

pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: March 27, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018-06565 Filed 3-30-18; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140-0031]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension without Change of a Currently Approved Collection; Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Implements of War on the U.S. Munitions Import List

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

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. **DATES:** Comments are encouraged and will be accepted for 60 days until June 1, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information

collection instrument with instructions, or desire any additional information, please contact Desiree Dickinson either by mail at Firearms and Explosives Imports Branch, 244 Needy Road Martinsburg, WV 25405, by email at desiree.dickinson@atf.gov, or by telephone at (304) 616-4584.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection* (check justification or form 83): Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Implements of War on the U.S. Munitions Import List.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number (if applicable): None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for profit. *Other (if applicable):* None.

Abstract: This information collection involves records of imported items that are on the United States Munitions Import List. The importers must register with ATF, file an intent to import specific items, as well as certify to the

Bureau, that the list of imported items were received. The records are maintained at the registrant's business premises where they are available for inspection by ATF officers during compliance inspections or criminal investigations.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50 respondents will utilize this information collection, and it will take each respondent approximately 5 hours to provide a response.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 250 hours, which is equal to 50 (total # of responses) * 5 (# of hours to provide each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: March 28, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018-06593 Filed 3-30-18; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bernard Wilberforce Shelton, M.D.; Decision and Order

On February 16, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, issued an Order to Show Cause to Bernard Wilberforce Shelton, M.D. (hereinafter, Registrant), which proposed the revocation of his DEA Certificates of Registration Nos. BS9770961 and FS6457407, as well as the denial of any pending application to renew these registrations or for any other registration. GX 2, at 1. As grounds for the proposed actions, the Government alleged that Registrant's continued registration is "inconsistent with the public interest" and that he is without state authority to handle controlled substances in the State of Michigan, the State in which he holds his registrations. *Id.* at 1-2 (citing 21 U.S.C. 824(a)(3) and (4), 823(f)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Registrant holds two

registrations, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a practitioner in the State of Michigan: No. BS9770961, at the registered address of 30140 Harper Avenue, Suite #300, Saint Clair Shores, which was due to expire on February 28, 2018, and No. FS6457407, at the registered address of 21700 Greenfield Road, Suite 130, Oak Park, which expires on February 29, 2020. *Id.* at 1.

As to the substantive grounds for the proceeding, the Show Cause Order alleged that the Michigan Department of Licensing and Regulatory Affairs (hereinafter, DLRA) summarily suspended Registrant's Michigan Medical License on January 12, 2017, and that pursuant to Mich. Comp. Laws § 333.7311(6), "a controlled substance license is automatically void if a licensee's license to practice is suspended or revoked under Article 15 of the Code." *Id.* at 2. The Order alleged that as a result of the DLRA's action, Registrant "is without authority to handle controlled substances in the State of Michigan," and "[c]onsequently, DEA must revoke [his] DEA registration." *Id.* (citing 21 U.S.C. 824(a)(3)).

Next, the Show Cause Order alleged that Registrant violated Federal law on numerous occasions when he issued controlled substance prescriptions to four patients outside the usual course of professional practice and for other than a legitimate medical purpose, and that these "multiple instances of unlawful prescribing in violation of federal law weigh[] in favor of the revocation of [his registration]." *Id.* at 2 (citing 21 U.S.C. 841(a)(1), 823(f)(2) and 823(f)(4) and 21 CFR 1306.04). The Order also alleged that Registrant's prescribing to the four patients violated Michigan law, *id.* (citing Mich. Comp. Laws §§ 333.7401(1), 333.7333, 333.7405(1)(a)), and the Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain (hereinafter, Michigan Guidelines). *Id.* at 2–3.

The Show Cause Order then alleged that between October 2013 and February 2016, Registrant failed to comply with Federal and State law and the Michigan minimal standards when he issued controlled substance prescriptions to an undercover investigator (hereinafter, UC) and three other patients, D.S., A.L. and R.H. *Id.* at 3–10.

Specifically, the Show Cause Order alleged that on April 1, May 1 and June 15, 2015, Registrant issued prescriptions to the UC for hydrocodone-acetaminophen, a schedule II controlled substance, and alprazolam, a schedule

IV controlled substance, which were not for a legitimate medical purpose and outside the scope of professional practice. *Id.* at 3–6 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)). The Order alleged that Registrant issued the controlled substance prescriptions to the UC "without undertaking actions typical of medical professionals or in accordance with the Michigan Guidelines, such as conducting and documenting a complete medical history, conducting a physical examination, or properly assessing the needs of [the UC] for controlled substances." *Id.* at 3. The Order further alleged that Registrant did not make any attempt to address or resolve numerous "red flags that [the UC] was abusing and/or diverting controlled substances" before issuing the controlled substance prescriptions to him. *Id.* at 3–6. Further, it alleged that Registrant's medical records for the three visits "contain multiple false or misleading statements which [are] inconsistent with the Michigan Guidelines standard that medical records are to be "accurate and complete"" and gave numerous specific examples. *Id.* at 4–6.

Next, the Show Cause Order alleged that Registrant issued a total of 73 prescriptions to patients D.S., A.L., and R.H., "despite failing in most instances to conduct an appropriate medical examination and meeting the minimal medical standards required under Michigan law in prescribing controlled substances (or documenting such in the patient's file)," in violation of Federal and Michigan law. *Id.* at 6–9 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)).

Specifically, the Show Cause Order alleged that "[f]rom on or about January 12, 2015, through on or about February 29, 2016," Registrant issued to D.S. 14 prescriptions for oxycodone 30 mg, a schedule II controlled substance; two prescriptions for phendimetrazine tartrate 105 mg, a schedule III controlled substance; four prescriptions for phentermine 37.5 mg and five prescriptions for Ultram (tramadol) 50 mg, both schedule IV controlled substances. *Id.* at 7. The Order also alleged that Registrant "issued these orders despite the presence of . . . red flags that D.S. was abusing and/or diverting controlled substances," including a Michigan Automated Prescriptions Report (MAPS) which showed "that D.S. had been prescribed combinations of opioids, benzoids and stimulants" between February and June 2011, by up to three different medical

providers; that his "medical records indicate that D.S. was likely suffering from drug dependence"; and that "D.S.'s urine drug tests showed signs of dangerous drug use or dependency," including positive results for methadone, cocaine and amphetamines when none of these drugs had been prescribed in the previous month. *Id.* at 7. The Order further alleged "there is no documentation in D.S.'s medical records demonstrating that [Registrant] conducted any appropriate medical examination or review to address or resolve these indicators of possible abuse and/or diversion." *Id.* at 8.

With respect to A.L., the Show Cause Order alleged that between October 17, 2013 and May 6, 2014, Registrant issued to her three prescriptions for Norco (hydrocodone/acetaminophen), then a schedule III controlled substance; three prescriptions for Adipex (phentermine) 37.5 mg, two prescriptions for Xanax (alprazolam) 2 mg, and three prescriptions for Soma (carisoprodol) 350 mg, and authorized two refills for each prescription. *Id.* at 8. The Order alleged that the combination of hydrocodone, alprazolam and carisoprodol is a drug "cocktail" known as the "Holy Trinity" and "is widely known to be abused and/or diverted." *Id.* The Order also alleged that on three occasions in 2011, Registrant prescribed to A.L. "another variation of the Holy Trinity cocktail," substituting Roxicodone (oxycodone) for hydrocodone and that "[t]here is no documentation in A.L.'s medical records demonstrating any legitimate medical need for prescribing her that cocktail." *Id.*

The Show Cause Order further alleged A.L.'s medical records show that she presented various red flags and that "there is no documentation in [her] medical records demonstrating that [Registrant] conducted any appropriate medical examination or review to address or resolve these indicators of possible abuse and/or diversion." *Id.* at 8–9. The Order alleged that these included a MAPS report dated January 24, 2011 showing that A.L. "had been prescribed combinations of opioids, benzoids, and stimulants by up to eight different medical providers" between January 2010 and January 2011, and that this combination of stimulants with opioids or benzoids or both is known to drug users as "speed-balling." *Id.* at 8–9.

