a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton,* 43 FR 27616 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[ ] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See, e.g., Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *Blanton,* 43 FR at 27616.

Moreover, revocation is warranted even when a state board has resorted to summary process in suspending a practitioner's dispensing authority and the state has yet to provide the practitioner with a hearing to challenge the board's action. This is so ''because 'the controlling question' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration '' 'is currently authorized to handle controlled substances in the [S]tate.' '' *Gentry Reeves Dunlop,* 82 FR 8432, 8433 (2017) (quoting *Hooper,* 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997))); *see also Bourne Pharmacy,* 72 FR 18273, 18274 (2007); *Wingfield Drugs,* 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the New Mexico Board has employed summary process in suspending Registrant's state license. What is consequential is that Respondent is no longer currently authorized to dispense controlled substances in the State in which he is registered.

In his reply to the Government's Motion for Summary Disposition, Respondent argued that the authority contained in 21 U.S.C. 824(a)(3) is a ''discretionary, not mandatory basis for revocation.'' Respondent's Reply, at 2. While Respondent cites *James Alvin Chaney,* 80 FR 57391 n.1 (2015), as support for his contention, footnote one of the Agency's Decision in *Chaney* addressed whether the respondent in that case had an active registration. Moreover, Respondent's contention that the Agency's sanction authority in cases involving a practitioner's loss of his state controlled substance dispensing authority remains discretionary, was squarely addressed and rejected in footnote 2 of the *Chaney* decision, as it has been in countless Agency decisions. *See Chaney,* 80 FR 57391 n.2; *see also, e.g., Charles Szyman,* 81 FR 64937, 64938 n.1 (2016); *see also Rezik A. Saqer,* 81 FR 22122, 22127 (2016); *James L. Hooper,* 76 FR 71371 (2011). And the Agency's rule has been upheld by two courts of appeals. *See Hooper* v. *Holder,* 481 Fed. Appx. 826, 828 (4th Cir. 2012) (''[b]ecause sections 823(f) and 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Administrator's] decision to construe section 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA''); *Maynard* v. *DEA,* 117 Fed. Appx. 941, 944–45 (5th Cir. 2004) (rejecting contention that DEA could not revoke practitioner's registration where state board's disciplinary panel ''merely temporarily suspended'' medical license ''without notice''). I will therefore order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No.FB5001538, issued to John D. Bray-Morris, M.D., be, and it hereby is, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f), I further order that any pending application of John D. Bray-Morris, M.D., to renew or modify his registration, or for any other registration in the State of New Mexico, be, and it hereby is, denied. This Order is effective immediately.[4]

Dated: July 27, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–16446 Filed 8–3–17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Marcia L. Sills, M.D.; Decision and Order

On January 21, 2015, the Deputy Assistant Administrator, of the then Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Marcia L. Sills, M.D. (hereinafter, Respondent). The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration AS1456361, pursuant to which she is authorized to dispense controlled substances in schedules II through V, at the registered location of 2741 NE 34 St., Fort Lauderdale, Florida. GE 1, at 6. As grounds for the proposed action, which also includes the denial of any pending application for renewal and any other applications for new DEA registrations, the Show Cause Order alleged that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that while Respondent's registration was due to expire on February 28, 2014, she ''submitted a timely renewal'' application. *Id.* The Order thus asserted that her ''registration continues in effect pursuant to 5 U.S.C. 558(c).'' *Id.*

As for the substantive grounds for the proceeding, the Show Cause Order set forth numerous allegations that between November 2011 and July 2012, Respondent violated Florida and Federal controlled substances laws in her prescribing of controlled substances to an undercover officer and seven other patients. *Id.* at 6–10. With respect to the undercover officer, the Order alleged that on both May 31, 2012 and July 16, 2012, Respondent issued prescriptions to him for both oxycodone 30 mg, a schedule II controlled substance, and clonazepam, a schedule IV controlled substance, which were not for a

[4] For the same reasons that led the New Mexico Board to summarily suspend Respondent's medical license, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

legitimate medical purpose in the usual course of professional practice under State and Federal law. *Id.* at 6–7. Specifically, the Order alleged, *inter alia,* that Respondent ''failed to conduct a sufficient physical exam,'' ''failed to provide a legitimate diagnosis,'' prescribed to the UC ''despite evidence that he had illegally obtained controlled substances,'' and had prescribed ''large quantities'' of oxycodone ''absent any reliable evidence that [the UC] had any tolerance to opioid medication and increased the quantities absent a legitimate medical purpose.'' *Id.* at 7. The Order also alleged that Respondent ''assisted the UC in his attempts to obtain controlled substances from a pharmacy without arousing suspicions that the prescriptions were issued for other than a legitimate medical purpose.'' *Id.* The Order thus alleged that Respondent violated both Federal and State law in issuing the oxycodone and clonazepam prescriptions. *Id.* (21 U.S.C. 829, 841(a); 21 CFR 1306.04(a) & 1301.71; Fla. Stat. Ann. §§ 455:44(3) & 456:072(1)(gg); Fla. Admin. Code r. 64B8–9.013).

The Show Cause Order also alleged that a medical expert who reviewed at least eight medical files of patients (including the undercover officer) treated by Respondent ''concluded that, in each case, [she] prescribed controlled substances to those patients without a legitimate medical purpose in the usual course of professional practice.'' *Id.* The Order specifically alleged that the expert found that Respondent ''distributed large amounts of controlled substances without conducting a sufficient medical history and/or physical examination and without determining the patients' tolerance to controlled substances,'' and did so ''even though the patients demonstrated evidence of drug abuse and/or diversion.'' *Id.* at 7–8. The Order then set forth detailed allegations regarding her prescribing to seven patients (other than the undercover officer), who presented such evidence. *Id.* at 8–9.

The Show Cause Order also notified Respondent of her right to request a hearing on the allegations, or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 10 (citing 21 CFR 1301.43). On February 2, 2015 the Government accomplished service by personally serving Respondent with the Show Cause Order. GE 26, at 4. (Declaration of Diversion Investigator (DI)).

On February 6, 2015, Respondent filed a motion for extension of the time to respond to the Show Cause Order on the ground that she had been charged in a criminal case based on ''essentially the same allegations and has maintained her [F]ifth [A]mendment right to remain silent pending trial'' and that she ''is not in a position to factually respond to this order until after her trial.'' Motion for Extension of Time Pursuant to 21 CFR 1316.47(b). Respondent further requested that the proceeding be ''abated . . . until the conclusion of the criminal matter.'' *Id.* On February 9, 2015, the Chief Administrative Law Judge (CALJ) denied the motion. Order Denying Resp.'s Motion for an Enlargement of Time to Respond to Order to Show Cause.

On February 19, 2015, Respondent filed a timely request for a hearing with the Office of Administrative Law Judges. In her request, Respondent ''denie[d] all of the factual assertions'' and legal conclusions of the Show Cause Order, and maintained that she ''did not violate any of the provisions argued by the [G]overnment.'' GE 20, at 1. However, on March 6, 2015, Respondent submitted a letter withdrawing her request for a hearing; the same day, the CALJ granted Respondent's request and terminated the proceeding. *Id.* at 3.

On October 13, 2016, the Government submitted its Request for Final Agency Action and an evidentiary record. Based on Respondent's letter withdrawing her request for a hearing, I find that Respondent has waived her right to a hearing. 21 CFR 1301.43. I therefore issue this Decision and Order based on relevant evidence submitted by the Government. I make the following factual findings.

Findings of Facts

Respondent is a physician licensed by the State of Florida. Respondent is also the holder of DEA Certificate of Registration No. AS1456361, pursuant to which she is currently authorized to prescribe controlled substances in schedules II–V, at the registered address of 2741 NE 34 Street, Fort Lauderdale, Florida. GE 1, at 1. In addition, she is authorized to dispense Suboxone and Subutex, pursuant to the Drug Addiction Treatment Act of 2000 (DATA), for the purpose of treating up to 30 opiate-addicted patients. *Id.; see* 21 U.S.C. 823(g)(2).

Respondent's registration was due to expire on February 28, 2014. While other agency records show that she submitted a renewal application on March 5, 2015, according to the Government, the ''renewal was marked received by the DEA mail room on March 1, 2014,'' and ''was likely received several days prior to March 1, 2014'' due to security screening measures. RFAA, at 1 n.1. Because Respondent's renewal was timely, I find her registration has remained in effect pending the resolution of this proceeding. *See* 5 U.S.C. 558(c). Government Request for Final Agency Action (RFAA), at 1.

At all times relevant to this proceeding (November 2011 to July 2012), Respondent was employed at the Pompano Beach Medical Center (PBM), located at 553 E. Sample Road, Pompano Beach, Florida. PBM was the subject of a criminal investigation which included undercover operations conducted on May 31 and July 16, 2012 by a former DEA Task Force Officer and Broward County Sheriff's Office Detective (hereinafter ''UC'') who posed as a patient at two medical appointments during which he was seen by Respondent, who prescribed various controlled substances to him.[1] GE 26, at 2.

During both visits with Respondent, the UC used audio and visual recording devices. *Id.* at 2–3. As part of the record, the Government submitted DVDs of the recordings as well as transcriptions of the recordings.[2] The Government also submitted copies of the prescriptions Respondent issued to the UC. GE 8, 10.

Following the UC's visits, the investigators obtained a state search warrant for PBM, and during the execution of the warrant, seized numerous patient files, including those of the UC and seven other patients. *Id.* at 4. The DI also obtained from various pharmacies copies of prescriptions which had been issued by Respondent to three of those patients. *Id.* Copies of the seven patient files and the prescriptions obtained by the DI are included in the evidence. *See* GE 12–18, 21, 23.

The Government's Expert

As part of its investigation, the Government retained Dr. Reuben M. Hoch, an Interventional Pain Medicine Specialist and Anesthesiologist, who reviewed the medical files, transcripts and recordings of the undercover officer's two visits with Respondent, as well as the patient files for seven other patients treated by Respondent. Dr.

[1] On August 16, 2012, Respondent was arrested and charged with two counts of Illegal Prescribing of Controlled Substances, two counts of Delivery of a Controlled Substance, one count of Racketeering, and one count of Conspiracy to Commit Racketeering. Declaration of DI, at 2 (citing Florida Statutes §§ 893.13(8)(a)(1) and (2), 893.13(1)(a)(1), 895.03(1) and (4)).

[2] The DI and the UC averred that true and accurate transcripts of the recordings were made and are provided in the evidence file, along with DVDs of the recordings. GE 25, at 5; GE 26, at 2–3. *See also* GE 3, 4, 5, 6, 7, 9.

Hoch received his medical degree from the Sackler School of Medicine at Tel Aviv University in 1988. GE 2, at 1. He has done an internship in internal medicine and both a residency in anesthesiology and a fellowship in pain management at New York University. *Id.* at 2. He is Board Certified in Anesthesiology and Pain Medicine by the American Board of Anesthesiology. *Id.* at 3.

Dr. Hoch, who is licensed in Florida and New York, currently practices pain medicine at Boca Raton Pain Medicine in Delray Beach, Florida, and previously served as the Chief of Multidisciplinary Pain Management Service in the Departments of Neurosurgery and Anesthesiology at The Brooklyn Hospital Center. *Id.* at 3–4. Dr. Hoch has served as an expert witness on approximately ten different occasions. *Id.* at 1. I find that Dr. Hoch is qualified to provide his expert opinion with regard to the prescribing practices of Respondent in her treatment of the UC and seven patients whose files he examined.

The Undercover Visits

On May 31, 2012, the UC presented at Pompano Beach Medical (PBM) and requested an appointment. GE 25, at 1 (Declaration of UC). The UC told the receptionist he had been working out of town for an extended period and had not been to PBM in the last five months.[3] *Id.* After the receptionist retrieved his file, the UC encountered the clinic's owner and told him that he had been out of town working; the owner then directed the receptionist to 'drug test' the UC. *Id.*

After the receptionist told the UC that the appointment would cost $230 plus $30 for the drug test, the UC made an appointment for later that day. *Id.* at 2. The UC returned later for his appointment and was drug tested. *Id.*

He also filled out various forms, including one titled: ''Patients [sic] Follow Up Sheet.'' GE 11, at 36. On the form, the UC circled the neck portion of a body diagram to indicate where he felt pain; according to the UC, he did so ''even though the MRI which [he] had previously provided to PBM was of [his] lower back.'' GE 25, at 2; *see also* GE 11, at 36. He also answered ''N'' (for no) to two questions: (1) ''Is the pain always there?'' and (2) ''Does the pain get worse when you move in certain ways?'' GE 11, at 36. In response to ''Has the pain affected any of the following: Social activities . . . Mobility . . . Work . . . Appetite . . . Exercise . . . Sleep?'' the UC circled ''Exercise.'' *Id.* He also noted that he had not been in any accidents since he had last visited PBM. *Id.*

On a numeric pain scale of 0–10, with 10 meaning ''hurts worst,'' [sic] the UC indicated the intensity of his pain as ''0'' ''with medication'' (''no pain'') and ''2'' ''without medication'' (''hurts little bit''). *Id.* Finally, he checked a printed statement stating ''I am *satisfied* with my current medication. I would *not* like to change it,'' and left unchecked the statement ''I am *not satisfied* with my pain medication and would like to discuss changes.'' *Id.* The UC then produced a urine specimen, had his weight and blood pressure recorded, and again spoke to the clinic owner, telling him that he had been in California where he had difficulty finding a pain clinic that would prescribe medications, and that it had been difficult to find pharmacies to fill prescriptions for oxycodone. GE 25, at 2 (UC's Declaration). According to the Drug Screen Results Form, which lists numerous controlled substances including ''Opiates/Morphine,'' ''Benzodiazepine[s],'' and ''Oxycodone,'' the UC tested negative for all drugs. GE 11, at 39.

The UC then met with Respondent, telling her that he was a film stuntman who often travelled, that he had been away for work and just returned, and that he had ''stiffness in [his] lower back and . . . neck.'' GE 7, at 1–2 (Transcript of May 31, 2012 visit). Respondent asked the UC how long it had been going on, and UC told her he had seen ''five . . . I think, six doctors'' and ''so I have a lot of times I have the stiffness . . . [u]mm aches.'' *Id.* at 2. He then stated ''two or three'' years, and when Respondent asked: ''It wasn't a car accident or anything?'' UC replied: ''No, no, no it's actually, no critical injury at all. It's you know muscle soreness from the work that I do.'' *Id.* at 3; *see generally* GE 3, V–0002, at 14:10:54–14:13:30.[4]

Respondent, reading paperwork, then asked the UC a series of questions, including whether he had a lockbox or safe to keep medicine in (telling him he should get one when he responded ''no''), whether he had little kids living with him, if he was on disability, and whether he had ''any problems with sleeping or anxiety?'' GE 7, at 3. The UC replied: ''Once in a while. I used to take a little bit of Xanax to sleep, but I think I can probably work without it.'' *Id.* Respondent stated: ''Okay if you need anything to relax you for anxiety we use Klonopin instead of Xanax''; UC replied ''Okay, I'll try it, sure.'' *Id.* Respondent checked both ''anxiety'' and ''insomnia'' in the Pain History section of the visit note. *Id.; see also* GX 3, V–0002, at 14:13:30–14:14:00; GE 11, at 3.

Respondent, who was still reading the form, then asked the UC if he had ''seen another pain management doctor in 28 days?'' UC responded ''No.'' GE 7, at 3. *Id.* Next, Respondent asked: ''Your quality of life is better with than without the medicine I assume?'' to which the UC replied ''Yes.'' *Id.* Respondent circled and/or checked the corresponding items on the form. GE 3, V–0002, at 14:14:00–14:14:08; GE 11, at 33.

After asking about recent hospitalizations, chest pains, shortness of breath or cardiac problems, Respondent asked the UC if he ''kn[ew] the risks of the medicine, addiction, overdose, death, damage to your liver or kidneys?'' GE 7, at 3–4. Without waiting for a reply from the UC, Respondent added that ''we have your blood work to check your liver and kidneys and I'll look at your MRI too.'' *Id.* at 4; GE 3, V–0002, at 14:14:08–14:14:24.

Respondent then asked UC to stand up ''carefully . . . let me see how you can bend forward.'' *Id.* UC responded: ''I'm pretty . . . from what I do.'' GE 7, at 4. The video recording shows that the UC stood up, turned to move his chair, and immediately bent down, touched his hands to the floor and straightened back up again. GE 3, V–0002, at 14:14:24–14:14:35. In his Declaration, the UC states he ''quickly touched my hands to the floor without hesitation or pain.'' GE 25, at 2.

After asking the UC his age, Respondent asked: ''[I]s your neck okay? . . . Good range of motion in your neck?'' GE 7, at 4. UC, shook his head left to right, and replied: ''Yeah I feel more stiffness when I do, you know, like I do heavy squats. Things like that. That's when I usually have those feelings.'' *Id.* Respondent asked if UC had numbness or tingling in his legs, which he denied, asking ''that would be bad, wouldn't it?'' *Id.* Respondent explained ''it means you might have a herniated disc that's you know pinching.'' *Id.; see also* GE 3, V–0002, at 14:14:35–14:15:03.

Respondent, while looking through paperwork, then stated: ''so these labs are okay. And I want to look at your MRI.'' GE 7, at 4. After briefly looking at the MRI, Respondent stated: ''[n]othing too terrible . . . I don't see any herniated discs,'' and while noting that he had a bulging disc, she added:

[3] The TFO, in his undercover capacity, had last visited PBM in January, 2012, and, prior to that from May–September 2011, when he was treated by different physicians.

[4] Due to the length of the citations to the videos, all such citations are provided at the end of each paragraph.

''a bulge kind of doesn't mean anything. You've got spasms.'' *Id.; see also* GE 3, V–0002, at 14:15:03–14:15:27.

Continuing, Respondent stated: ''we don't give narcotics for spasms . . . [a]nd we don't give [S]oma. I will give you another muscle relaxant.'' GE 7, at 5. Respondent added: ''[a]nd if you want something instead of Valium I'll give you something for that too.'' *Id.* UC responded ''Okay.'' *Id.;* GE 3, V–0002, at 14:15:27–14:15:41.

Respondent then told UC that Klonopin, ''like Valium and Xanax, is for anxiety. And the reason why people take it at night is to reduce anxiety so they can sleep. It is not a sleeping pill.'' GE 7, at 5. She added: ''so Klonopin is long acting unlike Valium and Xanax which are short acting benzos [sic] every 3 to 4 hours, Klonopin is 12 to 24.'' *Id.* When UC asked ''When will I take it, at night before bed?'' she responded: ''It's up to you . . . [n]ight time before bed . . . [b]ut it's not going to zonk you out and it won't give you fogginess. It brings down anxiety a bit.'' *Id.* The UC responded ''Okay.'' *Id.;* GE 3, V–0002, at 14:15:41–14:16:16. According to the UC, in all of his prior visits to PBM, he ''never disclosed that [he] suffered from anxiety.'' GE 25, at 3.

Respondent, looking at the UC's file, then returned to discussing the UC's MRI, stating: ''[o]kay so there's a bulge which by itself it wouldn't mean anything . . . [b]ut I'm gonna make a note here . . . the one up from your tailbone L4,5 . . . it has a small tear in the end which means that due to trauma, something was, the disc was trying to herniate and didn't quite make it . . . and also there is a little bit of pushing of the nerve . . . very little . . . but it is there.'' GE 7, at 5–6. The UC interjected with ''Okay'' sporadically throughout Respondent's discussion. *Id.; see also* GE 3, V–0002, at 14:16:16–14:16:51.

Respondent then asked the UC: ''[h]ow much Roxicodone were you taking? We don't do 120. What were you taking four or five a day? Tell me.'' GE 7, at 6. The UC responded ''[y]es,'' and Respondent asked: ''About four a day? Okay we're good for that. And . . . the Klonopin, I'm going to give you a milligram. . . . I'm also gonna give you some ibuprofen. Because if your [*sic*] filling in Florida which I encourage you to so you're on the computer list. Then . . . for two reasons: number one, the pharmacists usually want a non-prescription drug, a non-controlled substance drug rather . . . and ibuprofen is also good for inflammation.'' *Id.* UC responded with ''Gotcha'' and ''Okay.'' *Id.* Respondent continued: ''If you need something to relax your muscles . . . Let me give you some Flexeril. It's cheap and it works.'' *Id.;* GE 3, V–0002, at 14:17:10–14:18:15. Notably, Respondent had not even performed her physical exam prior to agreeing to prescribe the controlled substances to the UC.

As the video shows, only after she discussed the dosing of Flexeril, did Respondent leave her desk chair and approach the UC, who stood up. According to the UC, Respondent ''asked me to stand up again, placed a stethoscope on my chest for approximately two seconds, and asked me to sit.'' GE 25, at 3 (UC Declaration). While the video feed was blocked during that action, the audio reveals that Respondent told UC a story about a former patient and that she did not stop talking during the time she placed the stethoscope on the UC's chest. She then had him sit, and, according to the UC, ''squeezed my calves while asking if he had any tenderness here?'' *Id.* UC replied ''no.'' GE 7, at 7. Again she asked: ''[a]ny tenderness here?'' *Id.* UC replied ''No.'' *Id.; see also* GE 25, at 6. According to the UC, Respondent ''also struck my knees with a neurologic hammer to test my reflexes even though my feet still were planted on the floor.'' GE 25, at 3; GE 3, V–0002, at 14:18:15–14:19:25. As the video shows, the tests Respondent performed totaled less than one minute. *See generally* GE 3, V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18.

