 10, at 155.) The context of Respondent's conversation with SA O'Neil demonstrates that rather than being interested in finding out the facts of the patient's liquid oxycodone use, a substance that Respondent considered highly dangerous, Respondent clearly implied that he did not want to hear such information. (Gov't Ex. 14 at 30-32.) The evidence of Respondent's willful blindness to illicit drug use and evidence of diversion was also evidenced by his testimony regarding his departure from CMG over the falsification of a patient drug screen by a staff member. Respondent testified that when he left CMG he felt under duress, fear and danger, but did not report the incident to the police. (Tr. vol. 9, at 69-70, 74.)

Additional examples of Respondent's willful blindness to issues of diversion permeate the record, but further elaboration is unnecessary.

5. Respondent's Positive Experience in Dispensing Controlled Substances

Respondent offered testimony and evidence of his past positive experience in dispensing controlled substances, including his experience working in hospitals and with public safety departments. Additionally, Respondent offered testimony supported by patient files related to his positive experience in treating patients [C.E.], [D.P.], [J.B.], [R.C.], [L.K.], and [J.R.] (Resp't Exs. 11, 13, 15-17 & 19.) Respondent further testified that after becoming owner of CCHM, he implemented various improvements to include staff changes, an updated urinalysis process, and a clinic procedure manual.

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⁹⁴ Compare transcript with audio/video recording of undercover visit, with the latter reflecting Respondent's verbal reference to other clinics cutting a patient off from treatment. (Gov't Ex. 14 at 32; 2010-05-04_ONeil_24_vid.002 at 19:20-19:40.)

Respondent also argued that additional files in the Government's possession but otherwise unavailable to Respondent evidenced further instances of positive experience in dispensing controlled substances.

I have considered the evidence related to Respondent's past experience in dispensing controlled substances and find that with regard to Respondent's work with hospitals and public safety departments, he has in fact acted consistent with the public interest. Additionally, the un-rebutted evidence pertaining to patients [C.E.], [D.P.], [J.B.], [R.C.], [L.K.], and [J.R.] are consistent with Respondent's testimony and reflect positive prescribing experiences.

Respondent's claim that patient files in the Government's possession but not produced at hearing or otherwise made available to Respondent may contain additional evidence of positive prescribing is unsupported by record evidence since none of the "additional" patient records were produced by either party at hearing. Even if Respondent's claim of additional positive experiences were supported by patient files, 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).

While I have carefully considered the evidence of Respondent's past positive experiences in dispensing controlled substances, I find those experiences are vastly 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 to admit any wrongdoing with regard to his conduct at CMG⁹⁵ and CCHM.

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). 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. at 14.) Respondent's testimony at hearing repeatedly demonstrated Respondent's belief that he had engaged in no past misconduct and was in full compliance with existing laws and regulations.

(Tr. vol. 11, at 296.) Respondent's testimony further demonstrated a remarkable lack of acknowledgment and recognition of the risks of diversion. For example, Respondent testified in substance that he did not believe that a patient's use of the street term "blues" for Roxicodone constituted a "red flag" for diversion, even with knowledge of the patient's self-reported recent history of alcohol rehabilitation and illicit use of Roxicodone, because Respondent "didn't want to make a value"

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⁹⁵ As noted above, the Government has sustained its burden of proving by substantial evidence that Respondent prescribed Xanax to SA Bazile for other than a legitimate medical purpose or outside of the usual course of professional practice.

⁹⁶ 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.")

judgment" on the patient's use of the term "blues." (Tr. vol. 10, at 192-93.) Respondent testified in substance that with regard to another patient, he interpreted "in a positive way" the patient's statement that the patient was illicitly using another person's medication because the patient "had gotten relief" from pain, but did not make any substantive inquiry about the details of the patient's illicit use of the medication.

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

The record reveals that Respondent has not sustained his burden in this regard. In fact, as discussed above, Respondent's testimony in numerous instances was not credible and reflected an overall lack of admission of past misconduct, 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 demonstrate that he will not engage in future misconduct. I find that Factor Five weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest.

V. CONCLUSION AND RECOMMENDATION

I recommend revocation of Respondent's DEA CORs FW1453757, BW3918440, BW4448571, AW2065058, FW1338690, BW4362935, AW2654639, AW8594233 and BW0601446 as a practitioner, and denial of any pending applications for renewal or modification to include application WI0053115C,

on the grounds that Respondent's continued registration would be fully inconsistent with the public interest as that term is used in 21 U.S.C. §§ 824(a)(4) and 823(f).

Dated: July 25, 2011 s/Timothy D. Wing

Administrative Law Judge

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