The Order also alleged that on a "Health History Questionnaire" which A.L. completed when she first became Registrant's patient, she listed the drugs she was currently taking as including Roxicodone, Xanax and Soma, and that

this combination “also constitutes the ‘Holy Trinity’ drug cocktail.” *Id.* at 9. The Order further alleged that a Feb. 25, 2013 chart entry showed that A.L. was possibly engaged in diversion as it states: “She says she cannot get her pain medications and has to be buying it off the streets to satisfy her pain. The last time she was given pain medication from this office was in September of last year.” *Id.*

With respect to patient R.H., the Show Cause Order alleged that from June 2015 through February 24, 2016, Registrant issued to him 10 prescriptions for Norco (hydrocodone-acetaminophen ¹) 10/325 mg, 10 prescriptions for morphine sulfate 30 mg tablets, and 10 prescriptions for morphine sulfate 100 mg tablets, each of these being a schedule II controlled substance; five prescriptions for alprazolam 1 mg; and two prescriptions for Soma (carisoprodol) 350 mg tablets. *Id.* The Order again alleged that “there [was] no documentation in R.H.’s medical records demonstrating any legitimate medical need for prescribing him the [combination of Hydrocodone, Alprazolam and Carisoprodol drugs known as the] Holy Trinity cocktail,” “which is widely known to be abused and/or diverted.” *Id.*

The Show Cause Order also alleged that on six other occasions in 2011, Registrant prescribed other variations of this cocktail to R.H. despite the presence of red flags in his medical records. *Id.* at 10. Specifically, the Order alleged that Registrant’s “medical records indicated that R.H. was possibly suffering from drug dependency” because the “medical chart dated December 21, 2011 states ‘he [sic] is taking the valium three times ad [sic] although he is given it twice daily so he runs out early [sic].’” *Id.*

The Show Cause Order further alleged that R.H.’s urine drug test results showed signs of dangerous drug use or drug dependency. The Order alleged that on seven occasions during 2015 through 2016, R.H. tested positive for amphetamines and that on three occasions during 2015, he tested positive for benzodiazepines and that Registrant “had not prescribed” either class of drugs to him in the months preceding the positive results. *Id.* Finally, the Order alleged that “[t]here is no documentation in R.H.’s medical records demonstrating that [Registrant] conducted any appropriate medical

examination or review to address or resolve these indicators of possible abuse and/or diversion.” *Id.*

The Show Cause Order then asserted that Registrant “fail[ed] in most instances to conduct an appropriate medical examination” and failed to meet “the minimal medical standards required under Michigan law in prescribing controlled substances (or documenting such in the patient’s file).” *Id.* at 9 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)). The Order further asserted that Registrant’s conduct “completely betrayed any semblance of legitimate medical treatment” in that he “failed to take reasonable steps, like conduct medical examinations, to guard against diversion of controlled substances.” *Id.* at 10 (citing *Jack A. Danton* 76 FR 60,900 (2011); *Hatem M. Ataya* 81 FR 8221 (2016) (other citations omitted)).

The Show Cause Order notified Registrant of his 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 11 (citing 21 CFR 1301.43). The Show Cause Order also notified Registrant of his opportunity to submit a Corrective Action Plan in accordance with 21 U.S.C. 824(c)(2)(C). *Id.* at 11–12.

On February 23, 2017, a DEA Special Agent and a Diversion Investigator (DI) personally served Registrant with the Order to Show Cause at his office located at 30140 Harper Avenue, Suite #300, Saint Clair Shores, Michigan. GX 31 (Declaration of Special Agent), at 4. According to the Agent, Registrant signed a DEA Receipt for the Show Cause Order. *Id.*, see also GX 29.

On May 8, 2017, the Government filed its Request for Final Agency Action (RFAA) with my Office and forwarded the evidentiary record, stating that more than 30 days have passed since Registrant was personally served, and DEA has not received a request for a hearing or any other reply from Registrant. RFAA, at 1.

Based on the Government’s representations that more than 30 days have now passed since the date of service of the Show Cause Order and that Registrant has not submitted a request for a hearing or any other reply including a Corrective Action Plan, I find that Registrant has waived his right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant evidence contained in the

record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Findings of Fact

Registrant is the holder of DEA Certificate of Registration No. FS6457407, pursuant to which he is authorized to dispense controlled substances in schedules II–V, at the registered location of 21700 Greenfield Road, Oak Park, Michigan. GX 1 (Copy of Registrations). This registration does not expire until February 29, 2020. *Id.* Registrant also held DEA Certification of Registration No. BS9770961, pursuant to which he was authorized to dispense controlled substances at the registered location of 30140 Harper Avenue, Suite #300, in Saint Clair Shores. *Id.* He was also authorized, under DATA-Waiver Identification Number XO9770961, to dispense Suboxone and Subutex to up to 100 opiate-addicted patients pursuant to the Drug Addiction Treatment Act of 2000 (DATA). *Id.*; see 21 U.S.C. 823(g)(2). However, Registration No. BS9770961 and DATA-Waiver Identification No. XO9770961 expired on February 28, 2018, when Registrant failed to renew this registration.

Registrant holds a license to practice medicine in the State of Michigan, as well as several controlled substance and drug control licenses issued by the Michigan Board of Pharmacy. GX 30, at 1–2. However, on January 12, 2017, the Director of the Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs (DLRA), ordered the summary suspension of Registrant’s medical license based on the Department’s “find[ing] that the public health, safety, and welfare requires emergency action.” See GX 30, at 1. The Order also stated that “[Public Health] Code § 7311(6) provides that a controlled substance license is automatically void if a licensee’s license to practice is suspended or revoked.”²

According to the online records of the DLRA, of which I take official notice, see 5 U.S.C. 556(e),³ on July 12, 2017,

² According to the website of the Michigan Department of Licensing and Regulatory Affairs, Registrant held: a Pharmacy CS–3 license 5315079480, which was issued on November 23, 2016 but is currently in a “lapsed” status; a Pharmacy Drug Treatment Program Prescriber license 5304001334, which was issued November 3, 2016 but is currently in “lapsed” status; and a Pharmacy Drug Control Location license 5315079209, which was issued November 14, 2016 but is also currently in “lapsed” status. See <https://w2.lara.state.mi.us>.

³ In the RFAA, the Government noted that it had been notified by the DLRA that a settlement had been reached with Registrant subject to Board approval; however, the Consent Order had not been issued at the time the RFAA was submitted to my

¹ Effective October 6, 2014, combination hydrocodone drugs were moved from schedule III to schedule II. See DEA, *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combinations Products from Schedule III to Schedule II*, 79 FR 49661 (2014).

Registrant entered into a consent order with the Board of Medicine pursuant to which the summary suspension was dissolved but his medical license was suspended for 15 months to include the period “during which the order of summary suspension was in effect.” See *In re Bernard Wilberforce Shelton, M.D.*, No. 43–16–140510, Consent Order at 2 (Mich. Bd. of Med., July 12, 2017). The Consent Order further ordered that “[r]einstatement of [Registrant’s] license shall not be automatic” and he must petition for reinstatement. *Id.* Under the consent order, to obtain reinstatement, “Respondent must demonstrate . . . by clear and convincing evidence: (1) Good moral character; (2) the ability to practice the profession with reasonable skill and safety; (3) satisfaction of the guidelines on reinstatement adopted by the Department; and (4) that it is in the public interest for the license to be reinstated.” Consent Order, at 2.

The DLRA also required that Registrant pay a \$10,000 fine. *Id.* I also take official notice that Respondent’s medical license remains suspended as of the date of this Decision and Order. See also <https://w2.state.mi.us>.

The Investigation

In January 2015, DEA began its investigation of Registrant after receiving information from the St. Clair Shores Police Department and Michigan Blue Cross/Blue Shield (MBCBS) about the investigation they were conducting of Registrant. GX 31, at 1 (Declaration of Special Agent). DEA then initiated this investigation, which included supervising three undercover visits by an MBC/BS investigator (hereinafter, also referred to as UC) to Registrant at his office in St. Clair Shores. *Id.* at 1–2; see also GX 8. As part of the investigation, on September 29, 2015, a Special Agent (SA) and a Diversion Investigator (DI) interviewed Registrant. GX 31, at 2–3.

During the interview, Registrant informed the SA and DI about “his [patient] protocols . . . including how his office conducts drug screens and his new patient procedures, how he conducts physical exams on his patients, and how he determines what

controlled substances to prescribe over time.” *Id.* at 2. According to the SA, in the interview he “also discussed with [Registrant] his patient ‘James Howard’ (the MBC/BS investigator), specifically discuss[ing] the three visits and how Mr. Howard’s diagnoses were determined, . . . reviewed the associated patient records, discussed his urine drug screen results and how those were evaluated, and . . . discussed the controlled substances [Registrant] had prescribed to” the investigator. *Id.*

The same day, the St. Clair Shores Police Department executed a state search warrant at Registrant’s office and a second warrant at his residence. *Id.* at 2–3. During the execution of the warrant, the SA and another SA conducted a second interview with Registrant, who “stated that he conducts physical exams on his patients and that he can do an exam by looking at the patient.” *Id.* at 3.