After some unrelated discussion, Respondent asked the UC how often he came back, to which he replied ''I'll come every 28 days.'' GE 7, at 8. She then asked: ''[d]o you try to spread your medicine out if you don't have it?''; the UC replied: ''[y]eah well I do the best I can with what I have.'' *Id.* Respondent told the UC: ''[y]ou know the Roxicodones, this is the short acting. It's safe to break in half.'' *Id.* UC then asked: ''Gonna be thirties still?'' *Id.* Respondent replied: ''[t]hirties'' and added ''[w]e only give thirties.'' *Id.* Respondent then advised the UC to use a pill cutter and told him that ''the ones you can't break in half are the long acting. Because if you break them in half . . . the ones that they call (inaudible) you can overdose''; the UC said ''Okay.'' *Id.* Respondent added: ''all the people that break them in half they're using them for the bad purposes and they don't overdose because their body is so addicted, so.'' *Id.* After the UC stated ''right,'' Respondent added: ''I'm not allowed to say that.'' *Id.;* GE 3, V–0002, at 14:19:38–14:20:28.

Respondent then asked the UC if he ''had a pharmacy that would honor [his] prescriptions.'' GX 25, at 3; GX 7, at 8. The UC told her that ''last time I had a problem. And I actually . . . a friend . . . sent me to an online pharmacy . . . and I sent them and they sent them back I think it was in Georgia.'' GX 7, at 9. Respondent told him ''I would highly recommend not doing that anymore in Georgia because DEA is looking at things across the states. If you can find an online pharmacy . . . okay, a lot of them have been shut down since you've been here.'' *Id.;* GE 3, V–0002, at 14:20:28–14:21:00.

The UC then asked if there ''are any pharmacies that are known to the facility here that are pretty . . .?'' and Respondent replied: ''let's ask them in the front.'' GX 7, at 9. Respondent stated that she ''can't recommend one. They know who goes to where. If you have a relationship with one I then was gonna [sic] encourage you to go back . . . that's your best bet.'' *Id.* The UC told Respondent that when he ''tried to go there, they were out . . . and when I last went there, you know what they were telling me . . . a lot of people are moving to Dilaudid because the oxys are so short.'' *Id.* Respondent replied: ''[t]rue and the Dilaudid is getting short so then they moved to short acting morphine.'' *Id.* Respondent then stated: ''[s]o here's the deal, if you can't find this within a week, um anytime within a week . . . giving it a good college try, come back free and I'll swap it.'' *Id.;* GE 3, V–0002, at 14:20:00–14:21:48.

Respondent further told the UC what days of the week she was at the clinic, prompting him to ask: ''[w]hat would you recommend? If it wasn't the oxycodone, morphine or Dilaudid?'' GE 7, at 9. Respondent replied: ''I would go with the Dilaudid myself.'' *Id.* After summarizing her prescriptions to the UC, and a brief discussion of how and when to take the new prescriptions, she asked him if he had any allergies, to which he replied ''no,'' and the office visit ended. *Id.* at 9–10; GE 3, V–0002, at 14:21:48–14:22:52.

Respondent wrote the UC prescriptions for 112 tablets Roxicodone (oxycodone) 30 mg ''for pain,'' 28 tablets Klonopin (clonazepam) 1 mg ''for anxiety,'' 56 tablets Ibuprofen 400 mg, and 28 tablets Flexeril 10 mg. GE 8 (copies of prescriptions); GE 11, at 32 (Encounter Summary). A report in the UC's file shows that he filled the Roxicodone prescription on June 5, 2012 at Coral Springs Specialty Pharmacy in Coral Springs, Florida. *Id.* at 22. An unsigned and undated handwritten note on the report page asks ''Where is patient filling? Or did he have different address in past?'' *Id.*

The UC's file includes a three-page visit note signed by Respondent on May

31, 2012. GE 11, at 33–35. The first page lists the UC's name, date of the visit, and vital signs, below which is a section titled: ''Pain History Follow Up''; this section includes various words to circle and fill-in-the-blank statements which correspond to the questions Respondent asked UC during the visit.[5] *Id.* at 33.

On the form, Respondent circled ''back'' and ''lower'' as the location of UC's pain, noted the ''Duration of pain'' as ''3 yr[s],'' and that the ''Severity of Pain'' was ''severe'' (as opposed to ''mild'' or ''moderate''). *Id.* at 33. Under ''precipitating event,'' she wrote ''unknown'' with ''work—stuntman'' handwritten nearby. *Id.* Under ''character of pain,'' she checked ''throbbing'' and ''sharp,'' and listed ''anxiety'' and ''insomnia'' as ''Co-morbidities.'' *Id.*

The form also contains blanks for noting the UC's ''Pain Scale off meds (0–10)'' and ''on meds.'' *Id.* In the blank for ''off meds,'' the form contains the scratched-out number ''2,'' followed by the number ''5''; in the blank for ''on meds,'' the form states ''0''. *Id.* As for the blanks regarding the UC's quality of life both off and on medications, Respondent checked ''worse''' for ''OFF medications'' and ''better'' for ''ON medications.'' *Id.* After ''New Events Since Last Visit'' she wrote ''stuntman for movies—was in Cal. Last here Jan 18, 2012.'' *Id.*

The form's first page also contains a checklist for ROS (Review of Systems), on which Respondent checked: ''All negative unless checked.'' *Id.* This page also includes a section captioned with ''PE'' (physical exam), which list various exams items. *Id.* In this section, Respondent drew check marks and diagonal lines through various findings to include: (1) ''HEENT'' (head, eyes, ears, nose and throat), with check mark through ''inspection wnl,'' (2) ''Chest,'' checkmark through ''clear,'' (3) ''Cor,'' diagonal line draw through ''rrr,'' (4) ''Abd,'' diagonal line drawn through ''soft, non tender,'' (5) ''Skin,'' diagonal line through ''wnl, no rash,'' (6) ''Ext,'' line drawn through ''nontender, full ROM,'' (7) Neuro/psych, with checkmark drawn through ''Ox3,'' and (8) ''Gait,'' with a check mark drawn through ''normal.'' *Id.*

The form also includes four diagrams of the human body, including a posterior view; on this diagram, Respondent circled the neck and noted ''ROM WN,'' circled the lower back and noted ''Flex 90 Ext 10,'' and circled the back of the knees and noted ''reflexes =.'' *Id.* She also noted on this page that the UC's UDS (urine drug screen) was negative ''today.'' *Id.*

The form's second page included entries for a Neurological exam. *Id.* at 34. Respondent checked ''yes'' for each item which included: ''Cranial Nerves: II–XII intact,'' ''Sensory Exam: Gross wnl to light touch,'' ''Reflexes +2 bilateral and symmetric upper ext'' and ''+2 bilateral and symmetric lower ext,'' ''Muscle Strength: bilat upper and lower.'' *Id.* Respondent also circled ''−,'' this noting that the UC had a negative straight leg raise with respect to both his right and left legs. *Id.*

Under ''Assessment,'' Respondent made marks next to the following entries:

> Patient satisfied, doing well on current medication and treatment plan; pain condition stable.
>
> Patient taking meds as prescribed and no adverse side effects, no new problems and no changes;
>
> Denies any drug charges or arrests since last visit;
>
> Medication storage and safety issues addressed and patient uses lock box; Diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.[6]
>
> *Id.*

Under ''Diagnosis, Respondent checked ''Anxiety,'' ''Disc Bulge,'' ''Muscle Spasms,'' ''CHRONIC NON-MALIG PAIN SYNDROME,'' and ''Other,'' after which she made a handwritten note stating: ''L45 Bulge tear annular Bilat neural foraminal encroachment.'' *Id.*

Under ''Plan,'' Respondent made lines through multiple entries. These included: (1) ''wt loss, smoking cessation, reduce salt and caffeine, F/U with PCP''; (2)'', ''refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed''; (3) ''F/U in one month to follow the success of treatment and need for adjustments''; (4) ''Patient understands importance of weaning meds to minimum effective dose''; (5) ''Yoga, stretching exercises; Fish oil at 3–6 grams/day; glucosamine/Chondroitin Sulfate as suggested''; (6) ''Discussed informed consent, risks/benefits of given medications, alternate therapies; pt understands''; and (7) ''Continue meds,'' followed by for a second time, ''patient understands importance of weaning meds to minimum effective dose.'' *Id.* Respondent did not, however, place a checkmark next to the entry for ''urine tox screen twice a year or as needed to monitor addiction/diversion.'' *Id.*

The third page includes a pre-printed list of both controlled and non-controlled drugs. Of note, the only narcotic listed on the pre-printed form is Roxicodone in the 30 milligram dosage form, next to which the form contains the pre-printed notations of ''#84 #112 #140 #168,'' with ''#112'' circled on the UC's form. *Id.* at 35. Respondent also checked the box for Klonopin, circling the dosage of ''1 mg'' and the ''#28,'' as well as the boxes for the non-controlled drugs, Flexeril and Ibuprofen 400 mg #56. *Id.*

On checking out, PBM's receptionist provided the UC with the four prescriptions. GE 25, at 3. She also provided him with an appointment card, which listed his next appointment as scheduled for June 28, 2012. *Id.*

In his declaration, the UCs stated that at no time during his visit with Respondent did she inquire ''about any past treatments for pain other than to note what other doctors at PBM had prescribed, that there was no inquiry into any underlying or coexisting diseases or conditions, the effect of pain on my physical and psychological function, or whether I had any history of substance abuse.'' GE 25, at 5.

On July 16, 2012, the UC returned to PBM. *Id.* at 3. *See also generally;* GE 5 V–0003 (video recording). On the ''Follow-Up Sheet,'' the UC again circled the neck region of a body diagram to show where he felt pain. GE 11, at 29. He also circled ''N'' for no in answer to the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.*

Another question on the form asked: ''Has the pain affected any of the following: Social Activities, Work, Exercise, Mobility, Appetite, Sleep.'' *Id.* The UC circled none of these. *Id.* The UC also indicated that intensity of his pain was ''0'' ''With Medication'' and ''1–2'' ''Without Medication,'' ''1–2.'' *Id.* However, the UC also checked the statement: ''I am *not satisfied* with my

[5] During the office visit, the video shows Respondent filling out the form, which lists various items which were either circled or had a place for providing a checkmark: Location of Pain: Neck, Back (upper mid lower) Radiation ____ Head Face Chest Abdomen, R/L: Shoulder F-arm Elbow Arm Wrist Hand Hip Thigh Leg Knee Ankle Foot, Duration of Pain ____ Severity of pain ____ mild ____ moderate ____ severe, Precipitating Event ____ MVA ____ Fall ____ Accident ____ Other ____ Unknown, Character of Pain __ throbbing __ sharp __ dull __ tingling Comorbidities __ anxiety __ insomnia __ other, Lock Box __ Y __ N Kids __ Y ___ Ages __ N Pysch Visits/SS Disability past 5 yr ___ Y___ N, Have you seen another Pain Management Doctor in the past 28 days? ___Y ___N, Pain Scale off meds (0–10) ____ Pain Scale on meds (0–10) ____, Quality of life OFF medications __ better __ worse / Quality of life ON medications __ better __ worse, New Events Since Last Visits _____, GE 11, at 33.

[6] Respondent did not, however, make a mark next to the entry for ''Activities of living, quality of life improved with medication.'' GE 11, at 34.

medication and would like to discuss changes.'' *Id.*[7]

After greeting the UC, Respondent asked him when he had last been to the clinic, to which the UC replied that he was two weeks late and offered the explanation that Respondent was gone the first week and then had a job out of town. GE 9, at 1–2. Respondent then spent several minutes preoccupied with a cellphone text message, after which she asked him a series of questions because the clinic had redone ''all the forms'' since his last visit. *Id.* at 2–4. While making notations on paperwork at her desk, Respondent asked: ''[t]hrobbing, sharp, dull, what would you say?'' *Id.* at 4. The UC replied ''No, no just you know like I said that muscle soreness is the best way I can say it.'' *Id.; see also* GE 5, V–0002, at 15:32:10–36:21, V–0003, at 15:36:30–15:36:41.

Respondent then asked the UC ''no disability, no rehab, no addiction?'' to which the UC answered ''no,'' followed by whether he had ever ''ha[d] surgery for [his] back?'' and ''physical therapy, injections?,'' with the UC answering ''no'' and ''nope.'' GE 9, at 4; GE 5, V–0003, at 15:36:30–15:36:48.

Respondent said, ''Okay, just the meds. You haven't seen anyone else in the past 28 days?'' GE 9, at 4. UC replied ''No.'' *Id.* GE 5, V–0003, at 15:36:48–53.

Next, Respondent asked the UC for his pain level ''[o]ff medicine . . . on a scale of ten to zero.'' GE 9, at 4. After the UC replied: ''[o]ff medicine, two,'' Respondent looked up from her desk at him and demonstrated a line on the desk, explaining, ''Okay, ten is the worst . . . zero is perfect. Without medicine it would be closer to ten.'' *Id.* at 4–5. UC replied: ''Okay, uh, what probably, I'm not sure, on the pain scale . . . four or five? Is that better?'' *Id.; see also* GE 5, V–0003, at 15:36:53–15:37:17.

Respondent then asked ''Okay and then with medicine?'' to which UC replied ''Zero?'' GE 9, at 5. Respondent stated that she was not ''not trying to you know,'' prompting the UC to state that he ''totally underst[ood],'' after which Respondent explained that ''I have to go over this each time. . . . Pain worse lifting, bending, sitting, standing?'' *Id.* UC replied: ''Working out. You know just once in a while when I'm done working out.'' *Id.;* GE 5, V–0003, at 15:37:17–15:37:33.

Respondent asked: ''What makes it better? Lying, resting, ice, heat, massage?''; the UC replied: ''I don't really do any of those things, so it's you know, like I said, it's just'' before Respondent interjected by stating ''Meds'' and asked ''does the pain affect your work, sleep, mood, etc?.'' GE 9, at 5. *Id.* UC answered ''No,'' prompting Respondent to ask: ''[w]hat does the pain affect in your life?'' to which Respondent replied: ''my recovery time from working out for sure.'' *Id.;* GE5, V–0003, at 15:37:33–15:37:52.

Respondent replied ''Okay. Uh, well we certainly wouldn't just give pain medicines and narcotics so your [sic] working out is better,'' to which UC replied, ''No, no, no I understand, I understand.'' GE 9, at 5. The following exchange then ensued:

> Respondent: ''So does the pain affect anything else in your life?''
> UC: ''What are the options again?''
> Respondent: ''Work'' (stated slowly and emphatically).
> UC: ''Let's say work.''
> Respondent: ''Sleeping.''
> UC: ''Work.''
> Respondent: ''Relationships.''
> UC: ''Work.''
> *Id.* at 5–6; GE 5, V–0003, at 15:37:52–15:38:14.

Next, Respondent asked the UC if his ''quality of life [is] better with medicine than without?''; UC answered ''sure.'' GE 9, at 6. Respondent then stated: ''Otherwise you shouldn't be on the medicine,'' to which the UC replied ''right.'' *Id.* Respondent also asked the UC, ''no blood pressure, diabetes, nothing else?'' and if he drank or smoked. *Id.* UC denied all but ''drink[ing] socially but very rarely'' and having ''a cigar occasionally but that's about it ever.'' *Id.;* GE 5, V–0003, at 15:38:14–15:38:37.

After Respondent and the UC discussed at length whether he needed to obtain a lockbox or safe for his medicine to protect it from being stolen, Respondent looked at the UC's MRI and stated: ''there was some muscle spasm there . . . bulges we don't treat. But your bulges have . . . what we call encroachment or it had narrowing of the disc in that area . . . which is kind of rare . . . I better put that down.'' GE 9, at 8; GE 5, V–0003, at 15:38:37–15:42:13.

Respondent then asked UC ''so you satisfied with the medicine?'' GE 9, at 9. UC told her that he thought she ''took me down just a little bit less from the last doctor which is no big deal but the two weeks off . . . definitely, definitely ran out of medication so.'' *Id.* After Respondent interjected ''oh its gotta be,'' the UC stated: ''my friend had some. So I was able to just hold me over until now.'' *Id.* Respondent nodded her head in agreement while the UC was talking and stated ''which we try not to do.'' *Id. See generally* GE 5, V–0003, at 15:42:13–15:42:53.

UC then told Respondent that from the list of seven pharmacies he had obtained from PBM at his previous visit, the seventh pharmacy filled the prescriptions. GE 9, at 9. The UC further stated that: ''[t]he first six said no or they didn't have it. The problem was that the last one is, the pharmacist said 'I can fill the oxycodone, I can fill the ibuprofen, and I can fill the . . . other . . . I don't even remember what the other one was to t[ell] you the truth.'' *Id.* Respondent looked at the chart and said, ''Roxicodone, Klonopin,'' and the UC told Respondent that the pharmacist told him ''she wouldn't fill the clonazepam'' and handed the prescription back to him, stating that she didn't ''feel comfortable filling'' it even though she had called and verified that the prescription was okay. *Id.;* GE 5, V–0003, at 15:42:53–15:43:29.

Respondent noted that ''Xanax is five times more dangerous than Klonopin,'' and the video shows that Respondent threw her hands in the air and stated: ''I don't understand this . . . this is a low dose. That is the first time I heard that.'' GE 9, at 9. UC told her that the pharmacist told him to go fill it somewhere else, to which Respondent replied: ''[t]hat's a cuckoo pharmacist.'' *Id.* at 10. UC told Respondent he didn't fill it because he didn't want to get her or Steve (the clinic owner) in trouble, but ''like I said my buddy just had a couple of Xanax and that was it.'' *Id.;* GE 5, V–0003, at 15:43:29–15:44:05.

Respondent the told the UC to ''[g]o take it to another pharmacy. That's not doctor shopping.'' GE 9, at 10. Continuing, Respondent stated: ''I want you to know doctor shopping is if you take more than one doctor . . . my prescription and another doctor to one or more pharmacies in 28 days. But if somebody refuses to fill a legitimate prescription you can go to another pharmacy. Try to go close to the same day so it all comes out the same.'' *Id.;* GE 5, V–0003, at 15:44:05–15:44:27.

Respondent then told UC she would ''write that and I'll write another non-narcotic. She's gonna [sic] fill Roxicodone but she won't fill one milligram of Klonopin?'' GE 9, at 10. The UC told Respondent that the pharmacist ''said she wouldn't fill the oxycodone without the other ones

[7] Another document in the UC's medical file bears the caption ''June ___ 2012 Audit Page Patient name'' with his undercover name printed. GE 11, at 31. The sheet includes the note: ''Intake 5/7/11—shoulder surgery 2002'' and that an MRI was received on ''5/12/11—Lumbar.'' *Id.* It also lists UDSs as having been done on both ''5/17/11'' and ''5/31/12'' and that both were ''negative,'' as well as his ''B/P'' and Pulse at various visits. *Id.* While the sheet also includes the note ''stuntman travels frequently for job in CA,'' the sheet is blank in the spaces for ''referral out,'' ''records ordered'' and ''records received.'' *Id.* Indeed, the file contains no medical records from other physicians.

either'' and ''I'm like okay. No. Fine. Fill them,'' and Respondent told the UC to ''[g]et another place.'' *Id.;* GE 5, V–0003, at 15:44:27–15:44:40.

UC stated that this was the reason he ''was sending them out to Georgia and getting them sent back,'' to which Respondent replied: ''If you're gonna do that then I have to have proof that you're getting them filled. . . . The reason why we have the state law is so we can track the narcotics . . . the medicines and if they go to Georgia we can't track them in Florida.'' GE 9, at 10–11. After the UC told Respondent he had ''filled the last ones here,'' Respondent told the UC that if he ever ''filled out of state . . . get us a paper copy . . . the exact medicines, the dosage and the date.'' *Id.* at 11; GE 5, V–0003, at 15:44:40–15:45:19.

After re-iterating that it was not doctor shopping for the UC to take the Klonopin prescription to another pharmacy, Respondent asked him to ''stand up . . . and let me see how you're bending.'' GE 9, at 11.[8] The UC stood up, bent his torso towards the floor and back up. Respondent listened to UC's back with a stethoscope and appeared to move his head, and asked ''Any pain going back?'' and ''No pain here?'' with the UC answering ''no'' to both questions. *Id.* at 12; *see also* GE 5, V–0003, at 15:45:19–15:46:22.

Respondent then told the UC to sit down and face her, and after he sat down, Respondent appeared to lift one leg straight out and then the other, asking ''Any pain in your back?'' GE 9, at 12. The UC replied: ''I'm just . . . my legs are just tight, tight, tight. I just did legs. My hamstrings feel like they're gonna light up.'' Respondent replied ''I'm talking about your back'' and UC replied ''No.'' *Id.;* GE 5, V–0003, at 15:46:22–15:46:47.

At this point, Respondent returned to her desk. As the video shows, the entire physical exam lasted just over one minute, during which the UC was never put in the supine position. GE 5, V–0003, at 15:45:36–15:46:47.

The UC then told Respondent that ''most problematic thing is when I do squats . . . . heavy squats'' and this is ''when I can feel the majority of any kind of stiffness in my back[,] but right now it feels good.'' GE 9, at 12. The UC then asked Respondent if he should ''have surgery for that tear,'' with Respondent stating that she ''wouldn't recommend it'' and then asked if his pain ''seem[ed] to be worse on one side versus the other.'' *Id.* The UC said ''no,'' and asked ''will it get worse gradually or no?'' *Id.* Respondent replied that the UC did not have ''a clear cut hernia,'' but that the condition would not heal by itself and ''might eventually develop into a hernia.'' *Id.* However, after the UC mentioned that his father ''had seven hernias,'' and that ''like three of them were repairs,'' Respondent clarified that she was ''talking about'' the UC's ''spinal column'' and herniated discs. *Id.* at 12–13; GE 5, V–0003, at 15:46:48–15:47:59.

After a short discussion of her having been ''away for a couple of days,'' Respondent, in an apparent reference to the quantity of the UC's next oxycodone prescription, stated: ''Alright let's go to one forty,'' prompting the UC to say ''okay,'' after which Respondent added: ''I can't justify more than that.'' GE 9, at 13; GE 5, V–0003, at 15:48:00–15:48:29.

While writing the prescription Respondent again was distracted by a cell-phone text message, which she returned before repeating: ''Okay so we're gonna [sic] go up to one forty . . . any side effects you let me know about. And I'm gonna write for Klonopin again.'' GE 9, at 13–14. After another brief discussion of why the pharmacist had refused to fill the previous Klonopin prescription with Respondent stating that the Klonopin ''is a very good match with oxycodone and doesn't potentiate the side effects of oxycodone,'' Respondent told UC she was going to give him two non-narcotic prescriptions so he could ''get them filled someplace else.'' *Id.;* GE 5, V–0003, at 15:48:29–15:50:25.

The UC and Respondent then discussed the street price of oxycodone, during which UC stated that ''you can buy them on the street for [13] dollars,'' prompting Respondent to state: ''[n]o, [y]ou can't buy them on the street for [13] dollars'' and that the price was ''at least double'' or ''triple.'' GE 9, at 14–15; GE 5, V–0003, at 15:50:25–15:50:53.

The UC explained that he knew that oxycodone was ''going for a lot of money up in Tennessee and places like that'' and that ''it's just crazy when you spend over a thousand dollars for a prescription''; Respondent stated: ''but they'll fill the Roxicodone. I mean, I'm just flabbergasted.'' GE 9, at 15. After the UC stated that he was also ''taken back by that,'' Respondent stated: ''[t]his is gonna be [140] for the pain. . . . How can a pharmacist . . . they'll fill the oxycodone . . . but they, I promise you there was another reason why that wouldn't fill it. There had to be another reason.'' *Id.* The UC told Respondent that ''it was a name of a pharmacy they gave me here,'' and after the UC reminded Respondent that the pharmacist had said that she did not ''feel comfortable filling this drug,'' Respondent stated that that was ''a cover.'' *Id.;* GE 5, V–0003, at 15:50:53–15:51:54.

Respondent then told the UC that she was giving him ''two small'' ''non-narcotic'' prescriptions for ''twenty-eight'' ibuprofen ''for each pharmacy that you might have to go to.'' GE 9, at 15–16. She then told Respondent that ''there's nothing to say if you went back to the same pharmacy . . . that another pharmacist wouldn't even bat an eyelash . . . because there's nothing to bat an eyelash over.'' *Id.* at 16; GE 5, V–0003, at 15:51:54–15:52:50.

Respondent then prepared on a computer prescriptions for 140 oxycodone 30 (''for pain'') and 28 Klonopin 1 mg (''for anxiety''), telling him to ''hold onto the Klonopin. If they won't fill it just take it.'' GE 9, at 16; *see also* GE 25, at 5. She also told the UC that ''I want you to keep the extra ibuprofen so if they won't fill the Klonopin again . . . you have another non-narcotic to use,'' and asked the UC: ''[m]ake sense?'' GE 9, at 17. The UC stated that ''it does make sense,'' and after an exchange of pleasantries, Respondent personally handed the UC one of the ibuprofen prescriptions and the visit with Respondent ended. *Id.;* GE 5, V–0003, at 15;52:50–15:53:45. Subsequently, a medical assistant handed the other prescriptions to the UC as well as an appointment card for his next visit. GX 25, at 5.

In addition to the oxycodone and Klonopin prescriptions, Respondent provided the UC with a prescription for 28 Flexeril 10 mg ''for muscle spasm,'' and two prescriptions for 28 ibuprofen 400 mg. GE 10, at 1–5; *see also* GE 11; at 23 (July 16, 2012 Encounter Summary). Of note, the oxycodone prescription lists five different diagnoses: ''Insomnia due to Medical Condition,'' ''Chronic Pain Syndrome,'' ''Lumbar Disc Displacement Without Myelopa,'' ''Lumbar or Lumbosacral Disc Degeneration,'' and ''Lumbago.'' GE 10, at 1.

In the UC's patient file for the July 16, 2012 visit, Respondent noted the lower back as the location of UC's pain, that the duration of his pain was three years, and checked the box indicating that his pain was ''severe.''' GE 11, at 25. As for the precipitating event, Respondent checked the box for ''unknown'' and wrote '''work-stunt man.'' *Id.* As to the character of his pain, she placed checkmarks next to ''throbbing'' and ''sharp''; she also made markings indicating that ''anxiety'' and ''insomnia'' were comorbidities. *Id.*

Respondent wrote the word ''meds'' to indicate his ''previous pain

[8] Respondent asked the UC to stand up and bend at 15:45:36 of the video.

management treatment.'' *Id.*[9] She also noted that ''off meds'' his pain was a ''5'' on a ''0–10'' scale, and ''on meds,'' his pain was ''0.'' *Id.* As to what made the UC's pain worse, Respondent checked ''lifting,'' ''bending,'' ''sitting, standing in one position too long,'' and ''other,'' after which she wrote ''working out.'' *Id.* She noted that only meds made his pain better. *Id.* She indicated that the pain affected the UC's sleep, mood, work (writing the word ''most''), daily activities, energy, and relationships, and that his quality of life off medications was worse (as opposed to better) and that his quality of life was worse ''off medications'' and was better ''on medications.'' *Id.* She noted that the UC's past medical and surgery record had not been received, and under ''social history,'' she circled ''none'' for no history of ''Etoh'' (alcohol use), ''smoke'' and ''drugs.'' *Id.* She also drew a single dash in the space for urine drug screen results, and indicated his past imaging studies included an MRI. *Id.*

On the second page, Respondent checked ''All negative'' for her review of the UC's systems. *Id.* at 26. As for the physical exam, Respondent either drew a circle or scribbled around various words to indicate that various portions of the purported exam were normal.[10] *Id.* Respondent also documented that she had performed a neurological exam which included testing the UC's cranial nerves, a sensory exam, a deep tendon reflex test of both the upper and lower extremities, and a muscle strength test of both his ''upper'' and ''lower,'' each of which she found to be normal. *Id.* Respondent also made various entries indicating that she had performed various orthopedic tests, including a straight leg raise on his right leg which provided a positive result, a Kemps test of the UC's lumbar region which was also positive, as well as several other tests, none of which are corroborated by the video. *Id.; see also* GE 5, V–0002, at 15:32:50–15:36:21 and V–0003, at 15:36:30–15:54. This page also includes four diagrams of the human body including a posterior view, which appears to have the letter ''T'' for ''Tenderness'' drawn over the lower back and buttocks. GE 11, at 26.

The form's third page includes Respondent's ''Assessment.'' *Id.* at 27. Therein, Respondent placed a check mark next on the line which states ''Patient not satisfied, request change,'' wherein she handwrote ''still ↑ pain on 4 q day—stuntman.'' *Id.* Respondent also placed a check mark on the line for ''Patient will take meds as prescribed and reports *no* side effect'' as well as the line for ''Patient will take meds as prescribed and reports these side effects.'' *Id.* Respondent also placed a checkmark next to the line for ''Activities of living quality are improved with medication.'' *Id.*

In the Diagnosis section, Respondent checked ''Anxiety,'' ''Disc Bulge,'' ''Muscle Spasms,'' ''Chronic Non-Malignant Pain Syndrome'' and ''Other,'' after which she handwrote what appears as ''post. Bulge c torn annulus + bilat foraminal encroachment.'' *Id.* And in the section for her ''Plan,'' she made a checkmark next to ''Referral: Ortho, Neuro, Psych, Sloan Center/Mr. Brown, CAP.'' *Id.* She also indicated a negative ''Tox screen'' and negative ''Chemistry screen''; however, neither test was done at this visit. *Id.* Finally, she placed check marks next to the entries for ''Wt loss, smoking cessation, reduce salt and caffeine'' and ''Goal to relieve 80% of pain, accomplished.'' *Id.*[11] *Id.*

As with the form used at the previous visit, page 3 lists both controlled and non-controlled medications with specific dosage quantities and quantities. As before, the only narcotic listed is Roxicodone 30 mg with four different quantities: 84, 112, 140 and 168. Consistent with the prescriptions she issued, Respondent checked ''Roxicodone 30 mg and circled ''#140,'' as well as Klonopin and circled both ''1 mg'' and ''#28.'' *Id.* She also checked Flexeril and Ibuprofen 400mg. *Id.*

The Expert's Review of Respondent's Prescribings to the UC

Dr. Hoch, the Government's Expert, reviewed the medical files, transcripts and recordings of the UC's two visits with Respondent. Based on his review, the Expert found that Respondent ''failed to establish a sufficient doctor/patient relationship with [UC] and that the prescribing of controlled substances was outside the usual course of professional practice and for other than a legitimate medical purpose.'' GE 24, at 3. The Expert provided extensive reasons for his conclusion.

First, the Expert explained that ''[t]he documented record fails to show that [Respondent] conducted an adequate evaluation of the [UC]'' in that ''a complete medical history was not taken.'' *Id.* According to the Expert, the records lack sufficient documentation ''to show that [Respondent] made a serious inquiry into the cause of [UC's] pain.'' *Id.* The Expert further explained that ''[i]n a valid doctor/patient relationship, a physician must inquire into whether the pain is the result of an injury or another disease process. That was not sufficiently done. All [Respondent] did was determine that [UC] was a stunt performer and had not been in a car accident.'' *Id.* at 3.

The Expert also found that while the UC ''stated that he had seen as many as six other doctors for his pain'' and ''signed a release authorizing [PB] to obtain and review his prior medical records,'' there are no records from physicians who treated the UC prior to his going to PBM. *Id.* According to the Expert, ''[i]n completing a sufficient medical history, it is important to review the records of other physicians who have treated the patient.'' *Id.*

The Expert further found that Respondent ''failed to conduct an adequate physical examination of'' the UC. *Id.* According to the Expert, during both physical exams, the UC ''failed to demonstrate pain sufficient to justify the repeated prescribing of controlled substances, especially strong opioid medications such as thirty milligram tablets of oxycodone.'' *Id.* The Expert specifically faulted Respondent for determining that the UC ''suffered from muscle spasms without any evidence,'' as well as for concluding that ''he suffered from anxiety without any inquiry into his mental state or sleeping habits,'' and when, ''[i]n fact, [he] never disclosed that he suffered from anxiety.'' *Id.* at 3–4. The Expert then observed that ''Respondent noted 'anxiety' in the medical record and issued prescriptions for clonazepam which specifically stated they were being issued to treat anxiety.'' *Id.*

The Expert also faulted Respondent for having increased the quantity of the UC's oxycodone prescription from 112 to 140 dosage units at the July 16, 2012 visit. *Id.* at 4. As the Expert found, Respondent ''increased the amount of oxycodone she prescribed without any medical justification, falsely writing that [UC's] pain had increased, when, in fact, [UC] initially rated his untreated pain as a '2' and changed the rating only after being prompted.'' *Id.*

[9] Respondent drew relatively straight lines in the spaces next to the words ''Surgery,'' ''PT,'' and ''Injections.'' GE 11, at 25.

[10] Specifically, for ''Heent,'' she circled ''inspection''; for ''Chest,'' she drew scribble around ''clear''; for ''Cor,'' she scribbled around ''rrr''; for ''Abd,'' she scribbled over ''soft''; for ''ext,'' she scribble over ''nontender''; and for ''Psych,'' she circled ''Ox3.''

[11] The plan section also included entries for ''[i]f any problems develop, go to ER for any emergency,'' ''[y]oga, stretching, swimming or other cardiovascular exercises suggested,'' ''[f]ish oil recommended at 3–6 grams per day/glucosamine and Chondroitin Sulfate recommended,'' and ''[d]iscussed informed consent, risks/benefits of given medications, alternative therapies; pt understands.'' GE 11, at 27. Next to each of these Respondent made stray marks, the intent of which cannot be determined.

Next, the Expert faulted Respondent because she ''also failed to determine and/or document the effect of pain on the [UC's] physical and psychological function.'' *Id.* The Expert further noted that ''[t]here is no documentation in the record to show that [Respondent] made any attempt to adequately address this important standard of pain management'' and that she ''appeared to coach [the UC] into stating that the pain affected his 'work' after he repeatedly states he was seeking narcotics to recover from muscle soreness due to exercising.'' *Id.*

The Expert also found that Respondent ''failed to create and/or document a sufficient treatment plan.'' *Id.* The Expert explained that despite UC's history of treatment at PBM and receipt of ''prescriptions for controlled substances on prior occasions, [Respondent] recommended no further diagnostic evaluations or other therapies.'' *Id.* The Expert then observed that the UC's ''MRI . . . failed to demonstrate serious enough pathology for him to receive the large amounts of controlled substances that were prescribed.'' *Id.* The Expert further explained that ''[b]ulging discs can usually be addressed by other means such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, injections such as nerve blocks with corticosteroids,'' but that ''[n]one of these options was offered or discussed by'' Respondent. *Id.* The Expert then opined that ''[i]gnoring these options constitutes an inferior, if not non-existent, treatment plan.'' *Id.*

The Expert also concluded that his review of the transcripts and recordings of UC's visits with Respondent ''indicates that [Respondent] herself doubted there was a legitimate medical need to prescribe the large amounts of opioid medications that were prescribed.'' *Id.* The Expert specifically noted that ''[i]nitially, on May 31, 2012, [Respondent] stated that [the UC's] MRI showed 'nothing too terrible,'' adding that 'a bulge kind of doesn't mean anything' and that she would not 'give narcotics for spasms.' '' *Id.* (citing GE 7, at 4–5). The Expert also observed that ''[o]n the second visit, [Respondent] said she 'certainly wouldn't just give pain medicines and narcotics so [his] working out is better.' '' *Id.* (quoting GE 9, at 5).

The Expert further noted that Respondent ''never inquired as to the treatment UC may have received prior to coming to [PBM][,] [n]or did she discuss any non-narcotic treatment [he] may have received from any other doctor at PBM.'' *Id.* Based on his ''review of the medical records, transcripts and recordings'' of UC's two visits with Respondent, the Expert opined that: ''there was serious doubt as to whether treatment goals were being achieved. Yet there was no attempt by [Respondent] to evaluate the appropriateness of continued treatment except to increase the amount of narcotics and create a means by which [the UC] could fill his prescriptions without raising the legitimate concerns of pharmacists.'' *Id.* In the Expert's opinion, ''this shows there was an insufficient review of the course of treatment and the prescriptions provided by [Respondent] to [the UC were] inconsistent with [Respondent's] evaluation.'' *Id.* at 4–5.

Next, the Expert concluded that Respondent ''failed to sufficiently monitor [the UC's] compliance in medication usage.'' *Id.* at 5. The Expert noted that Respondent ''was well aware that [the UC] had run out of medication, and had illegally obtained both oxycodone and alprazolam from one or more friends.'' *Id.* The Expert noted that Respondent nonetheless ''increased the amount of oxycodone from 112 tablets to 140 tablets solely because of concerns that [the UC] might not return within 28 days, not because of any increase in pain.'' *Id.* (comparing GE 9, at 13 (discussing the two-week delay in appointment ''you need it two weeks ahead of time . . . alright let's go to one forty'') with GE 11, at 27 (medical record showing UC's pain increased despite taking four tablets a day)).

The Expert also found that Respondent ''ignored the numerous inconsistencies in the records which constitute red flags for abuse and/or diversion.'' *Id.* As support for this finding, the Expert noted that the medical record for July 16, 2012 indicates that the UC's pain affected his sleep, mood, work, daily activities, energy, and relationships, yet during the actual consultation, UC initially said the pain affected only his ''recovery time from working out.'' *Id.* However, when Respondent told the UC that this would not justify prescribing narcotics, the UC changed his answer to ''work'' and provided this answer in response to the questions of whether the pain affected his sleep and relationships. *Id.* (citing GE 11, at 5–6).

The Expert also noted that at the July 16, 2012 visit, the UC initially stated that his pain ''level was 'two' without medication,'' but when prompted by Respondent, he ''changed it to 'four or five.' '' *Id.* (citing GE 9, at 4–5). Moreover, the Expert noted that ''the medical record for that date shows a pain level of 1–2 [on the patient follow-up sheet], and a pain level of 5'' on the form signed by Respondent. *Id.* (citing GE 11, at 29 and 25). The Expert also noted that the form signed by Respondent documents that the UC's pain [was] made worse by ''sitting, standing in one position too long,'' but there is nothing on the record to indicate that he made such a claim. *Id.* (citing GE 11, at 29). The Expert thus opined that, at a minimum, Respondent ''should have had a discussion with [the UC] about his need for more medication, and made specific inquiries to determine if and how [his] pain had increased,'' given that the UC ''demonstrated that he was at risk for misusing his medications.'' *Id.*

Next, the Government's Expert opined that ''there was no legitimate medical justification for the amount of oxycodone prescribed to'' the UC by Respondent. *Id.* As support for his opinion, the Expert noted that ''prior to his first visit with [Respondent], [the UC] had not been seen by a [PBM] physician since January 18, 2012,'' and therefore, ''he was, in all likelihood, opiate naïve on May 31, 2012.'' *Id.* The Expert then explained that ''[p]rescribing 112 thirty milligram tablets of oxycodone in this situation was without medical justification and dangerous.'' *Id.*

The Expert also found that ''there was no justification for increasing the amount [on] July 16, 2012.'' *Id.* As Expert explained, although the UC ''indicated he ran out of medication because he was two weeks late for his second appointment with [Respondent], there was no indication that he would be late again. Also, there was no notation in the file to prevent UC from returning in 28 days and receiving another prescription identical to the one received on July 16, 2012.'' *Id.* The Expert thus found that Respondent ''failed to inquire into, or otherwise determine, whether there was a legitimate medical need for the additional medication.'' *Id.* She also ''failed to adjust the quantity and frequency of the dose of oxycodone according to the intensity and duration of the pain and failed to justify the additional prescription on clear documentation of unrelieved pain.'' *Id.*

The Expert further opined that ''there was no legitimate medical justification for prescribing clonazepam, a benzodiazepine utilized to treat anxiety and, in some cases, sleep disorders.'' *Id.* The Expert specifically found that Respondent ''made no attempt to a[ss]ess [the UC's] mental state or his sleeping habits.'' *Id.* at 5–6. The Expert noted that during the UC's first visit with Respondent, he ''provided no

information about these conditions except to say he 'used to take a little bit of Xanax to sleep, but [that he could] probably work without it.' '' *Id.* at 6. The Expert also observed that when the UC was asked during his second visit if ''his pain affected his sleep, [he] said 'work.' '' *Id.* (citing GE 9, at 5). The Expert thus found that ''[t]he record is devoid of any medical evidence justifying the need for prescribing clonazepam.'' *Id.* The Expert also noted that because Respondent ''fail[ed] to retrieve or cancel'' the clonazepam prescription that she had given the UC at the May 31, 2012 visit, she enabled the UC ''to obtain twice the amount as directed . . . by providing a second prescription [to him] on July 16, 2012.'' *Id.*

The Expert's ultimate conclusion was that the controlled substance prescriptions Respondent provided to the UC ''were not justified given [the UC's] complaints and medical findings, and certainly not in the dosages or frequencies prescribed.'' *Id.* at 6. The Expert further opined that the controlled substance prescriptions Respondent issued to the UC ''lacked a legitimate medical purpose and were issued outside the usual course of professional practice.'' *Id.* at 15.

The Expert's Review of Other Patient Charts

D.G.

On November 2, 2010, D.G., who was then 32 years old and listed his residence as being in Niceville, Florida, which is nearly 600 miles from Pompano Beach, first went to PBM and was seen by Dr. Gabriel Sanchez. GE 17, at 5, 22. According to the intake forms, D.G.'s chief complaint was ''sharp, intermittent pain in neck & upper back'' which started in 1999. *Id.* at 5. D.G. reported that on ''a scale of 0–10,'' with ''0 being no pain and 10 being the worst possible pain,'' his pain with medication was ''4'' and his pain without medication was ''9,'' and that the ''inciting event[s] [were a] weightlifting accident, several car accidents.'' *Id.* at 5. He further reported that he had chiropractic procedures, and that he tried anti-inflammatories and anti-depressants, as well as oxycodone, Xanax, Vicodin and Percocet. *Id.* D.G. also noted that he had seen other doctors for his pain and that he thought he may have ''depression.'' *Id.* On another form, he checked that his symptoms ''in the past year'' included migraine headaches, loss of sleep, and neck and shoulder pain. *Id.* at 6.

D.G. also signed a Pain Management Agreement in which he agreed that the ''controlled substance prescribed must be from the physician whose signature appears on this agreement or in his/her absence, by the covering physician, unless specific authorization is obtained for an exception.'' *Id.* at 11. He also agreed that he would ''not attempt to obtain controlled medications, including opiate pain medications, controlled stimulants, or anxiety medication from any other doctor.'' *Id.* D.G. also signed two releases for the release of the information by which he authorized PBM to obtain a prescription profile from a pharmacy and diagnostic reports from a diagnostic center.[12] *Id.* at 18, 20. However, while D.G. indicated on the intake forms that he had seen other doctors for his pain, as well as that he had previously used anti-depressants, his file does not contain a release for a physician's treatment records. *See generally id.* Moreover, while it appears that PBM obtained D.G.'s MRI report on the date of his first visit, it did not obtain his prescription profile until July 6, 2011. *See id.* at 120–22.

D.G. was also subjected to a drug test at his first visit. *Id.* at 131. The test results were negative for all drugs. *Id.*

At D.G.'s first visit, Dr. Gabriel Sanchez[13] documented his findings on a one-page form including a diagnosis of chronic discogenic neck pain and issued him prescriptions for 150 Oxycodone 30 mg, 60 Oxycodone 15 mg, 60 Xanax 2 mg, 30 Motrin 800, and 30 Nortriptyline 25 mg. *Id.* at 128–30. One month later on December 2, 2010, D.G. returned to PBM, where Dr. Sanchez reissued each of the prescriptions. *Id.* at 124–26.