On approximately February 22, 2016, the SA subpoenaed various patient records, and Registrant provided copies of the electronic patient records that were requested. *Id.* The SA also subpoenaed Registrant’s records for specific patients, including those of D.S., A.L., and R.H., from Network Technology Inc., d/b/a RXNT, a firm which develops and implements products related to electronic health records and electronic prescribing. *Id.* at 2–3. On June 22, 2016, after reviewing MAPS and RxNT’s records to identify specific prescriptions, the SA also subpoenaed from various pharmacies copies of the prescriptions issued by Registrant to various patients, including D.S., A.L., and R.H. *Id.* Subsequently, the SA also subpoenaed and obtained from Registrant the patient records of the MBC/BS Investigator. *Id.*

The Undercover Visits

On April 1, 2015, the MBC/BS Investigator (UC) conducted the first of three undercover visits to Registrant at his St. Claire Shores Medical office. GX 12, at 5. During each visit, he posed as patient D.H., whose occupation was driving. *Id.* The investigative record includes video recordings of each of his visits, transcripts of the recorded visits, his medical file, and photographs of the vials containing the filled controlled substance prescriptions issued by Registrant. GXs 3–12.

At the visit, the UC filled out new patient paperwork which included a registration form, a health history questionnaire, a pain questionnaire, and signed a narcotics contract. GX 12, at 5, 6–9, 11–12, 13–14. On the Health History Questionnaire, the UC wrote the name of a referring doctor and stated

that his last exam had been in the “summer 2014,” and that “Nerves” and “Back” were “medical problems that other doctors have diagnosed.” *Id.* at 6. Under “prescribed drugs,” he wrote “Zanax [sic] Strength 1 Frequency Taken 2.” *Id.* at 7. He left the “Health Habits and Personal Safety” section mostly blank, including questions about his alcohol intake and recreational or street drug use. *Id.* at 7–8. In the Mental Health section, he circled “no” as his answer to the questions: “Is stress a major problem for you?”; “Do you feel depressed?”; “Do you feel panic when stressed?”; and “Have you ever been to a counselor?” *Id.* at 9. He circled “yes” to the question “Do you have trouble sleeping?” *Id.*

The UC also filled out a Pain Questionnaire. *Id.* at 11. This consisted of a body diagram where he circled the lower back portion, and a section where he was to circle words describing his pain, such as “Aching, Stabbing, Gnawing, Sharp, Burning, Exhausting, Tiring, Nagging, Numb, Miserable or Unbearable.” UC did not, however, circle any of these descriptors, and instead, wrote “Stiff.” *Id.* He indicated that his pain was “worst” in the morning, but left blank four questions which asked him to rate his pain level at its worst, least, average for the month, as well as “right now,” on a scale of one to ten. *Id.* He wrote that “Meds” made his pain better, and left blank what made it worse. *Id.* at 12. He circled “None” in answer to “what treatment or medication are you receiving for your pain?” *Id.* He also left blank a series of questions asking him to rate the level of interference of pain on his general activity, mood, normal work, sleep, enjoyment of life, ability to concentrate, and relationships with other people. *Id.* He signed and dated this form “7–9–70.” *Id.* A section at the bottom of the form for Notes, Action Plan details and the Clinician’s Signature are blank. *Id.*

UC also signed a narcotic contract, stating that he would use a Walgreens pharmacy. *Id.* at 13–14.

The video recording and transcript of the visit show that after he filled out the paperwork, he saw a nurse in an exam room, who asked a series of questions from a form while taking notes, including: “Have anxiety? I noticed that you take uh . . .” GX 4, at 3. UC stated “I don’t know what you call it. . . uh . . . you know my nerves get jacked up and what not. I don’t know what you call it.” *Id.* UC added that he took Xanax and Norco, and that he had previously seen a physician in Flint, but it was “too far and I travel a lot.” *Id.*; GX 3, Video Recording (VR) 2, at 15:45:20–15:46:41.

office. RFAA, at 2 n.1. Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” U.S. Dept. of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). While under DEA’s regulations, “any party, on timely request, shall be afforded [an] opportunity to controvert such fact,” 21 CFR 1316.59(e), Registrant waived his right to a hearing or to submit a written statement and is therefore not entitled to refute my findings with respect to the Consent Order.

The nurse asked: "As far as your medical history goes you want me just . . . to put anxiety down?" GX 4, at 3. UC stated: "Whatever you call that, I don't know what the word," which prompted the nurse to ask: "What brings you here?" *Id.* UC answered: "Just to get Xanax refills." *Id.* The nurse then asked UC if he "had pain anywhere?" and UC answered: "Ah . . . like my back is stiff. But I don't know . . . Pretty much a stiff back. I drive a lot and what not, know what I'm saying." *Id.* at 3–4; GX 3, VR 2, at 15:46:41–15:47:11.

Following a discussion of Registrant's background, the Nurse then told UC that Registrant "drug test[s] everybody." GX 4, at 4. As the Nurse proceeded with obtaining his weight, UC said that he was "cool," that he did not "want to cause any problems for anybody" including Registrant, and that he was "[m]ore or less healthy. You know what I'm saying?" *Id.* at 4–5; GX 3, VR 2, at 15:47:11–15:48:48.

After determining UC's marital status, the nurse said: "So, basically, you don't even—you don't have any problems besides the little bit of anxiety and your back gets stiff because of driving." GX 4, at 5. UC replied: "Yeah, yeah. You got it." *Id.*; *see also* GX 3, VR 2, at 15:48:48–15:49:22.

The nurse continued to take UC's vitals as the two discussed his work as a driver, after which UC mentioned a patient in the lobby who, in UC's words, was "yip-yapping and jaw-jacking." GX 4, at 6–7. The nurse denied that patients could easily get their prescriptions and stated that patients were tested and "if they have other stuff in their system they cannot get their script . . . because they could drop dead if they mix." *Id.* at 7–8. Continuing, the nurse stated that Registrant is "really strict about that" and UC said: "The worst thing I do is drink moonshine here and there. Little liquor on the weekends you know. But when I take that Xanax, I'm pretty chilled, so I don't really need to drink too much. You know it keeps me from getting stupid." *Id.* at 8; GX 3, VR 2, at 15:49:22–15:53:59.

As the nurse continued to review UC's medical history and discussed various subjects with him, UC noted that a sign on the wall "says our office is no longer writing prescriptions for . . . ah . . . oxycodone or [R]oxicodone. Is that what that says?" GX 4, at 11. The nurse replied: "I don't think it says that. He writes that." *Id.* UC pointed out where he read the statement, and the nurse replied that "it's for people that come in here just one time . . . [T]hey can't come in here

(unintelligible).⁴ *Id.* at 11–12; *see also* GX 3, VR 2 at 15:53:59–16:01:44.

Registrant eventually entered the exam room, greeted UC while donning a headphone set connected to the computer, resolved an issue with another patient, and appeared to dictate and record into the computer while he spoke to UC. GX 4, at 14. The nurse informed Registrant that UC was a new patient, and Registrant read aloud UC's height, weight, age and occupation from the computer screen. *Id.* at 16; *see also* GX 3, VR 3, at 16:16:23–16:19:39.

Registrant confirmed with UC that he drove for a living, and asked: "And you have pain or what?" "What is your problem mostly?" GX 4, at 17. UC stated: "My back gets stiff because I drive a lot so sitting down too much. My back, you know, so it's stiff pretty much." *Id.* Registrant determined that UC did not have a CDL (commercial driver's license) and asked, "You don't use methadone?" UC responded: "Absolutely not. I use moonshine. You know what that is?" *Id.* Registrant asked: "Too much?" UC answered: "No" and "You know if I take that Xanax it keeps me from drinking too much so it works out good." *Id.* at 17–18; GX 3, VR 3, at 16:19:40–16:21:22.

Registrant then asked: "So what can I give you today to help you out?" *Id.* UC answered: "Usually Xanax helps me out. And Norco helps my back. That's all I really need. I don't have any—I'm pretty healthy." GX 4, at 18; GX 3, VR 3, 16:21:27–16:21:41.

Thereafter, Registrant resolved a problem with accessing the dictation software on his computer and began dictating into it, stating that UC "is here for his first visit. . . . He is suffering also from anxiety and back spasms due to his long sitting. He currently does not have a CDL." GX 4, at 18. After UC told Registrant that he drove eight to 12 hours a day, Registrant stated: "He denies drinking or using any stimulants such as methadone." *Id.* Registrant then asked whether UC was diabetic, and after UC said that he was not, Registrant dictated: "He only uses Xanax occasionally for his anxiety. . . . Today, he is complaining mostly of some level of anxiety." *Id.* Registrant then asked UC if he had ever seen a psychiatrist and UC answered: "No, if I did, it was a long, long time ago." *Id.*; GX 3, VR 3, at 16:21:41–16:24:16.