Thereafter, D.G. did not return to PBM until July 6, 2011. *Id.* at 117. While D.G. completed a Follow-Up Sheet on which he noted that his pain was ''always there,'' that it got ''worse when [he] move[d] in certain ways,'' that it affected multiple life activities and provided pain ratings both with and without medication, the two-page visit note is largely blank and contains no entries in the section of the form for documenting his prescriptions. *Id.* at 117–19. Nor does D.G.'s file contain copies of any prescriptions bearing the date of July 6, 2011. *See generally id.*

D.G.'s record shows that his next visit occurred on September 7, 2011, on which date he again noted on the Follow-Up sheet that his pain was ''always there,'' that it got ''worse when [he] moved in certain ways,'' checked various activities his ''pain affects,'' and rated his pain ''without medication'' as an 8, and ''with medication'' as between 3 and 4. *Id.* at 113. At the visit, D.G. was required to complete a form titled as ''MEDICAL DISCLOSURE (LAST 30 DAYS).'' *Id.* at 115. On the form, D.G. wrote ''N/A'' in both the space where he was to list ''Prescriptions [sic] meds from other physicians'' and ''Prescriptions [sic] medications from other source.'' *Id.*

Yet a Drug Screen Results Form indicates that D.G. tested positive for oxycodone at this visit. *Id.* at 116. Moreover, a form titled as ''Patient Compliance Instructions,'' which was signed by D.G. at this visit, states: ''All Patients Must Pass Their Initial and Random Urine Drug Screening Test!'' *Id.* at 114. However, notwithstanding the inconsistency between what D.G. reported on the Medical Disclosure Form and his positive oxycodone test, Dr. T.R. issued D.G. prescriptions for 140 Oxycodone 30, 25 Xanax 2 mg, 50 Mobic 7.5 mg, and 28 Nortriptyline 50 mg. *Id.* at 110–111.

Thereafter, D.G. went to PBM monthly where he saw Dr. T.R., who increased his oxycodone 30 prescription from 140 to 168 du (during his November 2, 2011 visit ''as per pt. request'') as well as 24 Xanax 2 mg, (along with Nortriptyline and Mobic), after which D.G. saw Dr. A.E., who also issued him prescriptions 168 du of oxycodone 30 and 24 Xanax 2 through March 22, 2012. *Id.* at 74–110.

On April 19, 2012, D.G. was treated by Respondent. On his ''Patients [sic] Follow-Up Sheet,'' he again reported that his pain was always there, that it was worse when he moved in certain ways, and that it affected his social activities, work, exercise, mobility and sleep. *Id.* at 61. He rated his pain ''with medication'' as a 3 and ''without medication'' as an 8. *Id.* He also indicated that he was satisfied with his current medication and would not like to change it. *Id.*

In the ''Pain History Follow Up'' section of the visit note, Respondent indicated that D.G. has severe neck pain which was throbbing, sharp, and tingling, that the pain's ''duration'' was 15 years, and wrote ''football'' as the precipitating event.[14] *Id.* at 65. She

[12] D.G.'s patient file includes an MRI report dated April 10, 2010 which showed degenerative changes at C5–6 and C6–7, mild kyphosis at C5–6, a bulging disc at C4–5 with no spinal stenosis, narrowing of the disc at C5–6 and C6–7 with herniated disc protrusions and mild bone spurs. GE 17, at 132–133. D.G.'s file also includes a patient profile from Santa Rosa Pharmacy covering the period of January 1, 2011 through July 6, 2011. *Id.* at 120–22.

[13] Dr. Sanchez's DEA registration was the subject of Show Cause proceedings and revoked effective October 25, 2013. *See Gabriel Sanchez,* 78 FR 59060 (2013).

[14] Respondent also drew a horizontal line (rather than a check mark) in the space for noting if the pain radiated. GE 17, at 65. It is unclear what this line was intended to document, if anything.

checked ''insomnia'' under co-morbidities, and noted that his pain level was 8 when ''off meds'' and 3 when ''on meds.'' *Id.* Under ''New Events Since Last Visit'' she wrote ''none—some ↑ pain at work.'' *Id.*

Under Review of Systems, she indicated that all were negative. *Id.* Under PE [Physical Exam], she made checkmarks suggesting that she had examined D.G.'s HEENT, Chest, Cor, Abd, and made scribbles next to Skin, Ext, Neuro/psych and Gait. *Id.* She added handwritten notes regarding the extent to which he could rotate his neck as well his range of motion for the extension and flexion of his neck, a notation ''Hand grip'' followed by an illegible word, and noted ''Lock Box discussed.'' *Id.*

On the second page of the note, Respondent placed check marks next to ''yes'' for various neurological exam items and made no notation that D.G. had any focal deficits. *Id.* at 64. In the orthopedic section, she indicated that she had done a straight leg raise test on both D.G.'s right and left legs with a negative result on each leg. *Id.*

In the section for her ''Assessment,'' Respondent placed a checkmark next to ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable.'' *Id.* She also placed a checkmark next to ''Patient taking meds as prescribed and no adverse side effects, no new problems and no new changes.'' And as for her ''Diagnosis,'' Respondent checked ''Cervicalgia,'' ''Disc Herniation C56/67,'' ''Hypertension'' and ''Chronic Non-Malignant Pain Syndrome.'' *Id.*

Under Plan, Respondent marked a series of marks next to each item on the list, to include ''wt. loss, smoking cessation, reduce salt and caffeine, F/U with PCP''; ''Refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed''; ''urine tox screen twice a year or as needed to monitor addiction/diversion''; ''Yoga, stretching exercises, Fish oil at 3–6 grams/day; Glucosamine/Chondroitin Sulfate as suggested''; ''Discussed informed consent, risks/benefits of given medications, alternate therapies; pt understands''; and ''Continue meds, patient understands importance of weaning meds to minimum effective dose.'' *Id.*

As with the UC's visit notes, Page 3 contained a list of medications at varying strengths and dosages, but only listed a single narcotic, that being Roxicodone 30 mg, next to which Respondent wrote a checkmark and circled ''#168'' (the maximum number listed). *Id.* at 63. She also placed a checkmark next to Xanax, circling ''2 mg'' and handwrote ''↓'' and ''#20'' (fewer than the listed choices of #28 or #56). *Id.* In addition, she placed a checkmark next to Amitriptyline, after which she wrote ''50'' and circled ''#28'' and wrote in Lisinopril under ''Other Meds.'' *Id.* Under Radiology, she wrote ''MRI Cervical,'' and under Consults she wrote: ''MS Contin 30 BID #56.'' *Id.* On the form she also added: ''Goal: Cont. working ↑ meds so He can cont his business.'' *Id.* She also wrote ''Labs next time'' and signed and dated the form. *Id.*

A computer-generated ''Encounter Summary'' lists diagnoses of ''Cervical Spinal Stenosis,'' ''Cervicalgia,'' and ''Chronic Pain Syndrome.'' *Id.* at 66. Under medications, it lists each of the drugs discussed above including 56 MS Contin 30 mg. *Id.* The Encounter Summary also lists a prescription for an ''mri no contrast C Spine DX: herniated disc.'' *Id.*

On May 17, 2012, D.G. returned to PBM and again saw Respondent. D.G. filled out his ''Patients [sic] Follow-Up Sheet'' answering each question exactly as before, including indicating his pain was a ''3'' with medication and an ''8'' without medication. *Id.* at 58.

Respondent filled out the Pain History Follow Up sheet, indicating that the neck was the location of D.G.'s pain, that it was severe, throbbing, and sharp, that it had been present for 15 years and precipitated by ''football.'' *Id.* at 55. She listed no new events since D.G.'s last visit. Also, she checked no co-morbidities and circled ''N'' for ''Psych visits/SS Disability.'' *Id.*

Under ROS, she noted that all findings were negative, and in the PE section, she made a series of scribbles over the various descriptors for normal findings for each exam item. *Id.* On the body diagram's posterior view, she circled the neck portion and wrote ''Rotation 80 R 90 L'' as well as ''Flex 45 Ext 10''; she also circled both elbows and noted ''Reflex +2='', and finally, she circled both hands and wrote ''no hand numbness good grip.'' *Id.*

In the neurological exam section, she checked ''Yes'' next to each of the items listed, and in the orthopedic section, she again noted a negative for both a right and left leg raise test. *Id.* at 56. In the Assessment section, she placed a check mark next to ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable'' and ''Activities of living, quality of life improved with medication.'' *Id.*[15]

Under Diagnosis, she again checked Cervicalgia, Disc Herniation ''C56/67,'' Hypertension and Chronic Non-Malignant Pain Syndrome. *Id.* However, in contrast to D.G.'s previous visit, she also placed check marks next to ''Anxiety'' and Insomnia.'' *Id.* Under Plan, she checked each item as at the previous visit, but circled ''F/U with PCP'' and noted ''HTN.'' *Id.* And below the Plan section, she handwrote ''*goal:* cont to be sales rep.'' *Id.*

On the page containing the list of medications, strengths and dosages, Respondent again checked the boxes for Roxicodone 30 (circling ''#168''), Xanax 2 mg (writing ''↓'' and ''#15''), and Amitriptyline #28, writing ''50'' for the drug strength. *Id.* at 57. She noted ''must get PCP to get BP evaluation [and] meds,'' ''MRI C-Cervical'' and ''MS Contin 30 BID #56,'' and added notes about Lisinopril. *Id.* She also wrote ''next mth. stop Xanax'' and ''Add Klonopin 1 mg BID #56'' at the bottom of the page below her signature and the date. *Id.* The Encounter Summary printout reflects the prescriptions listed. *Id.* at 54.

D.G.'s next appointment with Respondent was on June 14, 2012. *Id.* at 47. He reported no changes on the ''Patients [sic] Follow-Up Sheet,'' indicated that his pain level was 3 ''with medication'' and ''8'' ''without medication,'' and that he was satisfied with his current medication. *Id.* at 51.

Respondent filled out the revised Pain History form, with few differences from the previous visit, notably that D.G.'s ''Pain Scale off meds (0–10) [was] 10''; ''Pain Scale on meds (0–10) [was] 3.'' *Id.*at 47. She checked ''insomnia'' as a co-morbidity, and for the question ''[w]hat makes your pain better,'' she left blank ''lying, resting, stretching, exercise, heat, ice massage'' and checked ''other'' with ''meds'' handwritten next to it. *Id.* She also made a handwritten notation ''Has Lock Box!'' *Id.* On the line for what activities the pain affected, she place a checkmark next to sleep, a horizontal line next to mood, and short diagonal line next to work, energy, and relationships. *Id.* She also indicated that D.G.'s quality of life was worse ''off medications'' and better ''on medications.'' *Id.* Under ''Past Imaging/Studies,'' she circled ''MRI'' and noted ''4–10 see DX section.'' *Id.*

As at the previous visit, she checked ''all negative'' in the review of system, scribbled over various normal findings in the physical exam section, circled ''yes'' for each item in the neurological section, and indicated that various ''orthopedic'' tests were negative. *Id.* at 48. *S*he also noted that D.G.'s cervical range of motion was 45 degrees in flexion and 10 degrees in extension, and made findings as to D.G.'s ability to rotate his neck. *Id.*

[15] Respondent made no mark next to ''Patient taking meds as prescribed. . . .'' GE 17, at 56.

Under Assessment, Respondent checked the line for ''Patient Satisfied, understands how to take current medication and treatment plan.'' *Id* at 49. In the Diagnosis section, Respondent checked ''Anxiety,'' ''Cervicalgia,'' ''Disc Herniation,'' ''Hypertension,'' ''Insomnia,'' and ''Chronic Non-Malig Pain Syndrome.'' *Id.*

As for her plan, Respondent checked the line for ''PCP obtained/referred for following conditions'' after which she added: ''For HTN in Ft Walton Bch, Fl,'' below which she wrote: ''Pt will Bring copy of Doctors HTN Report Next Visit.'' *Id.* She also noted: ''Tox screen due 2 mths'' and ''Chemistry screen due now—pt will get,'' as well as checked several other line items. *Id.*

Respondent prescribed 168 Roxicodone 30 mg, 56 MS Contin 30 mg BID, discontinued the Xanax and added #56 Klonopin 1 mg.[16] *Id.* at 49; *see also id.* at 45–46 (copies of Rxs and Encounter Summary). On a form with the caption: ''Reason for Prescribing Over a 72 hour Quantity of Substance(s),'' Respondent made additional notations, including: ''CMP script—pt will do outside lab,'' ''UDS next 1–2 mth,'' ''C-Spine MRI with script given previously,'' ''Must see PCP for HTN Pt advised he must 1. Get labs 2. Bring copy of physician report on HTN or can *not* be seen next time.'' *Id.* at 50.

D.G.'s file contains a memo from the Clinic Director of the Hope Medical Clinic, a free clinic located in Destin, Florida, which was faxed to PBM on July 11, 2012, one day before D.G.'s next appointment. *Id.* at 42. The memo stated that D.G. ''has an appointment with us on September 20th where we will be able to begin his long term primary care for chronic illness. Our program is full until this date as our services are at no cost to patients.'' *Id.*

On July 12, 2012, D.G. returned to PBM and again saw Respondent. On the ''Patients [sic] Follow-Up Sheet,'' he again indicated that the pain was ''always there,'' that it affected his social activities, work, exercise, mobility, and sleep, that the pain was 3 ''with medication'' and 8 ''without medication,'' and that he was satisfied with his current medication. *Id.* at 40.

Respondent filled in the blanks in the Pain History section of the visit note, making the same notations as before, including that D.G.'s pain scale ''off meds'' was ''10'', but ''3'' with medication. *Id.* at 35. She again noted that a cervical MRI from ''4–10'' was the only imaging report. *Id.* Her examination notations on the remaining forms were nearly identical to those made at the previous visit. *See id.* at 37–38. Moreover, she checked the same diagnosis findings and the same items under her plan. *Id.* Respondent again prescribed 168 Roxicodone 30 mg, 56 Klonopin 1 mg, 56 MS Contin 30 mg BID, and Amitriptyline. *Id.* at 38; *see also id.* at 33, 36 (copies of prescriptions and Encounter Summary).

The Expert reviewed D.G.'s medical file, and concluded that the controlled substance prescriptions Respondent issued to D.G. between April 19, 2012 and July 12, 2012 were issued outside the usual course of professional practice. GE 24, at 13. The Expert set forth multiple reasons for his conclusion.[17]

First, he found that ''the medical history and physical examinations [were] inadequate and that it was not reasonable for Registrant to rely on the evaluations of other providers at'' PBM. *Id.* He further found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history of D.G.'' in that ''she relied on . . . superficial checklists which are insufficient for evaluating the types of complaints that D.G. communicated.'' *Id.*

The Expert also found that Respondent ''prescribed additional narcotics without any medical justification.'' *Id.* The Expert specifically noted that ''on April 19, 2012, she added a prescription for morphine sulfate, stating that . . . D.G. needed more medication in order to continue his restaurant business and that his pain had increased at work.'' *Id.* The Expert noted that that ''[t]his contradicts statements D.G. made that same day, in which he declared he was satisfied with his current medication.'' *Id.*

The Expert further found that D.G.'s ''records contain no evidence that [Respondent] addressed the effect of pain on D.G.'s physical and psychological function. The Expert further explained that ''the checklist is devoid of any explanation for how D.G.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* (citing GE 23, at 39–42, 49–52, 57–60, 62–63, 65–67).

The Expert similarly opined that Respondent's ''treatment plan was wholly inadequate and . . . consisted only of a checklist of recommendations.'' *Id.* The Expert noted that there is no evidence that any of the recommendations were either discussed or followed. *Id.* He also noted that while Respondent placed a checkmark suggesting that referrals to physical therapy and other specialist physicians were part of her plan for D.G., there is no evidence ''that any referrals were made.'' *Id.* at 13–14.

Finally, the Expert opined that Respondent ''ignored numerous 'red flags' for diversion.'' *Id.* at 14. More specifically, the Expert noted that while D.G. had signed PBM's pain management agreement, in which he agreed that he would not obtain controlled substances from any other doctor, the Santa Rosa Pharmacy printout showed that he had obtained both oxycodone and alprazolam in June 2011. GE 24, at 14. Indeed, the printout showed that he had obtained controlled substances from another physician, who was located in Lake Clark Shores (which is in Palm Beach County), on multiple occasions between his visit in December 2010 and July 2011. GE 17, at 122.

The Expert noted that on September 7, 2011, D.G. ''tested positive for oxycodone despite no evidence he had received a prescription after June 2011.'' GE 24, at 14. He also noted that ''[o]n that date, [D.G.] denied having seen other 'medicating prescribing pain doctors' and denied receiving any prescriptions from other physicians.'' *Id.*

Finally, the Expert noted that D.G. resided in Niceville, Florida, which is approximately 596 miles from PBM. *Id.* The Expert observed that ''there was no information in the medical records to explain why D.G. would travel such an extraordinarily long distance'' to receive medical care. *Id.* He then concluded that ''[t]hese red flags indicate . . . that Respondent failed to monitor D.G.'s compliance in medication usage and failed to give special attention to D.G., who was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion.'' *Id.* The Expert thus concluded that the controlled substance prescriptions Respondent issued to D.G. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Patient J.A.

On February 28, 2011, J.A., a resident of Plantation, Florida, was initially treated at PBM by Dr. Gabriel Sanchez. GE 18, at 132–33. At his first visit, his chief complaint was nerve damage to his back and neck which had started

[16] She also prescribed 28 Amitriptyline 50 mg.

[17] Earlier in his declaration, the Expert explained with respect to the individuals whose charts he reviewed, that Respondent ''provided them with prescriptions for controlled substances in contravention of the standards of care and practice in the State of Florida and with indifference to various indicators or 'red flags' that the patients were engaged in drug abuse and/or diversion.'' GE 24, at 6.

five years earlier. *Id.* at 4. J.A. wrote that the inciting event was ''burn + hit with pot in back,'' and that his pain was an 8 ''with medication'' and a 10 ''without medication.'' *Id.* He also reported he had had chiropractic procedures and trigger point injections, that he had tried anti-inflammatories and Gabapentin, as well as oxycodone, methadone, Xanax and Vicodin. *Id.* He also indicated that he had seen other doctors for his pain. *Id.*

J.A. also signed two releases for medical records. *Id.* at 19–20. However, while an MRI was faxed to PBM, and that MRI report even lists the name of the referring physician, J.A.'s file contains no records from that physician or any other physician who treated him. *Id.* at 135; see *generally* GE 18.

J.A. presented an MRI report for his lumbar spine (which was done two months earlier) which showed ''[m]inimal central bulges L4–5 and L5–S1 without nerve root compressions'' and ''[m]inimal facet and ligamentum flavum hypertrophy at the same 2 levels.'' *Id.* at 135. He was also subjected to a urine drug test. *Id.* at 134.

According to the initial evaluation form, during the neurological exam, J.A. had a positive Spurlings test bilaterally and a positive straight leg raise test bilaterally. *Id.* at 133. Dr. Sanchez also documented range of motion findings for both J.A.'s cervical and lumbar spine, as well as that J.A. had chronic mid-back and neck pain for 8 years and that his MRI showed disc bulges at L4–S1. *Id.* The only other exam findings were that J.A.'s lungs were ''clear'' and his extremities were ''N.'' *Id.*

Dr. Sanchez listed his diagnosis as ''Chronic Discogenic Mid Back and Neck Pain.'' *Id.* He prescribed to J.A.: 150 Oxycodone 30 mg, 60 Methadone 10 mg, 60 Xanax 2 mg, as well as 30 Ibuprofen 800 mg, and 30 Nortryptyline 25 mg. *Id.* at 131–33. Other notations on the evaluation note state: ''Recommend Orthopedic evaluation,'' ''Needs blood work'' and ''Needs MRI Thoracic.'' *Id.* at 133.

J.A. was seen monthly at PBM by Dr. Sanchez and other physicians through July 2011, and again on October 24, 2011. *Id.* at 98–130. At his March 29, 2011 visit, J.A. reported that his pain relief was an ''8–10/10'' and Dr. Sanchez reissued the same set of prescriptions. *Id.* at 125–27. At his April 25, 2011 visit, J.A. reported that his pain with medication was a 4; Sanchez again issued the same set of prescriptions. *Id.* at 121–22.

Yet at his May 26, 2011 visit, J.A. reported that his pain level was a 10 ''with medication'' and either 6 or 8 ''without medication.'' [18] A different doctor saw J.A., noting that he was at the clinic for a follow up of chronic ''lower back'' pain but also noting under his Physical Exam findings that J.A. was ''in no acute distress.'' *Id.* at 113. While this physician prescribed 150 oxycodone 30, he also reduced the quantity of J.A.'s methadone prescription to 28 dosage units and his Xanax prescription to 28 one (1) mg. dosage units. *Id.*

On June 23, 2011, J.A. was seen by still another doctor, who noted that he complained of ''constant pain upper thoracic spine'' and that his pain level was ''9/10.'' *Id.* at 109. The doctor noted that J.A. had said that he had gone for an MRI of the thoracic spine but that the MRI was not in the chart. *Id.* As for his PE findings, the doctor noted: ''neck limited motion []flexion'' and ''[t]enderness over most of [t]horacic [s]pine.'' *Id.* The doctor issued J.A. prescriptions for 140 oxycodone 30 mg and 28 Xanax 1 mg, while discontinuing the methadone. *Id.* at 107–09.

J.A. returned to PBM on July 21, 2011, this time listing his pain as an 8 ''with medication'' and a ''10'' without medication. *Id.* at 103. The examining physician documented that J.A.'s pain radiated ''down the back'' and was ''constant [and] aching.'' He also drew diagonal lines next to ''Physical Therapy'' and ''Chiro.'' *Id.* at 103. As for his ''Pertinent Physical Findings,'' he listed ''L/S F30 E10,'' ''Rotational ROM Fair,'' ''Head/Toe—wnl''; it also appears that he documented a positive finding on the ''SLR,'' although a portion of the entry is illegible. *Id.* at 104. The physician listed his diagnoses as ''chronic Discogenic LBP'' and ''Lumber Facet Syndrome.'' *Id.* The physician issued J.A. a prescription for 160 oxycodone 30. *Id.* He also resumed prescribing methadone 10 (28 dosage units) and doubled the strength of the Xanax prescription to 2 mg dosage units. *Id.*

J.A. did not return to PBM until October 24, 2011, three months later, when he was seen by Dr. T.R. *Id.* at 95. On the ''Patients [sic] Follow Up Sheet,'' J.A. indicated that his pain was 6 ''with medication'' and 10 ''without medication.'' *Id.* at 100. However, he did not indicate that the pain affected any life activities. *Id.* He was also subjected to a drug test, which was positive for opiates/morphine, methadone and oxycodone, *id.* at 43, even though he had not been at the clinic in three months and denied seeing other pain physicians who prescribed medication. *Id.* at 98.

Dr. T.R. noted his ''pertinent physical exam'' findings as ''H/T N,'' ''SLR—thigh pain,'' and the ''L/S ROM'' was ''F 60'' and ''E 20.'' *Id.* at 99. He listed his first diagnosis as ''Chronic Multifactorial LBP'' and listed the factors as ''Discogenic'' and ''Lumber Facet Syndrome''; he listed his second diagnosis as Insomnia. *Id.* Dr. T.R. issued J.A. prescriptions for 154 du of oxycodone 30 and 24 du of Xanax 2 mg, as well as Gabapentin and Mobic (meloxicam). *Id., see also id.* at 95.

On November 21, 2011, J.A. returned to PBM and saw Respondent for the first time. *Id.* at 93. A ''Patients [sic] Follow-Up Sheet'' in the record appears to have been completed by J.A. for that visit; it is, however, dated ''5/17/63'', which, according to the copy of J.A.'s Florida Identification Card in his patient file, is his date of birth. *Id.* at 96, *see also id.* at 22, 23. J.A. circled the upper back/thoracic spine as the area where he felt pain, but did not answer the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.* at 96. He further indicated that his pain level was a 7 ''with medication'' and 10 ''without medication'' but left unanswered the remaining question whether ''the pain affected [sic] any of the following: Social Activities, Work, Exercise, Mobility, Appetite and Sleep.'' *Id.* at 96. J.A. also signed a Patient Compliance Instruction form regarding drug testing, proper use of medication, prohibitions against self-medicating, and zero tolerance for doctor shopping, trafficking, selling and distributing medications. *Id.* at 97.

Respondent completed a ''Pain History Follow Up'' where she indicated that the location of J.A.'s pain was his lower back. *Id.* at 93. She also circled the word ''radiation'' but then wrote ''none''; she also placed checkmarks indicating that his pain was severe and throbbing, and sharp, and that he had experienced the pain since 2001 when he suffered an accident noted as ''burn, chef-pot hit him.'' *Id.* Under ''Co-morbidities,'' Respondent checked ''anxiety'' and ''insomnia.'' *Id.* She noted that J.A.'s ''Pain Scale off meds (0–10)'' was ''9–10'' and that his ''Pain Scale on meds (0–10)'' was ''5–6.'' *Id.*

A handwritten note ''10–24 UDS + opi + mtd + oxy'' also appears on this form. *Id.* Under ''ROS,'' Respondent checked ''all negative unless checked,'' and for the various items listed under ''PE,'' she placed checkmarks or scribbled on the line next to normal findings. *Id.*

On the view of body diagram, Respondent circled the back of the neck

[18] As to the different ratings, on the numeric pain scale J.A. circled ''8'' and on the ''Faces Pain Rating Scale'' he circled ''6.'' GE 18, at 114.

and noted ''full ROM''; she also circled the entire back and wrote ''no obvious scars or defects,'' as well as the lower back, writing ''ROM WNL.'' *Id.* She also circled the back of the knees, but made no note, and off to the side of the diagram, she wrote: ''Risks discussed Sills.'' *Id.*

In the Neurological section, she filled in the ''Yes'' line for all neurological exam items indicating that there were no focal deficits, and in the Orthopedic Section, she indicated that she did a straight leg raise test which was negative for both legs. *Id.* And at the bottom of the form, she wrote ''old records show 10 yr ago 1° burn face & neck 2° back.'' *Id.* J.A.'s patient file includes records from the Emergency Department of the SUNY Stony Brook University Hospital from May 2001 corroborating that he was treated for burns in the upper back and posterior neck region. *Id.* at 90–92. Those records show, however, that J.A. was treated and discharged within three hours. *Id.* at 88, 92.

On the second page of the form for this visit, Respondent handwrote ''no'' next to the statement: ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable.'' *Id.* at 94. She then put a checkmark next to each additional Assessment line entry, including ''Patient taking meds as prescribed . . . no adverse side effects, no new problems and no changes,'' ''Activities of living, quality of life improved with medication,'' as well as those regarding the denial of drug charges or arrests, medication storage and safety issues including lock box usage, and that the ''diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.'' *Id.*

Under the Diagnosis section, Respondent checked ''Disc Bulge'' and handwrote ''L45/L5S1,'' as well as checked ''Insomnia,'' ''Chronic Non-Malignant Pain Syndrome'' and handwrote ''Ligamentum flavum,'' ''Neuropathic pain?'' and ''Facet Hypertrophy.'' *Id.* She checked off all ''discussion points'' under the Plan, and circled ''neurologist'' on the line stating: ''refer to PT, neurologist, neurosurgeon, psychiatrist, addiction specialist as needed.'' *Id.* She also handwrote ''Labs next visit'' and ''work—[?] w/o pain.'' *Id.*

In the section for listing medications and other recommendations, she checked ''Roxicodone 30 mg,'' circled ''#140'' and handwrote ''wean next visit''; she also checked ''Xanax'' and circled ''1 mg'' and ''#28'' and handwrote ''wean ↓.'' *Id.* She checked ''Gabapentin,'' circled ''300 mg,'' handwrote ''BID'' and circled ''#168,'' and under other meds, she added ''Mobic 7.5 qd.'' *Id.* Finally, under ''Radiology,'' she wrote ''MRI c-spine'' and under ''Consults,'' she wrote ''neurology.'' *Id.* The Encounter Summary for this visit reflects that Respondent wrote J.A. prescriptions for 140 Roxicodone 30 mg ''for pain,'' 28 Xanax 1 mg ''for anxiety,'' as well as for 168 Gabapentin 300 mg and 28 Mobic 7.5 mg. *Id.* at 89.

Respondent next saw J.A. on December 19, 2011. *Id.* at 86. On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled his upper back and thoracic spine, answered ''yes'' to the questions: ''[i]s the pain always there?'' and ''[d]oes the pain get worse when you move in certain ways?'' *Id.* J.A. did not, however, circle any life activities that his ''pain affected.'' *Id.* J.A. rated his pain as a 6 ''with medication'' and a 10 ''without medication.'' *Id.*

Respondent filled out the Pain History Follow Up form indicating that J.A. complained of severe lower back pain with no radiation due to burns from the 2001 incident. *Id.* at 84. She also indicated that J.A.'s pain was ''throbbing'' and ''sharp'' and checked ''insomnia'' as a co-morbidity. *Id.* She indicated that J.A. had not seen another pain management doctor in the past 28 days, that his quality of life was worse ''Off medications'' and better ''On medications,'' and that he had been ''working more hours'' since his last visit. *Id.* at 84. Moreover, she noted that his pain scale ''off meds'' was ''9–10'' and ''on meds'' was 7–8. *Id.*

In the ROS (Review of Systems) section, Respondent checked the line indicating ''all negative,'' and in the ''PE'' section, she checked the box for normal findings for every item except ''Ext,'' which she left blank. *Id.* On the posterior view of the body, Respondent circled the neck (next to which she wrote ''Rom'' followed by undecipherable scribble), the lower back (next to which she wrote ''Ext 10 Flex 90'') and knees (next to which she wrote ''Reflexes' followed by more scribble); off to the side of the diagram she wrote ''Risks discussed.'' *Id.* Finally, Respondent checked ''yes'' for each of the items listed under ''Neurological,'' thus indicating that there were no focal deficits, and indicated that she did a straight leg raise test which was negative on both legs. *Id.*

On Respondent's Assessment checklist, she checked all options, including ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable'' and ''Activities of living, quality of life improved with medication.'' *Id.* at 85. Under Diagnosis, Respondent checked ''Cervicalgia,'' ''Disc Bulge'' and wrote ''L45/L51,'' ''Insomnia,'' ''Chronic Non-Malignant Pain Syndrome,'' and under ''Other, '' she added ''Ligamentum Flavum,'' ''Needs neuro consult,'' ''Ligamentum [illegible] hypertrophy,'' and ''Facet Hypertrophy.'' *Id.*

Under Plan, she again checked ''refer to PT, neurologist, neurosurgeon . . . as needed, circling ''neurologist.'' *Id.* She also placed checks marks next to multiple items, including ''urine tox screen twice a year or as needed to monitor addiction/diversion.'' *Id.* She also wrote ''next time LABS,'' ''Plan on *wean next* visit,'' ''Couldn't get MRI—cspine → will get after holiday.'' *Id.* On the line for consults, she wrote ''neurology after 1–1–12'' and ''Pt. advised if no MRI + neuro consult by Feb—2011 cannot cont meds.'' *Id.*

As for the prescriptions, Respondent circled ''Roxicodone 30 mg'' and ''#140,'' ''Xanax,'' ''1mg'' and ''#28, after which she wrote ''wean more next visit.'' *Id.* She also circled Gabapentin, and noted ''Mobic 7.5 #35'' under ''Other Meds.'' *Id.* The Encounter Summary for this visit reflects that she issued these four prescriptions to J.A. *Id.* at 82.

On January 16, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 75. He again completed the ''Patients [sic] Follow-Up Sheet'' exactly as he did as at the previous visit, circling the upper back/thoracic spine on the body diagram, did not circle any life activities that were affected by his pain, and circled 6 for his pain ''with medication'' and 10 for ''without medication.'' *Id.* at 80.

Respondent filled in the Pain History Section, on which she again indicated that J.A.'s pain was in his lower back, that it was severe, throbbing, and sharp, but did not radiate. *Id.* at 76. She checked insomnia as a co-morbidity. *Id.* And under ''New Events since Last Visit,'' she noted: ''Lost Xanax & Gabapentin script.'' *Id.*

In the ROS section, she again noted that all systems were negative, and in the PE section, she drew either checkmarks or lines next to the normal findings for each of the various items. *Id.* And next to one of the body diagrams, she circled the neck (noting ''rotation 45,'' ''Flex 45''and ''Ext 5,''), the lower back (noting ''Ext 10'' and Flex 90''), and knees (noting ''Reflexes +2''); she also noted ''Risks discussed.'' *Id.* In the Neurological section, she checked yes for each item indicating that they were normal, and in the Orthopedic section, she indicated that the straight leg raise test was negative for each leg. *Id.* at 77.

In the Assessment section, she again made checkmarks next to each of the various items including that the patient was ''doing well on current medication and treatment plan'' and that the ''Activities of living, quality of life improved with medication.'' *Id.* Under Diagnosis, she checked ''Cervicalgia,'' ''Disc Bulge'' writing ''L4/5L5S1,'' ''Insomnia,'' ''Chronic Non_malig Pain Syndrome,'' and ''Other,'' after which she wrote ''Ligamentum Flavum Hypertrophy,'' ''neuropath,'' and ''old burns on back.'' *Id.*

Under Plan, Respondent placed markings next to all but one of the line items and again circled ''neurologist'' in the line item regarding referrals.[19] She also handwrote: ''PLAN ↓ pain to cont work'' at the bottom of the page. *Id.* at 77.

As for the prescriptions, Respondent checked: ''Roxicodone'' and circled ''30 mg'' and ''#140.'' *Id.* at 78. Next to the entry for Xanax, she wrote ''last Xanax 2 days''; she also checked Xanax, next to which she wrote ''.5,'' circled ''#28,'' and wrote ''weaning.'' *Id.* Respondent noted that she was prescribing Gabapentin and Mobic 7.5 as before. *Id.* She further wrote: ''needs neuro consult,'' ''getting MRI c-spine,'' and ''Pt advised again if no MRI by Feb no more meds!!'' and circled ''Pt. advised again.'' *Id.* The Encounter Summary for the visit reflects the prescriptions for 140 Roxicodone 30 mg and 28 Xanax .5 mg, as well as the non-controlled medications. *Id.* at 75. The file also includes a Referral form signed by Respondent for an MRI on J.A.'s cervical spine. *Id.* at 83.

J.A.'s file contains a report (dated February 8, 2012) for an MRI on his cervical spine. *Id.* at 117. The report lists the following findings: a midline bulge at the C3–C4 disc ''without neuroforaminal narrowing,'' a minimal disc bulge at the C4–C5, a disc bulge at C5–C6 ''without neuroforaminal narrowing or central spinal canal stenosis,'' an ''irregularity of the endplates, anterior marginal osteophytes and a posterior bulge of the disc [at C6–C7] with extension into the left neural foramen with moderate to severe left neuroforaminal narrowing and moderate right stenosis,'' and a bulging disc at C7–T1 ''with right stenosis.'' *Id.*

On February 13, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 73. On the ''Patients [sic] Follow Up Sheet,'' J.A. circled his upper back/neck as the area of his pain, indicated that the pain affecting his ''mobility,'' but did not answer the question: ''Does the pain get worse when you move in certain ways.'' *Id.* As at the previous visits, J.A. indicated that his pain was a ''6'' ''with medication'' and a ''10'' and ''without medication.'' *Id.*

In the Pain History Follow Up section, Respondent noted the location of J.A.'s pain as both his neck and lower back, that his pain was severe, throbbing and sharp, and that the precipitating event was a ''fall'' and not the previously reported incident when he was hit by a pot. *Id.* at 67. However, Respondent indicated there were no new events since last visit. *Id.*

In the ROS section, she checked the line indicating that all were negative, and in the PE section, she placed checkmarks indicating that all exam items were normal. *Id.* On the body diagram, she circled the neck/cervical spine region and noted ''Rotation 25 L R'' and ''Worse,'' below which she wrote ''Ext: 10'' and ''Flex 45'' and ''Better.'' *Id.* She also circled the lower back and noted range of motion findings of ''Ext 10'' and ''Flex 90,'' as well as circled the knees and wrote ''Reflex +2.'' *Id.* She further noted that that J.A.'s recent MRI showed ''mild bulges C3C6,'' and ''severe stenosis at ''C6 7'' and ''C7 T1.'' *Id.* Again she wrote: ''Risks discussed.'' *Id.*

Under Neurological, she checked ''Yes'' for each exam item and wrote ''+ bilat hand strength =,'' and under Orthopedic, she indicated that the straight leg raise test was negative for both legs. *Id.* at 68. Under Assessment, she checked or drew a scribble next to each line. Under Diagnosis, she checked ''Cervicalgia,'' ''Disc Bulge'' writing ''L45/L5S1,'' ''Disc Stenosis'' writing ''C-spine,'' ''Insomnia'', ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' under which she wrote ''neuropathy'' and ''old burns on back.'' *Id.*

Under Plan, she checked or drew a scribble next to each item, and added ''Pt. wants neuro sx [surgical] opinion.'' *Id.* As for the prescriptions she checked ''Roxicodone 30 mg,'' circled ''#168,'' and added the notation: ''increase due to need to have ↓ pain to work as server.'' *Id.* at 69. She checked ''Xanax,'' wrote ''.5,'' and circled ''#28.'' *Id.* She also prescribed Gabapentin and Mobic. *Id.* The Encounter Summary for this visit lists prescriptions for 168 Roxicodone 30 mg and 28 Xanax .5 mg, as well as the other drugs. *Id.* at 66.

On March 12, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 59. On the ''Patients [sic] Follow-Up Sheet'' which accompanies the visit note,[20] J.A. circled ''yes'' in answering the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.* He also circled his neck, mid-back and knee area on the body diagram to indicate his pain, and noted that his Pain Intensity ratings remained at 6 ''with medication'' and 10 ''without medication.'' *Id.* He also left blank the question regarding what life activities are affected by his pain. *Id.*

Respondent's notes in the Pain History Follow Up section, as well as her markings in the ROS and PE sections were exactly the same as those she made at J.A.'s previous visit. *Id.* at 60. As for her Range of Motion findings, with respect to J.A.'s neck, she noted: ''rotation 45 LR Better.'' *Id.* However, her other Range of Motion findings for J.A.'s neck and back, as well as her reflex test findings on his knees were exactly the same as before. *Id.* Respondent also noted ''normal hand grip'' and ''risks discussed.'' *Id.* Also, as at the previous visit, in the Neurological section, Respondent checked ''yes'' for each of the tests thus indicating that there were no focal deficits, and in the Orthopedic section, she indicated that both straight leg raise tests were negative. *Id.* at 61.

Under Assessment, Respondent again placed a mark next to each line item. *Id.* She also circled each of the same diagnoses as at the previous visit, adding the note ''c-spine'' to the diagnosis of ''Disc Bulge.'' *Id.* Under Plan, Respondent placed a mark next to each item. *Id.* As for the prescriptions, she issued the same prescriptions of 168 Roxicodone 30 mg and 28 Xanax .5 mg (as well as Gabapentin and Mobic) as before. *Id.* at 62; *see also id.* at 59 (Encounter Summary listing prescriptions).

Next to the medication list, Respondent also wrote: ''Goal: cont to work as chef'' and ''needs meds to control pain so He can work + support Kids.'' *Id.* Yet in the Pain History Follow Up, Respondent had circled ''N'' (rather than ''Y'') in the space for noting whether the patient had ''Kids''; she also left the blank the space for listing the ''Ages'' of any kids. *Id.* at 60.

On April 9, 2012,[21] J.A. returned to PBM and again saw Respondent. Respondent's notations were the same

[19] Respondent did not, however, place any mark next to the line stating: ''Continue meds, patient understands importance of weaning meds to minimum effective dose.''

[20] J.A. dated this Patient Follow Up Sheet ''2/12/12.'' GE 18, at 64. However, this document was placed next to the visit notes for J.A.'s visit of March 12, 2012, and the evidence shows that J.A.'s February visit occurred on February 13, 2012.

[21] There is no Patient Follow Up Sheet in the file which is dated April 9, 2012. There are, however, two copies of the Follow Up Sheet dated 5/7/12. GE 18 at 53, 49.

as to the location, character, levels and precipitating event of J.A.'s pain, and the co-morbidity of insomnia. *Id.* at 56. So too, Respondent circled ''N,'' indicating that J.A. did not have kids. *Id.* While Respondent wrote ''none'' as to whether there were new events since J.A.'s last visit, she added: ''Patient Had long weekend—server for High Holy Days,'' below which she wrote ''Risk discussed.'' *Id.*

Under ROS, Respondent again indicated that all systems were negative, and under PE, she again placed marks indicating normal findings for her PE. *Id.* On the body diagram, she circled the neck (writing ''Rotation 25 L R more''), the lower back (writing ''Ext 10'' and ''Flex 45''), and the knees (writing ''reflex +2''). *Id.* Under Neurological, she checked ''Yes'' for each item indicating that there were no focal deficits, and under Orthopedic, she indicated that she had done a negative straight leg raise test on both legs. *Id.* at 57.

As before, in the Assessment section, Respondent made a mark next to each item. *Id.* She also listed the diagnoses of ''Cervicalgia,'' ''Disc Bulge'' after which she wrote ''C spine'' and ''L45/L4S1,'' ''Disc Stenosis'' after which she wrote ''Cspine,'' ''Insomnia,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other'' after which she wrote ''neuropathy 2'' and ''Back Burns.'' *Id.*

Under Plan, Respondent placed a mark next to each of the line items. *Id.* Respondent also wrote: ''goal cont to work as chef & support kids.'' *Id.* at 58. Respondent reissued to J.A. prescriptions for 168 Roxicodone 30 mg, 28 Xanax .5 mg, as well as Gabapentin and Mobic. *Id.* at 58; *see also id.* at 55 (Encounter Summary).

On May 7, 2012, J.A. returned to PBM and again saw Respondent. On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled various areas of his body where he felt pain and against rated his pain as a 6 ''with medication'' and a 10 ''without medication.'' *Id.* at 49. However, J.A. did not answer any of the other questions on the form. *Id.*

In the Pain History Follow Up section of the visit note, Respondent made the same notations as before, with the exception of noting under ''New Events,'' ''heavy hours server.'' *Id.* at 46. While the body diagram is not visible on this form, in the same place where the body diagram appears on the other forms, Respondent drew three circles with arrows and noted ''Rotation L 25 R 45'' near the top circle, ''Reflex + 2,'' ''Ext 10'' and ''Flex 90'' near the middle circle, and ''Reflex +2'' near the bottom circle; she also noted ''Hand grip + 2.'' *Id.*

Respondent documented the exact same findings in the Neurological and Orthopedic sections of the visit note, and placed either a checkmark of vertical line through each item in the Assessment section. *Id.* at 47. Under Diagnosis, Respondent added ''Anxiety'' and ''Muscle Spasm C spine'' to her previous diagnoses of ''Cervicalgia,'' ''Disc Bulge C-Spine L45/,'' ''Disc Stenosis C-spine,'' ''Insomnia,'' ''Chronic Non-Malig Pain Syndrome,'' and Neuropathy 2'' and ''Back Burn.'' *Id.*

As for her Plan, Respondent placed a check mark next to the line stating: ''wt lost, smoking cessation, reduce salt and caffeine, F/U with PCP,'' circling the latter and writing ''CXR.'' *Id.* She also placed a checkmark next to the line for various types of referrals. *Id.* As for the other items, she either drew a diagonal or vertical line next to the item. *Id.* And on the last page, Respondent indicated that she was prescribing 168 Roxicodone 30 mg and 28 Xanax .5 mg, along with Flexeril (a non-controlled muscle relaxant) and Mobic. *Id.* at 48. *See also id.* at 45 (Encounter Summary listing prescriptions).