Registrant then asked UC if he "suffered from any childhood mental disorder" such as "attention deficit" disorder. GX 4, at 18. UC said: "Well . . . yeah. I don't know what they called

it, but I didn't do very good in school." *Id.* Registrant asked: "But not diagnosed? Not medicated?" *Id.* UC replied: "I use to take ADD—Ritalin." *Id.* Registrant asked: "Ritalin as a child?" *Id.* at 19. UC replied: "Yeah. You know sometimes I do lose focus so I mean it might help me focus." *Id.* Registrant then resumed dictating and stated: "After questioning the patient, admits to having had some childhood diagnosis of attention deficit disorder and was on Ritalin occasionally as a child. Sometime he complains of losing some focus but other than that he is doing well." *Id.* After dictating several additional comments, Registrant told UC to "[l]ook at me" and said "ok." *Id.*; GX 3, VR 3, at 16:24:16–16:25:18.

UC told Registrant that he was "[p]retty much a healthy guy" and "I try to take care of myself." GX 4, at 19. Continuing, UC said: "Drink a little too much on the weekends sometimes, but you know." *Id.*; GX 3, VR 3, at 16:25:18–16:25:29.

Registrant then told UC: "You know in this business of what I do, I don't know who is who. I have to be very careful when patients come in here." GX 4, at 19. UC replied: "Oh you don't want trouble makers coming in here" and Registrant said:

Not the trouble makers. You know people come in here in all different shapes and forms. Sometimes they are investigators. Sometimes they are undercover cops.

Sometimes they're anything and when I miss something it's just the right time for them to jump on me for something. So don't be worried that I'm paying attention to almost everything, you know. Did they give you a urine screen and test?

Id. UC said "[n]o." *Id.* Registrant again asked UC if he gave a urine; UC again said "no." *Id.*; GX 3, VR 3, at 16:25:30–16:26:20.

Again looking at his computer screen, Registrant stated: "Your last physician recorded here was Dr. Vora Kandarp. He gave you Norco. He also gave you Xanax 0.5mg. He also gave you Naproxen. You saw a Dr. Miky in September." GX 4, at 19. UC said, "I did," after which Registrant named three other doctors who he believed UC had seen in July and May of the previous year, noted that one of doctors had prescribed Adderall, and named the drug store which had filled this prescription. *Id.* Registrant then asked UC if he had high blood pressure because "somebody gave you blood pressure medication." *Id.* UC denied having high blood pressure, stating that it was "low actually" and "I never took that." *Id.* at 19–20; GX 3, VR 3, at 16:26:20–16:27:15.

UC then asked Registrant: "How do you see that on there? You guys on the

⁴ The sign is not, however, visible on the video. GX 3, VR 2, at 16:00:52–16:01:44.

same computer system?" GX 4, at 20. Registrant replied: "Everything. Everything shows up." UC then noted that the nurse had said that Registrant had "a lot of problems with idiots coming in here trying to get drugs" but "that's not me." *Id.* Registrant discussed with UC his use of amphetamines, with UC noting that he "didn't take it all the time" and it "[t]ook [him] a while to use it." *Id.* Registrant stated that he "shouldn't take it all the time" and did not prescribe the drug. *Id.*; GX 3, VR 3, at 16:27:15–16:27:46; see also GXs 5 & 12.

Registrant then moved on to UC's use of Xanax, noting that "it seems like you started with .25 Xanax. You're up to .5 now, double it, to 60, that's in December. Is that sufficient for you?" GX 4, at 20. UC said "Yeah . . . Probably," and Registrant said: "Okay. I will do that for you, sir." *Id.*; GX 3, VR 3, at 16:27:45–16:28:11.

Registrant further noted, "And . . . you did get a few pain medication" and asked: "You want that too?" GX 4, at 20. UC said "[y]es" and Registrant said "[a]llright." *Id.*; GX 3, VR 3, at 16:28:11–16:28:18.

Registrant then stated: "It's just the good thing is nothing is hidden anymore, you know. You can't come and hide anything." GX 4, at 20. Continuing, Registrant said: "And these medications are good medications." Registrant then discussed the dosing of two non-controlled medications he was prescribing (Baclofen and Naproxen). *Id.* at 20–22; GX 3, VR 3, at 16:28:18–16:28:48.

Registrant proceeded to dictate dosing instructions for the prescriptions and asked UC which pharmacy he used. GX 4, at 22. UC asked if there was "a good pharmacy around here" or if he could "take them on paper and go wherever I want?" *Id.* Registrant suggested a pharmacy that was "right up the street." *Id.* UC asked: "They won't give me a hard time?" and Registrant said "no." *Id.* at 23. Registrant then wrote electronic prescriptions which he sent to the pharmacy that he and UC had agreed upon. *Id.*; GX 3, VR 3, at 16:28:48–16:31:56.

As the visit was about to end, Registrant noted that "we need to get a urine from him" and added: "All the new patients—did they draw blood from you? You'll give a urine on the way out." GX 4, at 23. UC said he wasn't "too good with needles" and avoided the blood test but provided a urine sample. *Id.* at 26. See also GX 3, VR 3, at 16:31:56–16:44:32.

In the subjective section of the visit note, Registrant documented UC's chief complaint as: "I drive for a living my

back gets very stiff anxiety as well." GX 12, at 16. Under "History of Present Illness," Registrant wrote that UC:

is here for his first visit . . . he is suffering also from anxiety and back spasms due to his long sitting . . . he denies drinking or using any stimulants such as methadone or is a diabetic nor . . . on insulin. On the only use is Xanax occasionally for his anxiety. Today he is complaining mostly of [] some level of anxiety. . . . [P]atient admits to having had . . . a diagnosis of attention deficit disorder. . . . Sometimes he complains of losing some focus but other than that he's doing well.

Id.

The visit note's Review of Systems section contained fourteen different areas. *Id.* at 16–17. With the exception of "BJE/Musculoskeletal," next to which Registrant noted "Back Pain" but "Negative for Arthritis [sic], Joint Pain, Joint Swelling, Muscle Cramps, Muscle Weakness, Stiffness and Leg Cramps," all the areas contained negative findings, including the entry for Psychiatric, next to which Registrant documented: "Negative for Anxiety, Depression, Hallucinations, Memory Loss, Mental Disturbance, Paranoia, Suicidal Ideation, Panic Attacks." *Id.*

In the "Physical Examination" section, Registrant noted UC's "General Appearance" as: "Patient appears to be appropriate for age dressed appropriate for work responded to questions and no acute distress at this time." *Id.* at 17. Registrant noted that there were "[n]o abnormal findings" with respect to the "exam" of UC's "[m]usculoskeletal" and "[n]eurologic" systems. *Id.* at 18.

Yet Registrant then noted diagnoses of "Spasm of Muscle," "Anxiety State not Otherwise Specified," as well as "Attention or Concentration Deficit."⁵ *Id.* For each diagnosis, he documented that "7/22/2015," a date more than three months into the future, was both the date of onset and the date of diagnosis; he also noted that each diagnosis was active. *Id.* at 18.

As for Registrant's treatment plan, he listed only medications, which included "naproxen 500 mg," "hydrocodone 7.5 mg-acetaminophen 325 mg,"⁶ and "alprazolam 0.5 mg," and a follow-up visit "after [one] month." *Id.* at 19. Consistent with other evidence, the record includes two photographs of a pharmacy bottle with the label for 90 tablets of hydrocodone APAP⁷ 7.5/325 mg prescribed to D.H. (UC's alias) by Registrant, to be taken three times daily as needed for back pain and stiffness, which was filled by a pharmacy in Mt. Clemens, Michigan on April 1, 2015. GX

5, at 1–2. Two other photos show the label attached to a vial which indicates that it was a prescription for 60 Alprazolam 0.5 mg, to be taken twice daily for anxiety, which was also prescribed by Registrant to UC and was filled at the same pharmacy. *Id.* at 5–6.

UC's medical file includes the report of the urine drug screen obtained at his April 1 visit, as well as a report run on the same date from the Michigan Automated Prescription System (MAPS). GX 12, at 20 (UDS report); *id.* at 3 (MAPS report). As for the drug screen results, which were reported back to Registrant on April 9, 2015, the results were negative for all controlled substances listed, including alprazolam, hydrocodone, and hydromorphone, the latter being a metabolite of hydrocodone. *Id.* at 20. As found above, UC had represented to Registrant (and his nurse) that he took both hydrocodone and Xanax, and the visit note listed hydrocodone as a current medication. GX 4, at 18 (transcript of visit); GX 12, at 7 (questionnaire), 17 (visit note), and 20 (UDS report noting UC was prescribed hydrocodone and Xanax).