On June 4, 2012, J.A. returned to PBM and saw Respondent for the final time.[22] On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled the neck, upper back and right knee on the body diagram to indicate where he felt pain. *Id.* at 40. He again indicated that his pain was a 6 ''with medication'' and a 10 ''without medication.'' *Id.* J.A. did not, however, answer any of the form's other questions nor indicate if he was ''satisfied with [his] current medication.'' *Id.*

In the Pain History Follow Up section, Respondent noted that J.A.'s pain was in his neck and lower back, that it was throbbing but not radiating, that it was precipitated by a ''fall,'' but did not check whether the ''[s]everity of pain'' was ''mild,'' ''moderate,'' or ''severe.'' *Id.* at 37. Respondent indicated that J.A.'s pain level was at the same numeric levels (6 with medication, 10 without) as he circled on the Follow-up Sheet. *Id.* She again indicated ''N'' for whether J.A. had kids, and in the line for listing ''[n]ew events,'' wrote: ''still very heavy hours as server.'' *Id.*

In the ROS section, Respondent indicated that all were negative, and in the PE section, she indicted that each item was normal. *Id.* On the body diagram, Respondent circled the neck (writing ''Rotation R 45 L 25'' and ''Flex 25 Ext 10''), the lower back (writing ''Ext 10 Flex 45 worse''), the right elbow (writing ''Reflexes + 2 bilat), and both knees (writing ''Reflex +2''). *Id.* Respondent also wrote: ''Hand grip +2.'' *Id.* Under Neurological, Respondent circled ''yes'' for each exam item thus indicating that there were no focal deficits, and under Orthopedic, she indicated a negative finding for the straight leg raise test on both legs. *Id.* at 38.

Under Assessment, Respondent circled the words ''Patient satisfied'' and ''Patient taking meds as prescribed,'' and she wrote ''yes'' next to the line stating ''[a]ctivities of living, quality of life improved with medications.'' *Id.* She also placed check marks next to the remaining three items. *Id.*

As for her Diagnosis, Respondent checked (and notated) the exact same diagnoses as she did at J.A.'s previous visit. *Id.* In the Plan section, Respondent either placed check marks or circled portions of each item; as with the previous visit, she circled ''F/U with PCP'' and wrote ''needs CXR-pt advised.'' *Id.* And at the bottom of the page, she wrote: ''goal Cont to work + support family.'' *Id.* Respondent then documented the same medications as she prescribed at the previous visit: 168 Roxicodone 30 mg, 28 Xanax .5 mg, and the non-controlled drugs Flexeril and Mobic. *Id.* at 39; *see also id.* at 30 (copies of prescriptions). J.A. also signed a Patient Compliance Instruction sheet on that visit.[23] *Id.* at 41.

The Government's Expert reviewed J.A.'s patient file and found that the medical history and physical examinations of J.A. were ''inadequate and that it was not reasonable for Registrant to rely on the evaluations of other providers at'' PBM. GE 24, at 14. The Expert also found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history,'' noting that ''she relied on the superficial checklists which are insufficient for evaluating the types of complaints that J.A. communicated.'' *Id.* The Expert further noted that on February 13, 2012, Respondent ''prescribed additional narcotics without any medical justification'' when

[22] When J.A. returned to PBM on June 27, 2012, he saw a different doctor.

[23] The file also contains a sheet titled ''June 13 2012 audit page.'' GE 18, at 44. This document lists handwritten notes pertaining to the dates that MRIs and labs were ordered and received, the dates of two UDSs and the results for one of the tests, blood pressure and pulse readings at J.A.'s visits, the date records were received (which lists only the May 2001 ER records), and ''Referral[s] Out.'' *Id.*

Notably, the Referrals included the following notes: (1) ''2/28/11—recommend ortho eval,'' (2) ''11/21/11—consult neurology,'' (3) ''5/7/12—F/U—PCP needs CXR,'' with an arrow pointing to (4) ''6/27/12—pt broke & can't have done.'' *Id.* Respondent's initials appear at the bottom of the page. *Id.*

she increased J.A.'s prescription for oxycodone from 140 tablets to 168 tablets ''based solely on the bald statement that the patient needed 'to have less pain to work.' '' *Id.*

The Expert also found that J.A.'s patient file ''contain[s] no evidence that [Respondent] addressed the effect of pain on J.A.'s physical and psychological function.'' *Id.* at 15. The Expert further explained that ''that the checklist is devoid of any explanation for how J.A.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.*

Next, the Expert found that Respondent's ''treatment plan was wholly inadequate,'' because it ''consisted of only a checklist of recommendations.'' *Id.* He further observed that J.A.'s file ''is devoid of any evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert noted that Respondent ''recommended Yoga and other exercise, fish oil and glucosamine/chondroitin sulfate,'' and ''also stated [that] she will ''refer to PT, Neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed.'' *Id.* The Expert then explained that ''[t]here is no evidence that any of these alternative measures were attempted [or] that any referrals were made.'' *Id.* at 15.

Finally, the Expert also found that Respondent ''ignored numerous red flags for diversion'' with respect to J.A. *Id.* These included that ''J.A. tested positive for methadone even though his last prescription for methadone had been issued five months earlier,'' and ''that he reported that he lost his Xanax, which was not discussed or resolved in the patient file.'' *Id.* The Expert further noted that J.A. ''presented a Florida Identification card instead of a valid driver's license'' and that ''[t]his raises questions as to whether . . . [J.A.] obtained the cars solely for the purpose of establishing temporary residence in Florida in order to obtain controlled substances'' *Id.* The Expert thus concluded that J.A. ''was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion'' and that Respondent ''failed to monitor the patient's compliance in medication usage and failed to give special attention to J.A.'' *Id.* The Expert further concluded that the controlled substance prescriptions Respondent issued to J.A. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Patient D.B.

Patient D.B., a 66-year-old resident of Okeechobee, Florida, first presented at PMB on January 31, 2012 with a chief complaint of back pain which started ''3 yrs ago.'' GE 14, at 13. D.B. noted that there was no precipitating event, and that his pain level was a 2 ''with medication'' and a 7 ''without medication.'' *Id.* He further noted that he had undergone chiropractic procedures and that he had tried or been on anti-inflammatories, Dilaudid, Percocet, and Xanax. *Id.* He answered ''yes'' to the question: ''Have you seen any other doctors for this pain?'' *Id.* And on an exhaustive list of ''symptoms you have or have had in the past year,'' D.B. checked nervousness, back and hip, high blood pressure, appendicitis, arthritis, heart disease, hepatitis, high cholesterol and a pacemaker, among other things. *Id.* at 15. D.B. was also subjected to a drug screen which was negative for all items tested including ''Opiates/Morphine'' and ''Oxycodone.'' *Id.* at 10.

On the visit note, another physician indicated that D.B. had a three-year history of middle and lower back pain as well as right and left hip pain, that the pain was moderate, severe, sharp and tingling; the physician also noted that D.B.'s pain ''off meds'' was an 8 and ''on meds'' a 3. *Id.* at 31. As to co-morbidities, the physician checked anxiety and insomnia. *Id.* As to previous pain management treatment, the physician circled only ''medication'' and next to the word ''PM Center,'' wrote ''[n]one.'' *Id.*

As to what made D.B.'s pain worse, the physician placed checkmarks next to ''lifting,'' ''bending'' and ''sitting''; she also circled ''standing.'' *Id.* As for what made D.B.'s pain better, the physician checked only resting. *Id.* The physician also placed checkmarks to indicate that the pain affected D.B.'s ''sleep,'' ''mood,'' ''work,'' ''daily activities,'' ''energy,'' and ''relationships.'' *Id.* After checking that D.B.'s was quality of life was ''worse'' off medications and ''better'' on them, the physician circled ''none'' for D.B.'s history of smoking and drug use, and circled ''occ'' for his alcohol use. *Id.*

Under current meds, the physician listed several non-controlled drugs including aspirin, Plavix, Diovan, and Amlodipine, but no controlled substances. *Id.* Under past imaging, the physician checked ''CT,'' placed a checkmark in the space for inserting the date of a lumbar scan but no date and placed a check to indicate that a thoracic spine scan had been done but left blank the date.[24] *Id.*

Under ROS, the physician indicated that all were negative, and under PE, the physician indicated normal findings with the exception of ''mildly obese'' on the line for Abd. *Id.* at 32. The physician documented four Range of Motion findings (''F 60, Ext 10, RL 65 and LL 65''), documented a positive straight leg raise test on each leg, and found no focal deficits with respect to any of the neurological exam items. *Id.* The physician further documented that D.B. ''was treated for 72 HR w/Perocet by PMD and referred to Pain Clinic for further management of pain. Was offered surgery by his Orthopod but declined for now.'' *Id.*

Under Assessment, the physician placed a check mark next to each item. *Id.* Under Diagnosis, she checked ''Hypertension,'' ''Lumbago,'' ''Sciatica,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she wrote ''Schmorl's Nodes' and ''multi level osteophytes.'' [25] *Id.* at 33. Under Plan, placed a checkmark next to each item and wrote ''No NSAIDS, PT is on Plavix and ASA [aspirin].'' *Id.* The physician also noted that she was prescribing 112 Lortab 10/500 (hydrocodone/acetaminophen). *Id.; see also id.* at 30 (Encounter Summary).

On February 28, 2012, D.B. returned to PBM and saw the same physician. *Id.* at 54. D.B. noted on the ''Patients [sic] Follow-Up Sheet'' that his pain was always there, that it affected his social activities and sleep, that his pain was a 3 ''with medication'' and a 7 ''without medication.'' *Id.*

In the Pain History section of the visit note, the physician noted that D.B.'s pain was located in his lower back and radiated, as well as in his thigh, leg and knee, that the pain was severe, and its duration was ''5 yrs.'' *Id.* at 50. The physician also noted that D.B.'s pain was precipitated by a motor vehicle accident; she also checked insomnia as a co-morbidity. *Id.* She further noted the same pain ratings with and without medication as D.B. had listed on the ''Patients [sic] Follow-Up Sheet.'' *Id.* As for new activities since his last visit, Respondent noted that D.B.'s pacemaker had been checked one week ago and that D.B. ''says activity level has increased, less anxiety.'' *Id.* The physician also noted that DC complained of ''inadequate pain control.'' *Id.*

Under ROS, the physician indicated that all were negative, and under PE, the

[24] The physician also noted the frequency of D.B.'s visits to his primary care physician and cardiologist, as well as listed various conditions he had such as ''HTN,'' ''COPD,'' ''Hx of Syncope,'' and that he had a pacemaker. GE 14, at 31.

[25] On the Encounter Summary, the physician noted an additional diagnosis of ''Insomnia due to Medical Condition Classified Elsewhere.'' GE 14, at 30.

physician circled normal findings for ''Heent,'' ''Chest,'' ''Cor,'' ''Abd,'' and ''Neuro/psych'' but made no markings as to ''Skin,' ''Ext,'' and ''Gait.'' *Id.* As for the Neurological exam, the physician indicated that each exam item was normal with no focal deficits. *Id.* However, under Orthopedic, she made no findings as to either straight leg raise tests or range of motion. *Id.*

In the Assessment section, the physician left unchecked each line item, and in the Diagnosis section, the physician checked ''Insomnia,'' ''Lumbago,'' ''Sciatica,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she wrote ''Osteophytosis,'' ''Schmorl's nodes,'' and ''OA.'' The physician then placed a checkmark next to each item in the Plan section and noted that she was discontinuing the Lortab and changing the prescription to 112 dosage units of Roxicodone 30 mg (one pill four times a day) ''for better pain control.'' *Id.* at 51–52. The physician also issued a prescription for 15 dosage units of Xanax 1 mg for ''insomnia/anxiety,'' and a prescription for 28 dosage units of Colace, a non-controlled drug, for constipation. *Id.* at 52; *see also id.* at 56 (Encounter Summary).

On March 5, 2012, D.B. returned to PBM and saw Respondent who noted that ''Pt here 2–28–12'' and that he had ''brought back'' both the oxycodone and Xanax prescriptions because he ''couldn't get scripts filled st Lucie + Okeechobee three dif pharmacies where he lived.'' *Id.* at 57. Respondent documented that she did a PE which was comprised of a straight leg raise test which was negative, that his range of motion of his lumbar spine was 45 degree in flexion and 10 degrees in extension, and that his patella reflexes were ''+2.'' *Id.* Respondent listed diagnoses of OA (osteoarthritis), HTN (hypertension), IDDM (insulin dependent diabetes mellitus), Osteopenia, Schmorl's nodes, and Kyphosis. *Id.* As for her ''Plan,'' Respondent listed ''CT Lumbar,'' and ''Renew meds [discontinue] oxycodone.'' *Id.* Respondent then listed prescriptions for 112 du of Dilaudid 8 mg, 15 Xanax 1 mg, and Colace. [26] *Id.*

D.B.'s file included a report of a CT scan on his lumbar spine which was done on March 15, 2012. *Id.* at 58. The report lists the radiologist's impression as: ''[b]ulging annuli as discussed. Prominent bulging annulus and mild lumbar spinal stenosis at L4–5. Right paracentral calcified disc protrusion/spur at the L5–S1 level.'' *Id.*

On March 27, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 64. On the ''Patients [sic] Follow-Up Sheet,'' D.B circled his lower back as the location of his pain, reported that the pain was always there and got worse when he moved in certain ways, and that it affected his social activities, mobility and sleep. *Id.* He indicated that the intensity of his pain was 4 ''with medication'' and 8 ''without medication.'' *Id.*

In the visit note's Pain History Follow Up section, Respondent noted that D.B.'s lower back pain was severe, throbbing, and sharp and had been precipitated by a motor vehicle accident in 2003. *Id.* at 60. She checked insomnia as a co-morbidity, noted that his pain scale off meds was ''8'' and on meds was ''4,'' that his quality of life ''Off medications'' was ''worse'' and his quality of life ''ON medications'' was ''better.'' *Id.* Also, following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

Under ''ROS,'' she indicated that all were negative. *Id.* Under ''PE,'' she placed a variety scribbles next to each item. *Id.* On the body diagram, she circled the thoracic spine (writing ''Kyphosis''), the lumbar spine (noting Range of Motion findings of ''Ext 10 Flex 90''), and the knees (noting ''reflexes +2''); she also noted ''−SLR'' as well as ''[r]isks discussed.'' *Id.* Also, under ''Neurological,'' she checked each items as normal with no focal deficits. *Id.* at 63.

In the Assessment section, Respondent indicated that D.B. was ''satisfied, doing well on current medication and treatment plan,'' that he was ''taking meds as prescribed,'' that he ''denied any drug charges or arrests since [his] last visit,'' and that the ''diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.'' *Id.* As for her Diagnosis, Respondent checked: ''Disc Protrusion'' and noted ''L5S1,'' ''Disc Stenosis'' and noted ''L45,'' ''Hypertension,'' ''Chronic Non-Malignant Pain Syndrome,'' and under ''Other,'' she wrote ''pacer,'' ''OA,'' ''IDDM'' (diabetes) and ''osteophytes.'' *Id.*

Under Plan, she placed check marks next to each item and handwrote ''Add glucosamine/chondroitin.'' *Id.* On the medications page, Respondent noted that ''April 2 is 28 days'' and that she was prescribing 112 du of Dilaudid 8mg and 15 du of Xanax 1 mg, as well as Ibuprofen 400 mg and Colace 100 mg. *Id.* at 62. The Encounter Summary states, however, that both the Dilaudid and Xanax prescriptions were not to be ''fill[ed] before [A]pril 2, 2012.'' *Id.* at 61.

On April 24, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 70. On the ''Patients [sic] Follow-Up Sheet,'' D.B. circled his lower back, again indicated that his pain was ''always there'' and got worse when he ''move[d] in certain ways,'' and that it affected his Social Activities and Mobility; he also indicated that his pain was a 4 ''with medication'' and an 8–9 ''without medication.'' *Id.* D.B. did not, however, indicate that the pain affected his ''Sleep.'' He also checked that he was ''satisfied with [his] current medication'' and ''would not like to change it,'' rather than the alternative choice of ''not satisfied'' and ''would like to discuss changes.'' *Id.*

In the visit note's Pain History Follow Up section, Respondent filled in the form with few changes since the last visit, except to add ''anxiety'' to the list of co-morbidities and noted that D.B. was ''Able to fill Dilaudid.'' *Id.* at 66. Under ROS, Respondent again indicated that all were negative, and under PE, Respondent checked or circled normal findings for each exam item. Following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

On the body diagram, Respondent circled the thoracic spine (writing ''Kyphosis''), the lumbar spine (noting Range of Motion findings of ''Flex 90'' and ''Ext 10''), and the knees (noting ''Reflex +2''). *Id.* She also placed checkmarks next to each of the Neurological exam items indicating that there were no focal deficits and noted that the straight leg raise test was negative for both legs. *Id.* at 68.

As for her Assessment, Respondent either checked or placed a scribble for each item, and in the Diagnosis section, Respondent checked and added each of the same conditions as before with the exception of Hypertension which she did not check. *Id.* at 68. Under Plan, Respondent checked or drew a vertical line next to each item and again wrote an entry for glucosamine/chondroitin. *Id.* As for the medications, Respondent again prescribed 112 du of Dilaudid 8 mg, noted that she was discontinuing Xanax, and added 28 Klonopin 1 mg ''[e]very [e]vening at [s]leep [t]ime.'' [27] *Id.* at 67, 69.

On May 31, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 72. On the ''Patients [sic] Follow-Up Sheet,'' he again reported that the pain was ''always there,'' got worse when he

[26] The Encounter Summary shows that Respondent also prescribed Ibuprofen. GE 14, at 59.

[27] She also noted that she was prescribing Colace and Ibuprofen, although the latter drug is not listed in the Encounter Summary. *Compare* GE 14, at 69, *with id.* at 67.

''moved in certain ways'' and affected his ''[s]ocial [a]ctivities'' and ''[m]obility.'' *Id.* As to the intensity of his pain, D.B. reported that it was an ''8'' ''with medication'' and a ''3'' ''without medication.'' *Id.* D.B., however, indicated that he was satisfied with his current medication and would not like to change it. *Id.*

In the Pain History Follow Up section of the visit note, Respondent again noted that D.B. suffered from lower back pain that was throbbing and sharp, and was precipitated by a 2003 motor vehicle accident. *Id.* at 76. Respondent checked ''anxiety'' and ''insomnia'' as co-morbidities,'' and as to D.B.'s pain level, Respondent recorded that ''off meds'' it was 8, and ''on meds'' it was ''4.'' *Id.* Following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

Under ROS, Respondent checked the line to indicate that all were negative, and under PE, she again placed a checkmark or scribbled over the various normal findings for each exam item. *Id.* On the body diagram, she again circled the thoracic spine (writing Kyphosis), the lumbar spine (noting ROM findings of ''Flex 90'' and ''Ext 10''), and the knees (noting ''Reflex +2). *Id.* In the Neurological section, Respondent again indicated that each item was normal with no focal deficits, and in the Orthopedic section, she indicated that the straight leg raise test was negative on each leg. *Id.* at 74.

Under Assessment, Respondent either placed a checkmark or vertical line through each item. *Id.* As for her diagnosis, Respondent added ''Anxiety'' and ''Insomnia'' to the previous diagnoses of ''Disc Protrusion L5S1,'' ''Disc Stenosis L45,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she added the same diagnoses of ''OA,'' ''Pacer,'' ''IDDM,'' and Osteophytes.'' *Id.*

As for her Plan, Respondent either made a checkmark or drew a vertical line next to each item. *Id.* As for the medication, she noted that she was issuing prescriptions for 112 du of Dilaudid 8 mg, 56 Klonopin 1 mg ''for anxiety,'' 28 Ambien .5 mg (zolpidem, a schedule IV drug) ''for insomnia,'' as well as Colace and Ibuprofen. *Id.* at 75; *see also id.* at 77 (Encounter Summary). Of note, the Klonopin prescription was double the quantity of previous prescription and the Ambien was a new prescription.

On June 28, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 78. He again reported that his pain was ''always there,'' that it ''got worse when [he] move[d] in certain ways,'' and affected his ''Social Activities'' and ''Mobility.'' *Id.* D.B. reported that his pain was a ''4'' with medication and a ''9'' without medication, and that he was ''satisfied'' with his ''current medication'' and ''would not like to change it.'' *Id.*

In the Pain History section of the visit note, Respondent again documented that D.B.'s pain was in his lower back, that it was severe and throbbing, and that it was precipitated by a 2003 motor vehicle accident. *Id.* at 83. She again noted co-morbidities of anxiety and insomnia, as well as that he had ''psych visits/ss disability'' in the past five years, that his only previous pain management treatment were ''meds,'' and that ''lifting'' and ''sitting/standing in one position too long'' made his pain worse, and that the pain affected his ''sleep,'' ''mood,'', ''daily activities,'' and ''energy,'' although ''sleep'' made his ''pain better.'' *Id.* Respondent also noted that his pain level was 8 ''off meds'' (D.B. had reported it as a ''9'') and a 4 ''on meds.'' *Id.* She also indicated that his ''quality of life OFF medications'' was ''worse'' and his ''quality of life ON medications'' was ''better.'' *Id.* She also noted that a CT exam on ''3–12 [had shown] stenosis.'' *Id.*

Under ROS, Respondent checked that all were negative, and under Physical Exam, she circled normal findings for each item. *Id.* at 80. However, she also noted ''+ palmar erythema.'' *Id.* Under Neurological, Respondent found each exam item to be normal with no focal deficits. *Id.* Under Orthopedic, Respondent circled ''+'' and ''30–60'' degrees for the straight leg raise test on each leg; noted that D.B.'s range of motion for his lumbar spine was ''45'' in flexion and ''10'' in extension; that Compression and Valsalva tests on his cervical spine were both negative; that a Kemps test on his lumbar spine was positive on the right side; and that his gait was normal. *Id.*

In the Assessment section, Respondent placed checkmarks to indicate that D.B. was satisfied and understood how to take current medication, that he would take medication as prescribed and had no side effects, that his life activities and quality of life were improved with medications, that medication storage issues were addressed, and that he lived in a stable condition with no drug related activity or persons in his home. *Id.* at 81. As for her diagnoses, Respondent checked anxiety, back pain, disc bulge, disc protrusion, disc stenosis, hypertension, insomnia, chronic non-malig pain syndrome, and other, under which she ''pacer'' and ''CAD [coronary artery disease] + stent.'' *Id.*

Under Plan, Respondent noted that ''PCP obtained/referred for . . . HTN'' and ''chemistry screen due from PCP.'' *Id.* As for the medications, Respondent checked Klonopin (circling ''1mg'' and ''#56'') and Ambien (circling ''5 mg'' and ''#28''), as well as Colace; she also wrote 112 Dilaudid 8 mg. *Id.; see also id.* at 82 (copies of prescriptions); *id.* at 93 (Encounter Summary).

The file also contains a release for medical records (including progress notes, a prescription profile and diagnostic reports) from a particular doctor which D.B. executed on June 28, 2012. *Id.* at 91. However, the release was not faxed to the other doctor until July 24, 2012. *Id.* at 92.

On July 23, 2012, D.B. saw Respondent a final time. *Id.* at 85. On the ''Patients [sic] Follow-Up Sheet,'' D.B. did not answer if the pain was ''always there.'' *Id.* at 86. However, he claimed that the pain affected his ''Social Activities,'' ''Mobility,'' and ''Sleep,'' as well as that it got ''worse when [he] move[d] in certain ways?'' *Id.* D.B. rated his pain as a ''2'' with medication and ''8–9'' without medication. *Id.* He also checked that he was ''satisfied with [his] current medication'' and ''would not like to change it.'' *Id.*

In the Pain History section of the progress note, Respondent noted that the pain was in D.B.'s lower back, that it was severe, throbbing, and sharp, and that it was precipitated by a 2003 motor vehicle accident. *Id.* She again indicated that ''lifting'' and ''sitting, standing in one position too long'' made his pain worse and that sleep made his pain better. *Id.* As for what the pain affected, she place checkmarks next to ''sleep'' and ''daily activities''; she also drew short diagonal lines next to ''mood'' and ''energy.'' *Id.* As for D.B.'s numeric pain rating, Respondent noted ''8'' for ''off meds'' and a ''4'' for ''on meds,'' which was different than the level (2) D.B. had circled. *Id.* at 85. Respondent also circled ''Y'' for ''Pysch visits/SS Disability,'' and noted that D.B.'s only previous pain management treatment was ''meds.'' *Id.*

Respondent made no checkmarks next to any of the items under ROS, and under PE, she again circled normal findings for each of the exam areas. *Id.* at 88. Under Neurological, Respondent circle normal findings with no focal deficits for each exam item. *Id.* Under Orthopedic, Respondent circled ''+'' and ''30–60'' degrees for the straight leg raise test on each leg; noted that D.B.'s range of motion for his lumbar spine was ''45'' in flexion and ''10'' in extension; that

Compression and Valsalva tests on his cervical spine were both negative; that a Kemps test on his lumbar spine was positive on the right side; and that his gait was normal. *Id.*

In the Assessment section, Respondent placed checkmarks to indicate that D.B. was satisfied and understood how to take current medication, that he would take medication as prescribed and ''reported no side effects,'' that his life activities and quality of life were improved with medications, that medication storage issues were addressed, and he lived in a stable condition with no drug related activity or persons in his home. *Id.* at 89. As for her diagnoses, Respondent checked anxiety, back pain, disc bulge, disc protrusion, disc stenosis, hypertension, insomnia, chronic non-malig pain syndrome, and other, under which she wrote ''pacer'' and ''CAD [coronary artery disease] + stent.'' *Id.*

Under Plan, she again noted ''PCP obtained/referred for . . . HTN,'' as well as ''chemistry screen due next visit.'' *Id.* She again prescribed 112 du of Dilaudid 8 mg, 56 du of Klonopin 1 mg for anxiety, 28 tablets of Ambien 5 mg for insomnia, and Colace. *Id.* at 84, 89.

The Expert reviewed D.B.'s patient's file and found that ''the medical history and physical examinations of D.B.'' that were done by the other doctor at PBM were ''inadequate and that it was not reasonable to rely on [those] evaluations.''' GE 24, at 9. The Expert also found that Respondent did not ''conduct[] an adequate physical examination or t[ake] a satisfactory medical history,'' and that she ''relied on the superficial checklists which are insufficient for evaluating the types of complaints that D.B. communicated.'' *Id.* He found that Respondent ''prescribed both clonazepam for anxiety and zolpidem for insomnia, [but] fail[ed] to record any information whatsoever to justify these prescriptions other than baldly noting that D.B. *had* anxiety and insomnia.'' *Id.* The Expert also noted that on May 31, 2102, Respondent increased D.B.'s clonazepam prescription ''without any justification.'' *Id.*

Continuing, the Expert found that Respondent's ''records contain no evidence that [she] addressed the effect of pain on D.B.'s physical and psychological function,'' and that ''[t]he checklist is devoid of any explanation for how D.B,'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* He also found that Respondent's ''treatment plan was wholly inadequate and, again, consisted only of a checklist of recommendations'' and that there was no ''evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert also noted that while Respondent ''recommended 'glucosamine/Chondroitin Sulfate,' and stated that she will 'refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, psychiatrist, addiction specialist as needed[,]' [t]here is no evidence that any of these alternative measures were attempted, [or] that any referrals were made.'' *Id.*

The Expert further found that Respondent ''ignored numerous red flags for diversion'' in her treatment of D.B., who lived ''approximately 95 miles from'' PBM in Okeechobee, Florida. *Id.* at 10. The Expert specifically noted that there was ''nothing in the medical file to explain why D.B. would travel so far to obtain prescriptions.'' *Id.* He also noted that ''D.B. came to [PBM] as an opiate naïve patient, having tested negative for *all* controlled substances on January 31, 2012, and having no prescription history.'' The Expert noted that D.B. ''was given a large quantity of narcotic[s]'' (112 du of hydrocodone) even though at the first visit he reported that his pain level ''was '2' while medicated [and] he was currently on *no* medication.'' *Id.* The Expert also noted that, notwithstanding that D.B. was prescribed hydrocodone, his pain level had increased to 3, and ''despite an enormous increase in the amount of opioid medication that Respondent prescribed on March 5, 2012,'' when she issued him a prescription for 112 du of Dilaudid 8 mg, his pain level with medication increased yet again to 4. *Id.*

The Expert further noted that D.B.'s chart contain inconsistent statements as to the duration of his pain, with D.B. reporting at his first visit (Jan 31, 2012) that he had the pain for three years, which he then changed at his second visit (Feb. 28, 2012) to five years (having been precipitated by an auto accident), only to claim at his fourth visit (Mar. 27, 2012) that it was of nine years duration. *Id.* And the Expert noted that when D.B. told her that he was unable to fill the oxycodone and Xanax prescriptions at a pharmacy in his home town as well as in Port St. Lucie, Respondent ''failed to investigate why [he] was allegedly refused service by three different pharmacies.'' *Id.*

The Expert thus concluded that ''these red flags indicate to me that Registrant failed to monitor the patient's compliance in medication usage and failed to give special attention to [him], who was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion.'' *Id.* The Expert further concluded that the controlled substance prescriptions Respondent issued to D.B. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Other Patients

In light of my findings with respect to the UC, D.G., J.A., and D.B., I deem it unnecessary to make detailed findings with respect to the remaining patients. I note, however, that the Expert concluded that Respondent ignored numerous red flags for diversion with each of these patients, including D.H. and J.B., who lived in Panama City, Florida, more than 500 miles from PBM, as well as W.B., who resided in Southport, Florida, which is approximately 547 miles from PBM. GE 24, at 7–8, 12–13. With respect to these patients, the Expert noted that there was ''no information in the medical records to explain why [they] would travel such an extraordinarily long distance to receive what amounted to be superficial, substandard medical care.'' *Id.* at 13–14.

With respect to each of the seven chart review patients, the Expert opined that Respondent ''repeatedly ignored readily identifiable red flags (aberrant behaviors) and continued to issue prescriptions for controlled substances despite unresolved red flags for abuse and/or diversion.'' *Id.* at 15. The Expert also opined that Respondent ''failed to prescribe in accordance with the level of care, skill and treatment recognized by a reasonably prudent physician under similar circumstances.'' *Id.*

Summing up, the Expert concluded that Respondent:

> failed to conduct a complete medical history and examination proportionate to the diagnosis that justified the treatment she provided. She failed to adequately document the (1) nature and intensity of the pain; (2) current and past treatments for pain; (3) underlying or coexisting disease and conditions; (4) the effect of pain on the patients' physical and psychological function. [She] failed to perform an adequate review of previous medical records, previous diagnostic studies, and each patient's history of alcohol and/or substance abuse. [She] failed to develop a written plan for assessing each patient's risk for aberrant drug-related behavior and monitor that risk. [She] failed to document an individualized treatment plan containing objectives to be used to determine treatment success . . . [and] failed to (1) adjust the drug therapy to the individual needs of the patient; (2) consider another's treatment modalities other than prescriptions for controlled substances; and (3) discuss the risk of abuse and addiction, as well as physical dependence and its consequences. *Id.* at 15–16.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

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

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

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

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

(5) Such other conduct which may threaten the public health and safety. *Id.* § 823(f).

''These factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.; see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am ''not required to make findings as to all of the factors.'' *Volkman,* 567 F.3d at 222; see also *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay* v. *DEA,* 664 F.3d 808, 821 (10th Cir. 2011).

The Government has the burden of proof. *See* 21 CFR 1301.44(e). Moreover, even where a Respondent waives her right to a hearing, the Government must provide substantial evidence to support the allegations and its proposed sanction. *Gabriel Sanchez,* 78 FR 59060, 59063 (2013).

The Government contends that the evidence with respect to Factors Two, Four, and Five establishes that Respondent's registration is inconsistent with the public interest and should be revoked.[28] Specifically, it argues that Respondent prescribed controlled substances to the UC and at least seven other patients without a legitimate medical purpose and/or outside the usual course of professional practice, and that she issued prescriptions without medical justification, without proper examinations, and in violation of both state and Federal law.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.; see also* Fla. Stat. § 893.05(1) (''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]''); *id.* § 893.13(1)(a) (rendering it ''unlawful for any persons to sell, manufacture, or deliver . . . a controlled substance'' except as authorized by the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. §§ 893.01 *et seq.*); *id.* § 458.331(q) (providing that prescribing ''any controlled substance, other than in the course of the physician's professional practice,'' is grounds for ''disciplinary action'').[29]

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430 F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (prescription requirement stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-

[28] As to Factor One, while Respondent is currently prohibited from practicing medicine, this is not the result of action taken by the Florida Board of Medicine but a condition of bail imposed by the Broward County Court. *See* Respondent's Motion for Extension of Time Pursuant to 21 CFR 1316.47(b). Moreover, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to Respondent, or taken any disciplinary action against Respondent. *See* 21 U.S.C. 823(f)(1).

However, even assuming that Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets this requirement for maintaining her registration, *see Frederic Marsh Blanton,* 43 FR 27616 (1978), this finding is not dispositive of the public interest inquiry. *Cf. Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the Government's proposed sanction of revocation. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

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

[29] Florida law defines the term ''prescription'' to mean, in relevant part, ''an order for drugs . . . written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs . . . issued in good faith and in the course of professional practice.'' Fla. Stat. § 893.02(22).

patient relationship. *Volkman,* 73 FR 30642.

By regulation, the Florida Board of Medicine has adopted ''Standards for the Use of Controlled Substances for the Treatment of Pain.'' Fla. Admin. Code r. 64B8–9.013. The Board has explained that these ''standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.'' *Id.* r.64B8–9.013(1)(g) (2011–2012). At the time of the events at issue here, the Board's standards provided as follows:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall 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 also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

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

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

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results; and

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with [Fla. Admin. Code] rule 64B8–9.003 . . . and [Fla. Stat.] Section 458.331(1)(m). . . .

Id. r.64B8–9.013(3)(a)–(f) (2011–2012).

The Florida Board has further explained that it ''will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.'' *Id.* r. 64B8–9.01391)(g) (2011–2012).[30]

Applying the Board's standards, the Government's Expert concluded that Respondent failed to establish a sufficient doctor/patient relationship with the UC. GE 24, at 3. He further opined that the controlled substance prescriptions issued by Respondent to the UC lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.; see* 21 CFR 1306.04(a). Indeed, with respect to the UC, there is sufficient evidence even apart from the Expert's declaration to support the conclusion that Respondent violated 21 CFR 1306.04(a) when she prescribed controlled substances to the UC. *See T.J. McNichol,* 77 FR 57133, 57147 (2011) (discussing cases finding violations of 21 CFR 1306.04(a), 21 U.S.C. 841, and similar state laws without requiring expert testimony), *pet. for rev. denied,* 537 Fed. Appx. 905 (11th Cir. 2013).

The Expert found that Respondent failed to make ''a serious inquiry into the cause of the patient's pain'' and failed to take a complete medical history of the UC's pain. *Id.* at 3. The Expert explained that ''in a valid doctor/patient relationship, a physician must inquire into whether the pain is the result of an injury or another disease process'' and that this ''was not sufficiently done'' as Respondent's questioning was limited to determining that the UC was a stunt man and had not been in a car accident and that there was ''no critical injury at all.'' *Id., see also* GE 7, at 3 (transcript of UC's visit with Respondent on May 31, 2012.) Indeed, the evidence shows that the UC simply complained of stiffness and muscle soreness from both his work and doing ''heavy squats''; he also denied having numbness or tingling in his legs. GE 7, at 3–4.

The Expert further noted that while the UC had stated that he had seen as many as six other doctors for his pain and provided signed releases for his medical records, those records were not obtained. GE 24, at 3. According to the Expert, as part of the history, ''it is important to review the records of other physicians who have treated the patient.'' *Id.* The Expert further noted that Respondent ''never inquired as to the treatment UC may have received prior to coming to [PBM]'' and did not ''discuss any non-narcotic treatment [he] may have received from any other doctor at PBM.'' *Id.* at 4. Also, in his declaration, the UC stated that Respondent never asked him if he had any history of substance abuse. GE 25, at 5.

The Expert also found that Respondent failed to conduct an adequate physical examination of the UC, noting that he ''failed to demonstrate pain sufficient to justify the repeated prescribing of controlled

[30] *See also* Fla. Admin. Code r. 64B8–9.003(2) (''A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.''); *id.* r. 64B8–9.003(3) (''The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed . . . . ; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.'').

substances, especially strong opioid medications such as'' oxycodone 30 mg. GE 24, at 3. Indeed, at his first visit, the UC reported that on a scale of 0 to 10, his pain level without medication was a 2. GE 11, at 36. Yet on the visit note, Respondent indicated that the UC's pain was severe and noted that his pain level ''off meds'' was a 5. *Id.* at 33. Respondent also indicated that the UC's pain was both ''throbbing'' and ''sharp.'' *Id.* Yet at no point during the UC's visit did he complain of having ''throbbing'' or ''sharp'' pain. Thus, the evidence supports the conclusion that Respondent falsified the UC's medical record by documenting symptoms which the UC never complained of and a higher pain level than what the UC complained of.

Moreover, as the video shows, Respondent's physical exam was limited to having the UC bend over; sit down and turn his head from side to side; placing a stethoscope on his chest; having him sit down, extend his legs and squeeze his calves and ask if there was any tenderness; and striking his knees with a neurologic hammer while his feet were still placed on the floor. GE 3, V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18; *see also* GE 25, at 2–3. Yet the visit note includes findings based on a variety of tests which were not done including testing his cranial nerves, doing a sensory exam, testing his reflexes for both the upper and lower extremities, testing his muscle strength both upper and lower, and doing a straight leg raise test on each leg. *Compare* GE 11, at 33–34 (visit note), *with* GE 3, at V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18. Indeed, the video shows that the various tests Respondent performed as part of the physical exam lasted less than one minute.

The Expert also found that Respondent diagnosed Respondent as having muscle spasms, without any evidence. Indeed, the UC never complained of spasms and the video shows that Respondent never palpated the UC's lower back. Moreover, Respondent diagnosed the UC has having anxiety and issued a clonazepam prescription to treat this condition, even though the UC told Respondent that ''[o]nce in a while'' he would ''take a little bit of Xanax to sleep,'' but he thought he could ''probably work without it.'' GE 11, at 4, *see also id.* at 27, 34. Also, in his declaration, the UC stated that during his visits to PBM, he ''never disclosed that [he] suffered from anxiety.'' GE 25, at 3.

The Expert concluded that Registrant ''failed to determine and/or document the effect of pain on UC's physical and psychological function, [because] there is no documentation in the record to show that she made any attempt to adequately address this important standard of pain management.'' GE 24, at 4.

The Expert also found that Respondent ''failed to create and/or document a sufficient treatment plan.'' *Id.* The Expert explained that despite UC's history of treatment at PBM and receipt of ''prescriptions for controlled substances on prior occasions, [Respondent] recommended no further diagnostic evaluations or other therapies.'' *Id.* The Expert then observed that the UC's ''MRI . . . failed to demonstrate serious enough pathology for him to receive the large amounts of controlled substances that were prescribed.'' *Id.* According to the Expert, ''[b]ulging discs can usually be addressed by other means such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, injections such as nerve blocks with corticosteroids,'' but that ''[n]one of these options was offered or discussed by'' Respondent. *Id.* The Expert then opined that ''[i]gnoring these options constitutes an inferior, if not non-existent, treatment plan.'' *Id.*

The Expert also found that the transcripts and recordings of UC's visits showed that Respondent ''herself doubted there was a legitimate medical need to prescribe the large amounts of opioid medications that were prescribed.'' *Id.* As the Expert noted, during the UC's May 31, 2012 visit, Respondent told the UC that his MRI showed '' 'nothing too terrible,' '' that '' 'a bulge kind of doesn't mean anything' '' and that she would not 'give narcotics for spasms.' '' *Id.* (citing GE 7, at 4–5). The Expert also observed that ''[o]n the second visit, [Respondent] said she 'certainly wouldn't just give pain medicines and narcotics so [his] working out is better.' '' *Id.* (quoting GE 9, at 5).

The Expert also concluded that there was no legitimate medical justification for the amount of oxycodone prescribed to the UC because, prior to the May 31, 2012 visit, the UC had not been seen by a pain clinic physician since January 18, 2012, and was, in all likelihood, opiate naïve at the May 31, 2012 visit. *Id.* at 5. As found above, at the May 31, 2012 visit, the UC was subjected to a drug test. GE 25, at 1. However, the UC tested negative for all controlled substances including opiates/morphine, oxycodone, and benzodiazepines. GE 11, at 39. According to the Expert, ''[p]rescribing 112 thirty milligram tablets of oxycodone in this instance was without medical justification and dangerous.'' *Id.*

With respect to the July 16, 2012 visit, the Expert noted that Respondent increased the amount of the oxycodone prescription from 112 to 140 dosage units without any medical justification. As the evidence shows and the Expert found, while the UC reported that his pain without medication was a ''2,'' he changed it only after being prompted by Respondent. *See* GE 9, at 4–5; GE 24, at 5. Also, on the ''Patients [sic] Follow-Up Sheet,'' the UC did not indicate that the pain affected any of the five listed activities and when Respondent asked if the pain affected his ''work, sleep, mood, etc,'' the UC initially answered ''no'' before adding that it affected his ''recovery time from working out.'' *Compare* GE 11, at 29, *with* GE 9, at 5. This prompted Respondent to state that ''we certainly wouldn't just give pain medicines and narcotics so your [sic] working out is better,'' to which the UC replied that he understood. GE 9, at 5. Thereafter, Respondent coached the UC to state that the pain affected his work.[31] *Id.*

Respondent also falsified the medical record at this visit by indicating that the UC's pain was made worse by ''sitting, standing in one position too long,'' as nothing in the record shows that the UC made such a claim. GE 11, at 25. And she again falsified the medical record by documenting findings for various neurological and orthopedic examination items (including a positive straight leg raise test on his left leg) when she never performed the tests. *Compare* GE 11, at 26 (visit note), *with* GE 5, V–0003, at 15:45:36–15:46:47.

Moreover, while looking at the UC's MRI, Respondent again noted that ''bulges we don't treat'' but that there was ''encroachment or . . . narrowing of the disc'' and that ''*I better put that down.*'' GE 9, at 8 (emphasis added). As with Respondent's coaching the UC to change both his pain rating and the type of activities that his pain affected from his answer of ''working out,'' this supports the inference that Respondent was looking for any justification that she could place in the chart for issuing the oxycodone prescription. Still later

[31] When asked at his second visit whether the pain affected his sleep, the UC replied ''Work'' and he had not circled ''sleep'' as being affected by his pain on the ''Patients [sic] Follow-Up Sheet'' he filled in at this visit. GE 11, at 29. As the Expert concluded, ''the record is devoid of any medical evidence justifying the need for prescribing clonazepam.'' GE 24, at 6. The Expert also found that by failing to retrieve or cancel the unfilled May 31, 2012 prescription at the July 16, 2012 visit, Respondent effectively enabled the UC to obtain twice the amount as directed by the physician when she gave him a second prescription. *Id.*

during the physical exam, the UC did not complain of any pain in his back but only of having tight hamstrings; he also again told Respondent that when he had back stiffness, this was caused by doing ''heavy squats.'' GE 9, at 12. Moreover, the UC was two weeks late for the second visit with Respondent and told her that while he had run out of medication, he was able to get some from a friend.[32] *Id.* at 10.