As for the MAPS report, it showed that on December 15, 2014, UC had last filled prescriptions which were issued by Dr. Vora of Gladwin, Michigan for 90 tablets of hydrocodone/apap 7.5/325 mg and 60 tablets of alprazolam .5 mg. *Id.* at 3. The report also showed that the UC had obtained four prescriptions for various quantities and dosages of alprazolam from four different providers, two of whom were located in Flint, the others in Marquette and Detroit. *Id.*

The Government also submitted a declaration by the UC. GX 32. With respect to the April 1 visit, UC stated that Registrant reviewed his alias's purported medical history and saw that he had seen at least three other doctors in the months prior to his first visit, but did not conduct any further inquiry or follow up with him on that issue. *Id.* at 2. UC also stated that during the April 1 visit, Registrant conducted virtually no physical examination, and that the portion of his visit with Registrant lasted only a few minutes and consisted mainly of answering questions. *Id.* He also stated that during the visit, Registrant was repeatedly distracted by issues he was having with the dictation software for his electronic patient records. *Id.* My review of the video evidence corroborates each of these statements. GX 3, VR 3, 16:15:22–16:33:22.

UC further stated that he reviewed Registrant's patient records for him and determined that portions of it either

⁵ He also documented a diagnosis of "Body Mass Index Between 29.0–29.9 Adult." GX 12, at 18.

⁶ Hereinafter, referred to as hydrocodone/apap.

misstate his statements during the visit or falsely indicate the extent to which he received or did not receive a medical examination. GX 32, at 2. UC explained:

For instance, the patient record lists “spasm of muscle” as one diagnosis, even though I did not complain of spasms during the visit. And the record states that I “den[ied] drinking” even though I indicated that I do drink. The record also documents findings from a physical exam in categories such as “Eyes,” “ENT,” “Cardiovascular,” “Musculoskeletal” and “Neurologic” even though other than the taking of my vitals no physical exam was performed during the visit.

Id.

Second Undercover Visit

On May 1, 2015, UC again saw Registrant at the St. Claire Shores clinic. GX 12, at 22; GX 6 (video recording of visit). After UC provided a urine sample, a medical assistant (MA) took his vitals and UC asked if he could get paper prescriptions. GX 7, at 12 (transcript of recording). The MA asked what medications he was taking, UC said “Norco and Xanax” and that he had gotten them last month. *Id.* As the MA continued to take his vitals, she asked UC if he had a “pharmacy problem” and UC said: “They take forever.” *Id.*; GX 6, VR 5, at 11:19:58–11:22:31.

The MA then asked: “[W]hat’s bothering you actually?” GX 7, at 12. UC replied: “Just refills. I’m just here for refills. I’m just here for my back pills and my nerves.” *Id.* The MA asked, “Your lower back?” and UC replied “Yeah.” *Id.*; GX 6, VR 5, at 11:22:31–11:23:03.

After she confirmed that “just your back is [the] problem,” the MA asked UC if he “had a back injury before?” GX 7, at 13. UC said that he didn’t know and didn’t “know what it was.” *Id.* The MA went through a list of symptoms including headaches and anxiety and asked if he had none of them; UC answered: “I get headaches when I drink too much liquor” and “I do it big sometimes.” *Id.* After a discussion of her shoes, MA asked UC: “just back right?” *Id.* UC said “Uh-Huh,” after which MA asked if he “sometimes” took medicine for headaches; UC answered: “No, I just take the Xanax and Norco.” *Id.*; see also GX 6, VR5, at 11:23:03–11:24:23.

The MA then asked if he had an “anxiety problem?” GX 7, at 13. *Id.* UC replied: “Yeah. No—I don’t know what you call it. But my nerves,” prompting the MA to interject “Anxiety” and UC said “I call it nerves.” *Id.* The MA then asked UC if he took Xanax, and after UC confirmed this and that he took the one milligram dosage form, UC added: “7.5 Norcos. That’s all I need. I’m easy. What

do you need?” after which the MA asked UC to fill out a questionnaire. *Id.*; GX 6, VR 5, at 11:24:20–11:25:44.

UC filled out the questionnaire, and after the MA asked him if he had undergone various tests and had his blood drawn, UC was escorted to Registrant’s office where the visit took place. Notably, the video shows that Registrant sat behind his desk for the duration of the visit, which lasted approximately three and a half minutes. See GX 6, VR 5, at 11:46:33–11:49:46; VR 6, at 11:49:47–11:50:01.

Registrant greeted the UC, confirmed his name, checked his computer screen, and discussed his lunch order with an unidentified employee, after which he asked UC about his insurance, and finally inquired if “the medication [he] had last time went well?” GX 7, at 16–17; UC replied “Yep.” After commenting about UC’s blood pressure and height, Registrant asked: “So you’re okay with what we have?” *Id.* at 18. UC said “Yes” and asked: “Can I get it on paper this time?” *Id.* Registrant asked “why” and if he went to a particular pharmacy, to which UC replied that “it took forever,” that he “waited in line behind eight people,” and he was “going the other way this time too . . . to Detroit.” *Id.* Registrant then agreed to give UC a paper prescription. *Id.*; GX 6, VR 5, at 11:46:3–11:48:05.

Registrant and UC proceeded to discuss the latter’s job as a driver for a car transporter and cars in general, and were interrupted by the MA. GX 7, at 18–20. While Registrant discussed another patient with the MA, she handed several paper prescriptions to Registrant. Registrant signed the prescriptions and handed them to UC, saying, “Here, sir” and “Alright, Take care.” *Id.* at 19–20. UC thanked Registrant and said he would see Registrant “in a month,” and the visit ended. *Id.* 20; GX 6, VR 5, at 11:49:23–11:49:46; VR 6, at 11:49:50–11:50:01.

The evidence includes a visit note dated May 1, 2015, which lists UC’s Chief Complaint as: “I am having lower back pain with anxiety problem[.]” GX 12, at 22. In the note’s Review of Systems section, Registrant documented: “BJE/Musculoskeletal: ‘Back Pain:—Negative for Arthritis [sic], Joint Pain, Joint Swelling, Muscle Cramps, Muscle Weakness, Stiffness, Leg Cramps.’” *Id.* Registrant noted UC’s psychiatric condition as “Anxiety:—Negative for, Depression, Hallucinations, Memory Loss, Mental Disturbance, Paranoia, Suicidal ideation, Panic Attacks.” *Id.* With respect to all other systems, including “neurological,” Registrant noted: “No symptoms at this time.” *Id.*

In the Physical Examination section, Registrant noted under “General Appearance,” that “patient doesn’t seem [sic] to be in any distress, appropriate to respond to questions alert,” and under “Musculoskeletal,” he noted “Limited Motion:—Arthritis.” *Id.* at 23. Registrant again listed his diagnoses as “Attention or Concentration Deficit,” “Spasm of Muscle,” and “Anxiety State Not Otherwise Specified.” *Id.* at 23–24. For each diagnosis, he again listed “7/22/2015” as both the date of diagnosis and the date of onset and noted that the diagnosis was “[a]ctive.” *Id.*

In the Plan section of the note, Registrant did not list any prescriptions. See *id.* The evidence, however, includes copies of the prescriptions he issued at this visit; these include a prescription for 90 hydrocodone/apap 7.5/325 mg, 60 alprazolam 0.5 mg, as well as naproxen and baclofen. GX 8, at 1–4. As part of his plan Registrant ordered a “urine drug screen” and noted a follow-up visit “after one month.” GX 12, at 24.

A result sheet for the urine drug screen which was done on this date and apparently tested by Registrant’s clinic⁷ states that UC’s test results were “normal” for amphetamines, benzodiazepines, opiates and oxycodone, as well as other controlled substances. *Id.* at 25. A second report shows the results of a test which was done by a lab (which were reported on May 6, 2015). *Id.* at 26. Notably, the lab reported “Not Detected” for both alprazolam and hydrocodone as well as each drug’s metabolites⁸ even though Registrant had prescribed the drugs at UC’s previous visit. *Id.*

In his declaration, UC stated that Registrant “did not conduct any physical examination” and “sat behind his [office] desk the entire time we talked” which “lasted only a few minutes.” GX 32, at 3. He also stated that he had reviewed Registrant’s patient records for the May 1, 2015 visit and determined that “portions of them either misstate my statements during the visit or falsely indicate the extent to which I received (or did not receive) a medical examination.” *Id.* These included the diagnosis of “spasm of muscle” even though “I did not complain of and was not found to have muscle spasms during the visit,” as well as that the medical “record quotes me as saying ‘I am having lower back pain’

⁷ The result sheet indicates that these results were obtained within 20 minutes of the time of the test.

⁸ These include hydroxylalprazolam, a metabolite of alprazolam, and norhydrocodone and hydromorphone, which are metabolites of hydrocodone. GX 12, at 26.

even though I made no such statement.” *Id.*

Third Undercover Visit

On June 15, 2015, UC again saw Registrant. GX 9 (Video Record), GX 10 (transcript), GX 32 (UC’s Declaration); *see also* GX 12, at 28 (Pt. file). According to the visit transcript, UC paid a co-pay and provided a urine sample. GX 10, at 1–3. Next, UC met with a nurse, who took his blood pressure and heart rate and asked him his weight and height. *Id.* at 4; GX 9, VR 3, at 13:32:58–13:35:43.

After UC noted that the last visit had taken place in Registrant’s office and that he had “sat across from the doctor who wrote me up,” the nurse asked: “you just needed your refills?” GX 10, at 5. UC said: “Yeah. That’s all I need. I’m easy. Easy for sure.” *Id.*; GX 9, VR 3, at 13:35:43–13:36:08.

The nurse accessed UC’s electronic medical record and asked: “So you’re here for meds?” *Id.* at 6. UC said: “That’s it. I’m pretty healthy.” *Id.* The nurse then asked: “Any new pain or anything? Pain is about the same?”; UC said: “It’s the same. Everything is the same.” *Id.* The nurse replied: “Unfortunately we still have to do all this charting, you know . . . [f]or DEA . . . It’s just really crazy . . . those controlled things are really . . . it’s like impossible to find meds . . . It’s being purposely done. People don’t realize that, but DEA is behind it . . .” *Id.* UC remarked “[c]lamping down?” to which she replied “Yep.” *Id.*; GX 9, VR 3, at 13:36:08–13:37:59.

The nurse had UC fill out some paperwork, after which she proceeded to question UC as to whether he had experienced various symptoms including appetite problems, chills, fatigue, fevers, night sweats, weight gain or loss, ringing ears (which prompted UC to say that “[m]y ears only ring after I drink a jug of moonshine”), blurry or double vision, coughing, difficulty breathing, wheezing, snoring, chest pain, or heart skipplings; UC answered “no” to each of these. GX 10, at 9–10; GX 9, VR 3, at 13:39:26–13:43:52.

Continuing, the nurse asked UC if he had “[a]ny muscular skeletal problems? Pain? Back pain, joint pain, and arthritis? No? No back pain?” GX 10, at 10. UC stated: “I got like, you know, the normal,” to which the nurse said, “No, I don’t” and asked again: “You got back pain?” *Id.* UC responded “I got stiffness.” Tr. at 10. UC then denied having joint pain. *Id.*; GX 9, VR 3, at 13:43:52–13:44:54.

The nurse then asked: “Any anxiety, depression?” GX 10, at 10. UC replied: “No. Just my nerves get jacked up a

little bit, but,” prompting the nurse to ask: “Panic attacks?” *Id.* UC replied: “I don’t know what you would call it. Like I drink a couple cocktails on the weekend and I’m cool or that Xanax pretty much chills me down, so . . . Basically I take that Xanax, I don’t need to drink too much. Everything is smooth. Makes sense?” *Id.*; GX 9, VR 3, at 13:44:54–13:45:16.

The nurse stated: “Makes perfect sense” and asked if UC had “[a]ny memory loss?” *Id.* UC denied memory loss. GX 10, at 10. The nurse asked UC “[w]hen was the last time” he had visited; UC stated “a month and a half ago” and added that the “last time they just let me go in his office.” *Id.* at 11; GX 9, VR 3, at 13:45:15–13:46:16.

The nurse then asked what medications UC was taking; he answered “Norco, Xanax, Baclofen” and “sometimes” Naproxen. GX 10, at 11. The Nurse asked UC about his daily dosing for each drug, before asking if he had “been out of some of these meds?” *Id.* at 12. UC admitted that he had been out, and after the Nurse noted that his visit had been on May 1, asked: “So what have you been doing?” *Id.* UC replied: “I have to get them from my neighbor. Well, I tried to get in here. They cancelled my appointment. The doctor was sick one day.” *Id.*; GX 9, VR 3, at 13:46:40–13:48:48.

The nurse and UC discussed what pharmacy he used, stating that Registrant wanted to have one in case UC needed to have something called in, and that it was easier for e-scripting. GX 10, at 12. The nurse then encountered some difficulty with the electronic records and stated she was “just putting no symptoms, because I’m not going through all that again. We already went through it.” *Id.* at 14; GX 9, VR 3, at 13:48:50–13:52:00.

After a discussion of the use of suboxone, the nurse asked: “Did you say you have joint pain, back pain?” GX 10, at 15. UC replied: “My back’s stiff, but when I take that Norco, I’m cool” and asked if “[t]hat make[s] sense?” *Id.* The nurse replied: “that’s a reason to have it . . . for insurance purposes. You know what I mean?” and UC said: “As long as I take that, I’m smooth.” *Id.*; GX 9, VR 3, at 13:54:36–13:54:47.

UC and the nurse then went to Registrant’s office, where the latter was seated behind his desk and an MA was seated facing him. During this period, the nurse and MA remained in the office, and Registrant asked UC if he was a new patient. GX 9, at 16. After UC said “No,” Registrant asked: “You a regular? How many times?” *Id.* UC said: “It’s the third time I’ve been here . . .

you cancelled me last time.” *Id.*; GX 9, VR 3, at 13:55:02–13:55:40.

After several minutes of discussing whether Registrant remembered UC, the nurse told Registrant, “he just needs these four,” and that “he needs them printed.” GX 10, at 17. Apparently referring to the pharmacy UC wanted to use, Registrant asked UC if he didn’t know which pharmacy he normally went to and whether he went “to different people?” *Id.* UC said he “was going to Walgreens,” but “last time they didn’t have some of my stuff. I had to come back two days later. So I’ll just take them on paper if I can.” *Id.* Registrant said “ok.” *Id.*; GX 9, VR 3, at 13:55:40–13:57:37.

Registrant and UC then discussed where the latter worked as well as Registrant’s car and its gas mileage, after which Registrant demonstrated the versatility of a Bluetooth speaker system in his office, followed by the MA, Registrant and UC discussing their musical tastes and sharing stories about Registrant’s daughter. GX 10, at 17–20. As the video shows, during the course of this conversation, Registrant checked his computer screen, signed the prescriptions which he handed to the nurse, who in turn handed them to the UC saying “[y]ou’re all set,” UC asked “Am I good, ok?” and Nurse said “yep.” *Id.* at 22. Registrant told the UC to “take care”; UC thanked Registrant and left his office. *Id.*; GX 9, VR 3, at 13:57:37–14:03:06.

The visit note lists UC’s chief complaint as “I am having lower back pains and anxiety.” GX 12, at 28. In the Review of Systems section, Registrant again noted “Stiffness” under BJE/ Musculoskeletal; however, he also noted “negative” for each of the symptoms that were listed including “back pain” and “muscle cramps.” *Id.* Under Psychiatric, he noted “Anxiety” and “Panic Attacks.” *Id.*

In the Physical Exam section, Registrant noted under “General Appearance” that “patient states he [sic] very anxious appears to be in mild pain alert to question and appropriate with his response.” *Id.* at 29. As for his purported “Musculoskeletal” findings, Registrant noted: “Limited Motion:— Muscle Spasm:—Tenderness:— Arthritis.” And as for his purported “Neurologic” findings, Registrant noted: “Abnormal reflexes:—Abnormal Gait:— Weakness Atrophy.” *Id.*

As for his diagnoses, Registrant again listed “Attention or Concentration Deficit,” “Spasm of Muscle” and “Anxiety State Not Otherwise Specified,” and noted “7/22/2015” as the date of both diagnosis and onset for

each diagnosis. He further noted that each diagnosis was “Active.” *Id.*

As for his plan, Registrant listed hydrocodone/apap 7.5/325 mg, Xanax 0.5 mg, as well as Baclofen 10 mg and Naproxen 500 mg. *Id.* at 30. He also noted a follow-up in one month. *Id.* The Government’s evidence includes copies of the prescriptions issued by Registrant to UC at this visit; the prescriptions include 60 tablets of alprazolam .5 mg and 90 tablets hydrocodone 7.5/325 mg, as well as baclofen and naproxen. GX 11.

UC’s patient file includes a report for a urine drug sample collected from him at the June 15, 2015 visit which was tested at Registrant’s clinic the same day. The report noted that neither benzodiazepines or opiates were detected and listed the results as “normal.” *Id.* at 31. While these results were available the same day, UC’s visit occurred approximately two weeks after the medication from his previous visit would have run out.⁹

In his declaration, UC stated that he told Registrant’s staff that when he ran out of medication, he obtained controlled substances from a neighbor to fill the gap between visits and that neither Registrant nor his staff conducted any further inquiry on this issue. GX 32, at 3. UC also stated that Registrant did not conduct any physical examination and that the portion of his visit with Registrant occurred in Registrant’s office, where Registrant “sat behind his desk the entire time.” *Id.* UC further stated that his patient record quotes him “as saying ‘I am having lower back pains’ even though I explicitly stated that I had ‘stiffness.’” *Id.* at 4 (*Compare* GX 12, at 28 with GX 10, at 10 (Nurse asks “You got back pain?” and UC responds: “I got stiffness.”). Finally, UC stated that the visit note lists the results of a musculoskeletal exam, but other than the taking of his vital signs, no physical exam was performed during this visit and none of the conditions listed were discussed or found. GX 32, at 4.