Based on the above, I conclude that Respondent knew that the UC was not a legitimate pain patient. I further conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing each of the controlled substance prescriptions to the UC. 21 CFR 1306.04(a).

As for D.G., I also conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to him. 21 CFR 1306.04(a). As found above, D.G. resided in Niceville, Florida, which is located nearly 600 miles from Respondent's clinic. Yet there is no evidence in any of D.G.'s records that Respondent inquired as to why D.G. was travelling these distances to obtain controlled substances from PBM.

Moreover, D.G.'s chart shows that while he obtained large prescriptions for multiple controlled substances at his first two visits at PBM, he then did not return to PBM until July 2011, seven months after his previous visit. To be sure, D.G.'s file contains a pharmacy printout showing that D.G. had obtained both oxycodone and alprazolam on multiple occasions (beginning on January 20, 2011 and ending on June 9, 2011) from a different physician who was located in Palm Beach County and yet filled each of the prescriptions in Santa Rosa Beach, Florida, which is in Walton County and near Niceville. Yet D.G.'s file contains no evidence that any inquiry was made as to why D.G. had returned to PBM. Nor is there any evidence that this other physician was contacted to determine whether D.G. was still seeing him.

While there is no evidence that D.G. obtained prescriptions at PBM at his July 6, 2011 visit, on September 7, 2011 he returned to PBM and denied having received prescription medications from other physicians as well as other sources in the last 30 days. Yet D.G. tested positive for oxycodone. Again, nothing in the chart reflects that this inconsistency was resolved. While Respondent did not treat D.G. at this visit, this information was nonetheless in his chart.

There are likely multiple legitimate pain management practices closer to Niceville, Florida than 600 miles (the distance to PBM) or 566 miles (the distance to Lake Clark Shores, where the other prescribing physician was located). Indeed, when D.G. finally presented evidence that he had made an appointment to treat his hypertension, he made the appointment with a free clinic in Destin, Florida, which is near Niceville. Yet the pharmacy profile showed that he paid cash for every prescription. GX 17, at 120–22. Likewise, given D.G.'s positive test for oxycodone while claiming that he had not obtained prescription medications from other sources clearly shows that he was non-compliant with the Pain Management Agreement he entered at his first visit.

I hold that the evidence that D.G. was travelling nearly 600 miles (one way) to obtain prescriptions at PBM, his disappearance for months only to later return, and his aberrant drug test (all of which are apparent in the chart) supports the conclusion that Respondent subjectively believed that there was a high probability that D.G. was either abusing controlled substances and/or diverting them to others. *See JM Pharmacy Group, Inc.,* 80 FR 28667, 28672 (2015) (citing *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769–70 (2011)) . As D.G.'s chart contains no evidence showing that Respondent attempted to resolve any of these issues with him, I further hold that she ''deliberately failed'' to acquire actual knowledge that D.G.'s purpose in seeking the prescriptions was to either abuse them or divert them to others. I thus conclude Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to D.G. 21 CFR 1306.04(a).

The Expert's review of D.G.'s chart buttresses this conclusion. As he explained, it was not reasonable for Respondent to rely on the evaluations done by the other providers at PBM. Indeed, at his first visit, D.G. tested negative for all drugs. As the Expert opined with respect to the UC, D.G. was likely opiate naïve. Yet Dr. Sanchez proceeded to issue D.G. prescriptions for both 150 oxycodone 30 mg and 60 oxycodone 15 mg and 60 Xanax 2 mg. This is a quantity of oxycodone even greater than the quantity Respondent prescribed to the UC at the first visit (112 du of 30 mg), which the Expert explained was without medical justification and dangerous. GE 24, at 5; *see also Roxicodone: Package Insert and Label Information, Dosage Information-Initial Dosage* (''Initiate treatment with ROXICODONE in a dosing range of 5 to 15 mg every 4 to 6 hours for pain). Thus, this dosage was more than 2.5 times the maximum recommended starting dose.

Moreover, as the Roxicodone Package Insert explains, ''[c]oncomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.'' *Id.* (Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants). Yet, Dr. Sanchez also prescribed Xanax in its strongest dosage form and neither of the visit notes contains a diagnosis of anxiety or findings that would support such a diagnosis. Indeed, at D.G.'s second visit, Sanchez drew a ''0'' next to sleep and wrote ''Ok'' next to ''Overall Mood.'' GE 17, at 126. The willingness of Dr. Sanchez to prescribe to these drugs to an opioid naive patient strongly suggests that PBM was not a legitimate medical practice but a pill mill.

Nor do the visit notes prepared by the other PBM physicians who prescribed to D.G. suggest otherwise. Indeed, it is telling that the pre-printed medication lists on which the PBM doctors would note the prescriptions they issued, includes only a single narcotic—Roxicodone—and only a single dosage form—30 mg—which just happens to be the strongest dosage of immediate release oxycodone available.

Moreover, the Expert found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history of D.G.,'' in

[32] The Expert also cited this as evidence of Respondent's failure to properly monitor the UC's compliance with his medication usage. GE 24, at 5. According to the Expert, ''before prescribing so much additional oxycodone [as she did at the July 16, 2012 visit], Respondent should have had a discussion with [UC] about his need for more medication and made specific inquiries to determine if and how [his] pain had increased.'' *Id.* The Expert thus concluded that Respondent failed to inquire or determine whether there was a legitimate medical need for the additional medication, and failed to adjust the quantity and frequency of the dose of oxycodone according to the intensity and duration of the pain and failed to justify the additional prescription on clear documentation of unrelieved pain. *Id.* And the Expert concluded that the UC demonstrated he was at risk for misusing his medications and that Registrant failed to give him the special attention required. *Id.* The Expert also concluded ''that there was serious doubt as to whether treatment goals were being achieved. Yet, there was no attempt by [Respondent] to evaluate the appropriateness of continued treatment except to increase the amount of narcotics and create a means by which [the UC] could fill his prescriptions without raising the legitimate concerns of pharmacists.'' *Id.* at 4. The Expert opined that ''there was an insufficient review of the course of treatment and the prescriptions provided by [Respondent] to [the UC] [were] inconsistent with [her] evaluation.'' *Id.* at 4–5.

that ''she relied on . . . superficial checklists which are insufficient for evaluating the types of complaints [neck and back pain] that D.G. communicated.'' *Id.* at 13. The Expert also found that D.G.'s ''records contain no evidence that [Respondent] addressed the effect of pain on D.G.'s physical and psychological function,'' even though the Florida Board's rule requires that a physician document ''the effect of the pain on physical and psychological function.'' Fla. Admin Code r. 64B8–9.013(1)(g). As the Expert observed, ''the checklist is devoid of any explanation for how D.G.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* (citing GE 23, at 39–42, 49–52, 57–60, 62–63, 65–67).

The Expert similarly found that Respondent's ''treatment plan was wholly inadequate and . . . consisted only of a checklist of recommendations.'' *Id.* The Expert noted that there is no evidence that any of the recommendations were either discussed or followed. *Id.* He also noted that while Respondent placed a checkmark suggesting that referrals to physical therapy and other specialist physicians were part of her plan for D.G., there is no evidence ''that any referrals were made.'' *Id.* at 13–14.

Finally, the Expert also found that Respondent ''prescribed additional narcotics without any medical justification.'' *Id.* at 13. The Expert specifically noted that ''on April 19, 2012, she added a prescription for [56 du of morphine sulfate [30 mg], stating that . . . D.G. needed more medication in order to continue his restaurant business and that his pain had increased at work.'' *Id.* The Expert noted that ''[t]his contradicts statements D.G. made that same day, in which he declared he was satisfied with his current medication.'' *Id.* Moreover, on the ''Patients [sic] Follow-Up Sheet'' he completed at his April 19, 2012 visit, D.G. reported the exact same pain level with medication—''3'' on a scale of 0 to 10—as he did at his previous visit. *Compare* GE 17, at 61, 71. D.G.'s record contains no further explanation as to how his pain at work had increased and how it affected his ability to function. *See generally* GE 17.

I therefore conclude that the record supports a finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the controlled substance prescriptions to D.G. 21 CFR 1306.04(a).

As for J.A., the evidence shows that he tested positive for opiates/morphine, methadone, and oxycodone at his October 24, 2011 visit to PBM, which immediately preceded his first visit with Respondent (Nov. 21, 2011). Notably, J.A.'s records showed that his previous visit to PBM was three months earlier on July 22, 2011, at which he received prescriptions for oxycodone and methadone for a 28-day supply. Moreover, at the October 24, 2011 visit, J.A. denied having seen any ''other medication prescribing pain docs.'' GE 18, at 98. While J.A.'s drug test was clearly aberrant, the October 24, 2011 visit note contains no documentation that J.A. was questioned as to why he was positive for these drugs when he had not been to the clinic in three months and denied seeing any ''other medication prescribing pain doctor doctors.''

More importantly, in the visit note Respondent prepared for J.A.'s November 21, 2011 visit, she noted that his October 24, 2011 drug screen was positive for opiates, methadone and oxycodone, and yet there is no evidence that Respondent questioned J.A. as to why he was positive for these drugs given his absence from the clinic and his having denied seeing other pain doctors. Here again, this evidence supports a finding that Respondent was willfully blind to J.A.'s likely purpose in seeking the prescriptions. She nonetheless issued him prescriptions for 140 Roxicodone 30 mg and 28 Xanax 1 mg, the latter being prescribed for anxiety.[33]

As to the latter prescription, while Respondent checked ''insomnia'' but not ''anxiety'' as one of her diagnoses, Respondent made no findings to support either diagnosis. Indeed, on the ''Patients [sic] Follow-Up Sheet,'' J.A. did not circle any of the six items (which included social activities and sleep) as being affected by his pain. Moreover, the Expert found that Respondent failed to conduct an adequate physical examination or take a satisfactory medical history to properly evaluate J.A.'s complaints. GE 24, at 14. The Expert also found that J.A.'s file ''contains no evidence that [Respondent] addressed the effect of pain on J.A.'s physical and psychological function.'' *Id.* at 15.

The Expert further found that Respondent's treatment plan was wholly inadequate. *Id.* Indeed, while in the Plan section of the visit note, Respondent checked the line for referrals and circled the word ''neurology'' to suggest that she was making such a referral, there is no evidence that any such referral was ever made or that J.A. ever went to a neurologist.[34] *Id.* Moreover, while in the December 19, 2011 visit note, Respondent wrote that if J.A. did not obtain a ''neuro'' consultation ''by Feb 2011'' [sic], he ''cannot cont. meds,'' GE 18, at 85, Respondent continued to prescribe both Roxicodone 30 mg and Xanax at each of J.A.'s monthly visits which occurred through June 4, 2012. While Respondent did eventually reduce J.A.'s Xanax prescription to the .5 milligram dosage form, at no point did she make findings to support her diagnosis of anxiety or insomnia.

Moreover, notwithstanding J.A.'s failure to comply with her instruction that if he did not obtain a ''neuro consult'' by his February visit, she would not continue the prescriptions, at the February 2012 visit, Respondent increased his Roxicodone 30 prescription to 168 dosage units. *Id.* at 69. On the visit note, Respondent noted: ''increase due to need to have ↓pain to work as server.'' *Id.* The Expert explained that Respondent's decision to increase the prescription was ''based solely on the bald statement that the patient needed 'to have less pain to work.' '' GE 24, at 14. The Expert further explained that this statement did not provide a ''medical justification'' to support the increase in the prescription. *Id.*

Of further note, while at J.A.'s first visit to PBM in February 2011, he reported that he had previously been treated by other physicians for his pain and provided signed release forms, GE 18, at 4, 19; the only such records obtained (other than an MRI report) was for his ER visit in May 2001, a decade earlier. As the Expert explained in discussing the UC's file, ''[i]n completing a sufficient medical history, it is important to review the records of other physicians who have treated the patient.'' GX 24, at 3. Of further note, Respondent saw J.A. eight times over the course of seven months and yet never obtained records from treating physicians other than those who

[33] Respondent noted under ''new events since last visit'' that J.A. reported that he lost his Xanax and gabapentin prescriptions on his January 16, 2012 visit with Respondent, and Respondent again noted that he ''lost Xanax 2 days'' on the medications sheet. GE 18, at 76, 78. While there is no other notation by Respondent that she discussed the lost medications with J.A., she wrote him a new prescription for 28 tablets of .5 mg Xanax along with prescriptions for the other medications.

[34] Even at J.A.'s February 2012 visit, which purportedly was the cut-off date for him to obtain a neurological consultation, Respondent noted: ''Pt. wants neuro sx [surgical] opinion.'' GE 18, at 68. There is, however, no notation as to why J.A. never got this opinion in the course of his seeing Respondent.

J.A.'s chart also states that at his first visit, the attending physician recommended that he obtain an orthopedic evaluation. GE 18, at 133. Here too, there is no evidence that J.A. ever obtained an orthopedic evaluation.

attended J.A. during the May 2001 ER visit.

Accordingly, I find that the record supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to J.A. 21 CFR 1306.04(a).

Turning to Respondent's prescribing to D.B., as the Expert noted, the history of the origin of his pain changed multiple time during the course of his visits to PBM. Significantly, at his initial visit, D.B. noted that his pain had started had three years earlier and he answered ''No'' as to whether there was ''an inciting event[] (Such as a car accident).'' GE 14, at 13. One month later, his pain was of five years duration and had been precipitated by a car accident. *Id.* at 50. And one month later, when Respondent saw him for the second time,[35] the duration of his pain had increased to nine years. *Id.* at 60. The Expert found D.B.'s changing story regarding the origin of his pain to be highly suspicious. GE 24, at 10. And the Expert also found it suspicious that D.B. resided in Okeechobee, Florida, approximately 95 miles from PBM, and yet was travelling to PBM to obtain prescriptions. *Id.* As the Expert noted, there is ''nothing in the medical file to explain why D.B. would travel so far to obtain [the] prescriptions.'' *Id.* Moreover, the Expert also noted that while D.B. told Respondent that the three pharmacies would not fill the oxycodone 30 and Xanax prescriptions he obtained from a different doctor one week earlier, Respondent ''also failed to investigate why [he] was allegedly refused service by'' the pharmacies. *Id.*

The Expert further noted that at D.B.'s initial visit, he reported that his pain level was a 2 with medication and his drug screen results showed that he was negative for all drugs including oxycodone and opiates/morphine. GE 24, at 10; *see also* GE 14, at 10, 13. According to the Expert, ''having tested negative for all controlled substances and having no prescription history, D.B. was an opioid naïve patient.'' GE 24, at 10. While a different doctor prescribed ''a large quantity of narcotics'' (112 du of hydrocodone 10 mg), when D.B. returned for his second visit, he then complained of that pain level on medication had increased to ''3.'' *Id.* Moreover, even after Respondent changed his prescription to 112 Dilaudid 8 mg, which the Expert characterized as ''an enormous increase in the amount of opioid medication'' over his prior hydrocodone prescription, at his next visit, D.B. reported that his pain had increased to ''4'' with medication. *Id.*

Based on the ''red flags'' of the distance D.B. was travelling, the changes in his story of how and when his pain originated, his story of being unable to fill the prescriptions at three different pharmacies, and his report of increasing pain levels even after being prescribed large and increasing dosages of narcotics, the Expert concluded that D.B. ''was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion'' and that Respondent ''failed to monitor [D.B.'s] compliance in medication usage and failed to give special attention to'' him. *Id.; see also* Fla. Admin. Code r.64B8–9.013(1)(e). Moreover, based on these circumstances, I find that Respondent subjectively believed that there was a high probability that D.B. was seeking the medications to either abuse them or divert them to others, and deliberately failed to acquire actual knowledge of his purpose in obtaining the prescriptions.

The Expert also found that ''the medical history and physical examinations of D.B.'' that were done by the other doctor at PBM were ''inadequate and that it was not reasonable [for Respondent] to rely on [those] evaluations.' '' GE 24, at 9. The Expert further found that Respondent did not ''conduct[ ] an adequate physical examination or t[ake] a satisfactory medical history,'' and she ''relied on the superficial checklists which are insufficient for evaluating the types of complaints that D.B. communicated.'' *Id.*

Moreover, as the Expert explained in discussing the UC, in determining a patient's pain history, ''it is important to review the records of other physicians who have treated the patient.'' *Id.* at 3. While D.B. noted on the form he completed at his first visit to PBM that he had ''seen . . . other doctors for this pain,'' GE 14, at 13, his file contains no records from any physician who treated him for his back pain.[36] *See generally* GE 14.

The Expert also found that Respondent's ''records contain no evidence that [she] addressed the effect of pain on D.B's physical and psychological function,'' and that ''[t]he checklist is devoid of any explanation for how D.B,'s pain affected his social activities, mobility, work, exercise or sleep.'' GE 24, at 9. The Expert further found that Respondent ''prescribed both clonazepam for anxiety and zolpidem for insomnia, [but] fail[ed] to record any information whatsoever to justify these prescriptions other than baldly noting that D.B. *had* anxiety and insomnia.'' *Id.* The Expert also noted that on May 31, 2012, Respondent increased D.B.'s clonazepam prescription ''without any justification.'' *Id.*

With respect to Respondent's treatment plan, the Expert found that it ''was wholly inadequate and, again, consisted only of a checklist of recommendations,'' and that there was no ''evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert also noted that while Respondent ''recommended 'glucosamine/Chondroitin Sulfate,' and stated that that she will 'refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, psychiatrist, addiction specialist as needed[,]' [t]here is no evidence that any of these alternative measures were attempted, [or] that any referrals were made.'' *Id.*

Based on the above, I conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to D.B. Indeed, with respect to D.G., J.A., and D.B., the Expert concluded that Respondent ''provided them with prescriptions for controlled substances in contravention of the standards of care and practice in the State of Florida and with indifference to various indicators or 'red flags' that the patients were engaged in drug abuse and/or diversion.'' *Id.* at 6.

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

The Government argues that Respondent's acts in providing the UC with two Ibuprofen prescriptions to help him fill his controlled substance prescriptions without suspicion constitute conduct to be considered under Factor Five (such other conduct which may threaten the public health and safety). RFAA, at 19. It contends there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Id.* (citing *Zvi H. Perper, M.D.,* 77 FR 64131, 64141 (2012) (*quoting Tony T. Bui,* 75 FR 49979, 49988 (2010))).

In *Perper,* the Agency adopted the ALJ's legal conclusion that the act of providing a prescription for a non-

[35] Respondent had seen D.B. three weeks earlier when he reported that he could not fill the oxycodone 30 and Xanax prescriptions written by another PBM doctor.

[36] Of further note, on several progress notes, Respondent circled ''Y'' next to the entry for ''Psych visits/SS Disability past 5 yr[s].'' *See* GE 14, at 60 (Mar. 27 visit), 66 (April 24 visit), 76 (May 31 visit), and 83 (June 28 visit). Yet no such records are in his file.

controlled drug such as Ibuprofen so as not to arouse a pharmacist's suspicion as to the legality of a controlled substance prescription and induce him to fill the prescription constitutes actionable misconduct under Factor Five. *See* 77 FR at 64141. Such conduct is, in essence, a form of subterfuge, and may threaten public health and safety by inducing a pharmacist into believing a controlled substance prescription is lawful rather than questioning its validity and refusing to fill it. *Cf.* 21 U.S.C. 843(a)(3) (''It shall be unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'').

Here, the evidence shows that at the UC's first visit, Respondent told him that she ''was gonna [sic] give you some ibuprofen. Because if you['re] filling in Florida which I encourage you to do so you're on the computer list. Then . . . for two reasons: Number one, the pharmacists usually want a non-prescription drug, a non-controlled substance drug rather . . . and ibuprofen is also good for inflammation.'' GE 7, at 6.

At his second visit, the UC told Respondent that a pharmacist refused to fill the Klonopin prescription she had issued previously. GE 9, at 9. Respondent advised the UC to take the prescription to another pharmacy and told him that it is not doctor-shopping if the pharmacist refused to fill the prescription; she also told the UC that she would ''write that [Klonopin] and I'll write another non-narcotic.'' *Id.* at 10. Respondent subsequently stated she would ''give [the UC] two small prescriptions'' for ibuprofen and ''one narcotic for each pharmacy that [he] might have to go to.'' *Id.* at 16. She added ''I want you to keep the extra ibuprofen so if they won't fill the Klonopin again you have another non-narcotic to use.'' *Id.* at 17.

In advising the UC how to avoid encountering difficulties in filling his prescriptions for controlled substances and in issuing non-narcotic prescriptions to minimize any suspicions by pharmacists, Respondent engaged in ''[s]uch other conduct which may threaten the public health and safety''). *See Perper,* 77 FR at 64141. *Cf. Nelson A. Smith,* 58 FR 65403, 65404 (1993) (holding that using strategies ''to avoid detection . . . such as falsifying patients charts and suggesting that the recipients of . . . illegal prescriptions go to different pharmacies'' is actionable misconduct under Factor Five).

I therefore hold that the Government's evidence with respect to Factors Two, Four, and Five establishes that Registrant ''has committed such acts as would render her registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because Respondent waived her right to a hearing (or to submit a written statement in lieu of a hearing), there is no evidence in the record to refute the conclusion that her continued registration is ''inconsistent with the public interest.'' *Id.* Accordingly, I will order that Respondent's registration be revoked and that any pending applications 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 Certificate of Registration No. AS1456361, issued to Marcia L. Sills, M.D., be, and it hereby is, revoked. I further order that any pending application of Marcia L. Sills to renew or modify the above registration, or any pending application of Marcia L. Sills for any other registration, be, and it hereby is, denied. This Order is effective September 5, 2017.

Dated: July 27, 2017.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–470P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2017

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2017 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before September 5, 2017. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2017 adjusted aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–470P'' on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.