The Government’s Expert

The Government retained Dr. R. Andrew Chambers, M.D., to review the videos, transcripts and prescriptions related to the undercover visits made by the UC investigator, as well as the medical files for three patients, D.S., A.L. and R.H., which were obtained during the investigation. Dr. Chambers

is an addiction psychiatrist in Indiana. GX 33 (Expert’s Declaration). He is also an Associate Professor of Psychiatry at the Indiana University (IU) School of Medicine in the IU Neuroscience Center where he trains psychiatrists and physicians on the diagnosis and treatment of mental illness and drug addiction. *Id.* at 1. He also runs a university-affiliated mental health center and addiction treatment clinic where he treats patients. *Id.* He has been board certified in addiction medicine since 2008 and addiction psychiatry since 2012, and has published over 40 peer-reviewed journal articles and approximately nine textbook sections. *Id.* In addition, Dr. Chambers has provided expert testimony which was found credible in a previous DEA proceeding. *See* *Lon F. Alexander*, 82 FR 49704, 49714, 49725–26 (2017).

Dr. Chambers stated that he reviewed various materials to familiarize himself with the standard of care for the prescribing of controlled substances in Michigan, including the Michigan Board of Medicine’s Guidelines for the Use of Controlled Substances for the Treatment of Pain, (hereinafter, “Michigan Guidelines”), as well as various state laws, a document of the Michigan Board of Pharmacy entitled “Pharmacy—Controlled Substances,” and information posted by the Michigan Advisory Committee on Pain and Symptom Management. *Id.* at 2.

Dr. Chambers stated that “as a professor and practicing psychiatrist, I have an understanding of how to prescribe controlled substances and the risks associated with doing so. I am also familiar with how doctors and practitioners should conduct themselves when prescribing controlled substances for a legitimate medical purpose in the usual course of their profession.” *Id.* Based on his “professional experience and review” of the Michigan Guidelines and state law, he opined that “the standard of care for prescribing controlled substances in Michigan is similar to and consistent with that in Indiana . . . and that the standards in Michigan are similar to and consistent with the national norms in the medical profession for prescribing controlled substances.” *Id.* He then discussed the standards for prescribing controlled substances in Michigan:

First, in accordance with Michigan state law, any controlled substance must be prescribed for a legitimate or professionally recognized therapeutic purpose. To determine that, the practitioner must take a complete medical history of the patient and conduct an adequate physical examination to determine if there is a legitimate medical basis for so prescribing. Second, as explained

in the Michigan Guidelines, “when evaluating the use of controlled substances for pain control, . . . [a] complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.” The guidelines also instruct on providing a written treatment plan, obtaining informed consent and agreement for treatment, conducting a periodic review at “reasonable intervals based on the individual circumstances of the pain,” and “referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.” Third, practitioners must keep accurate and complete records of the forgoing and other aspects of medical care. Although that requirement is explicitly stated in the Michigan Guidelines, I can also [] attest based on my knowledge and experience that keeping accurate and complete patient records is required to meet the standard of care for the prescribing of any controlled substance, not just that which relate to pain control.

Id. at 3.

Dr. Chambers also stated that he was “aware of red flags, or possible indicators of potential abuse, addiction or diversion, and the need for red flags to be addressed and resolved by a practitioner.” *Id.* According to Dr. Chambers, these include “patients seeking to have medications refilled early, patients asking for specific medications, and indications that the patient is addicted to or is diverting medications.” *Id.* He further stated that “under the standard of care, practitioners’ records should identify any potential red flags and steps taken to resolve them.” *Id.*

I find that Dr. Chambers is qualified to provide an expert opinion on the standards of professional practice for prescribing controlled substances under the Michigan Board’s Guidelines and Michigan law, as well as the standard of care generally with respect to the treatment of both pain and anxiety. I also find that Dr. Chambers is qualified to provide expert testimony as to the risks associated with prescribing controlled substances.

Dr. Chambers provided a written report regarding Registrant’s prescribing of controlled substances to UC and three other patients (D.S., R.H., and A.L.). With respect to UC, Dr. Chambers stated that he “reviewed the undercover videos, transcripts, and prescriptions,” as well as the medical records related to each of the three visits.

Dr. Chambers opined that Registrant prescribed both hydrocodone, an opioid, and alprazolam, a

⁹ UC file’s also includes the results of the UDS which was tested by an outside laboratory on June 18, 2015. GX 12, at 32. The report noted that the results were inconsistent with the drugs prescribed in that neither alprazolam nor hydrocodone were detected. *Id.*

benzodiazepine, and that this combination of drugs raises a serious overdose risk. *Id.* He further opined that “[t]here are three clinical contexts in which the risks associated with opioid and benzodiazepine combination therapies are considered acceptable, these being for hospice care, for ‘critical-care or closely monitored inpatient settings,’ and ‘for short-term, closely monitored detoxification protocols for patients with addictions,’ none of which are relevant in assessing Registrant’s prescribing to UC. *Id.* at 3–4.

Dr. Chambers opined that at UC’s first visit, Registrant failed to do a “proper evaluation of current substance use symptoms or substance disorder history.” GX 33, Attachment B, at 19. As Dr. Chambers explained, UC had admitted to significant alcohol use at this visit yet Registrant did not further question UC about his alcohol use. *Id.* While UC had represented that he was taking Xanax and Registrant reviewed his MAPS report which showed that he had obtained the drug from multiple providers, some of whom were hundreds of miles apart, Registrant did not do a “proper evaluation of current psychiatric symptoms or psychiatric history of present illness.” *Id.* Dr. Chambers also noted that while a nurse obtained UC’s vital signs and weight, “a physical exam was never performed” and yet the medical records include “normal physical examination findings.” *Id.* at 20. Moreover, the patient record “falsely states that the patient denies drinking.” *Id.*

With respect to Registrant’s diagnoses, Dr. Chambers opined that none of them was properly supported. As for the diagnosis of muscle spasm, Dr. Chambers noted that “there was no physical exam . . . to confirm muscle spasm or any other somatic source of pain or muscular-skeletal disorder.” *Id.* at 21. He further observed that Registrant prescribed opioids but there was no diagnosis of pain and “opioids are not indicated for muscle spasm.” *Id.*

As for the diagnosis of anxiety, Dr. Chamber reiterated that Registrant did not perform an “adequate psychiatric evaluation.” *Id.* Dr. Chambers also observed that the diagnosis of an attention or concentration deficit “was not evaluated[,] or measured in any current way.” *Id.* at 20.

Dr. Chambers observed that while Registrant went over the dosing instructions, he did not caution UC about the risks of combining opioids and benzodiazepines, which “may produce serious hazards for driving” even though UC said he was professional driver. *Id.* at 19.

Addressing UC’s second visit, Dr. Chambers noted that “there [was] no physical examination.” *Id.* at 19. Dr. Chambers further observed that “[t]he actual clinical encounter and evaluation with [Registrant] last[ed] three minutes” and that “[t]he most substantial evaluative questions” which Registrant asked the UC were: “Doing OK?” and “Med went well?” *Id.*

With respect to UC’s third visit, Dr. Chambers noted that UC had “again ma[de] comments that he engage[d] in significant drinking.” *Id.* Dr. Chambers then observed that “[t]his information was ignored and/or falsified in the Medical Record by” Registrant. *Id.* at 22.

Dr. Chambers also noted that UC stated that because his third appointment was two weeks late, he had run out of medications and had obtained controlled substances from his neighbor. *Id.* at 20. Dr. Chambers observed that “this activity was never addressed by” Registrant. *Id.*

As for UC’s interaction with Registrant, Dr. Chambers noted that this occurred in Registrant’s office, that the entire encounter lasted eight minutes, during which “there [was] essentially no clinical evaluation of the patient to assess symptoms, illness course or treatment response,” and “the only questions” asked by Registrant were “where the patient work[ed] and what pharmacy he use[d].” *Id.* Dr. Chambers also observed that most of the encounter was spent discussing matters that had nothing to do with the UC’s medical condition and a physical exam was not performed. *Id.*

In addition, Dr. Chambers noted that Registrant falsified the visit note in various respects. These include: (1) The statement that UC “appears to be in mild pain,” which Dr. Chambers opined was inconsistent with the UC’s “voice, affect and thought content,” notwithstanding that the video does not show how UC appeared; (2) the statement that “patient states he is very anxious,” which UC “never stated”; and (3) the exam findings of “limited motion, spasm, tenderness,” as well as “abnormal reflexes” and “weakness/atrophy,” as Registrant “never performed a physical exam or touched the patient.” *Id.* at 21.

Dr. Chambers thus concluded that “the controlled substances prescriptions that [Registrant] issued to the investigator during the undercover visits were not issued for any legitimate medical basis and were issued outside of the standard of care in . . . Michigan.” GX 33, at 4.

The Expert’s Chart Review of Registrant’s Patients D.S., A.L. and R.H.D.S.

Dr. Chambers reviewed the patient file for D.S., whose “typical chief complaints were back and neck pain, and sometimes knee pain” during the five years she was treated by Registrant. GX 33, at 4. According to the patient file, D.S.’s initial appointment with Registrant was on August 31, 2011. GX 14, at 5.

Dr. Chambers found that documented prescription records from Registrant’s electronic patient file showed a prescribing pattern which rapidly escalated from D.S.’s initial visit. GX 33, Attachment B, at 7. Dr. Chambers specifically expert found that on August 31, 2011, Registrant prescribed 90 mg/day morphine, yet only two weeks later (September 14, 2011), Registrant doubled the dosage to 180 mg/day. *Id.* Only one month later (October 14, 2011), Registrant increased D.S.’s dosing to 320 mg/day morphine and added 700 mg/day carisoprodol. *Id.* at 8.

Dr. Chambers also found that in two years of appointments between January 2014 and February 2016, Registrant’s records show diagnoses of pain and depression. *Id.* The Expert found, however, that over this period, D.S.’s patient file contained no evidence that Registrant did physical exams other than to take vital signs; he also found that Registrant’s treatment plans were essentially non-existent. *Id.* Yet during this period, Registrant prescribed to D.S. such narcotics as hydrocodone 10/325 mg. and oxycodone 30 mg. which included repeated prescriptions for 120 dosage units of the latter drug; he also repeatedly prescribed carisoprodol, a schedule IV muscle relaxant during this period. GX 13, at 1–48. Dr. Chambers noted, however, that the D.S.’s “records do not typically document evidence of improvement in pain symptoms.” GX 33, at 6.

Registrant also repeatedly prescribed other controlled substances including stimulants such as Adipex-P (phentermine) and Bontril (phendimetrazine), which are schedule III and IV controlled substances. GX 13, at 6. Dr. Chambers further found that Registrant’s introduction of these stimulants into D.S.’s medication regimen was “not accompanied by a diagnosis or clinical indication in the charting.” GX 33, Attachment B, at 8.¹⁰

¹⁰ He also found that Registrant made a diagnosis of depression on January 15, 2014, but there was no attempt to treat it. *Id.*, see also GX 15, at 1–3. In fact, the record shows that under Review of Systems, Registrant noted “no [psychiatric]

Dr. Chambers identified multiple instances in which D.S.'s medical records indicated that she was suffering from addiction. These include notes on April 11 and May 9, 2012 documenting "dependence," a note on June 8, 2012 that "she constantly needs more [pain medications]," a note on September 28, 2012 of "medication dependence," a note on October 26, 2012 of "[m]edication dependence illness," and a note on November 20, 2012 of "patient continues to display dependence." GX 33, at 6.

Dr. Chambers also identified multiple instances in which D.S. provided aberrant urine drug screens. These included tests which showed the presence of methadone on February 14, 2014 and buprenorphine on November 10, 2014, neither of which were prescribed to D.S.; the presence of cocaine on March 14, 2014; the presence of psychostimulants (amphetamines) on March 14, April 14, and May 12, 2014 which were not prescribed by Registrant; instances in which the tests were negative for drugs prescribed by Registrant (Nov. 10, 2014 negative test for oxycodone and morphine and June 22, 2015 negative test for oxycodone); and four tests which found levels of oxycodone which were above the recommended therapeutic range of those drugs.¹¹ GX 33, Attachment B, at 8–9.

Dr. Chambers explained that the drug test results show "a number of different problems that represent serious warning signs of dangerous drug use and or addiction." *Id.* at 8. He further observed that Registrant's records contain no acknowledgment of D.S.'s aberrational drug tests results and reflect that he did not change the treatment plan or any clinical actions to address the results. *Id.* at 9.

Dr. Chambers concluded that "D.S. was very likely suffering from drug addiction that was not adequately diagnosed or treated, and [Registrant] failed to act on an overall lack of treatment response to the controlled substance combinations he was prescribing." GX 33, at 6. He further opined that Registrant "was prescribing dangerous combinations of controlled substances without documenting a medical need for so doing, and he failed to adequately document ongoing examinations and treatment planning

. . . and/or he failed to perform these professional functions altogether." *Id.* Dr. Chambers thus concluded that Registrant issued numerous prescriptions without "any legitimate medical basis" and acted "outside of the standard of care in the state of Michigan." *Id.*

A.L.

Registrant treated patient A.L. from January 17, 2011 through April 30, 2014. *Id.* at 14–16. *See also* GX 18 (patient medical file), GX 19 and 20 (electronic patient files). Regarding Registrant's patient records for A.L., Dr. Chambers reported that they contain notes for various medical issues including anxiety, depression, and pain, the latter including knee, lower back, ankle and neck pain. GX 33, at 6–7.

Dr. Chambers reviewed 11 controlled substance prescriptions Registrant issued to A.L. between October 17, 2013 and May 6, 2014. *Id.* at 7. The prescriptions included three prescriptions for 120 du of hydrocodone/apap 10/325 mg with two refills, three prescriptions for 30 du of phentermine 37.5 mg with two refills, three prescriptions for 150 du of carisoprodol 350 mg with two refills, and three prescriptions for 120 du of alprazolam 2 mg. GX 17, at 2–23 (copies of prescriptions obtained from filling pharmacy, and pharmacy patient profile report).

Dr. Chambers observed that "[f]or the most part there are no physical examinations documented in the medical records." GX 33, at 7. Dr. Chambers also noted that "the combination of Hydrocodone, Alprazolam and Carisoprodol drugs . . . is a prescription 'cocktail' known among users and law enforcement as the 'Trinity,'" and that it "is widely known to be used non-therapeutically as part of a substance disorder and/or diverted." *Id.* He further noted that on four occasions in 2011, Registrant had also prescribed another variation of this cocktail, which substituted Roxicodone (oxycodone) for hydrocodone. *Id.* He then opined that "there is no documentation in A.L.'s medical records demonstrating a legitimate medical justification or clinical context for prescribing this dangerous combination of controlled substances." *Id.*

Dr. Chambers also found that "[t]here are numerous signs of addiction" in A.L.'s patient file, beginning with her initial visit with Registrant on January 17, 2011. *Id.* Dr. Chambers noted that the MAPS report showed that A.L. "had seen up to eight prior prescribers over the prior year for various controlled

substances, including combinations of opioids, benzodiazepines, and stimulants," resulting in 50 dispensings of drugs which included hydrocodone, oxycodone, morphine, morphine, diazepam, alprazolam and amphetamine. GX, 33 at 7–8; *see also* GX 18, at 32–40. He also observed that on her "Health History Questionnaire," which was completed in January 2011, she reported taking Roxicodone, Xanax, and Soma, which as Dr. Chambers previously explained, comprises the highly abused "'Trinity' drug cocktail." *Id.* at 8; *see also* GX 18, at 14.¹²

Dr. Chambers further noted that A.L.'s medical records documented that she "was possibly engaged] in diversion." *Id.* at 8. As support for this observation, Dr. Chambers pointed to a chart entry of February 25, 2013 which states: "She says she cannot get her pain medications and has to be buying it off the streets to satisfy her pain. The last time she was given pain medication from this office was in September of last year." *Id.* at 8; *see also* GX 19, at 8. Dr. Chambers found that there was no evidence in the patient record that Registrant "addressed or resolved these red flags." GX 33, at 8. Moreover, Dr. Chambers found that Registrant's "charting is devoid of UDS data collection or tracking." GX 33, Attachment B, at 18.

Based on his review of A.L.'s record and the prescriptions, Dr. Chambers concluded that that she "was suffering from a drug addiction that was not adequately diagnosed or treated; [that Registrant] was prescribing extremely dangerous combinations of controlled substances without documenting an appropriate medical context or justification for so doing, and [that he] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether." GX 33, at 8. Dr. Chambers thus opined that "the prescriptions [Registrant] issued to A.L. were not issued for any legitimate medical basis and were issued outside of the standard of care in the state of Michigan." *Id.*

R.H.

Dr. Chambers also reviewed the controlled substances Registrant issued to R.H. from June 2, 2015 through February 24, 2016. According to Dr. Chambers, during this time period, R.H. presented a variety of chief complaints which "included complaints of lower back and hand joint pain, anxiety,

symptoms at this time: Negative for anxiety, depression . . . mental disturbance . . . panic attacks." *Id.* at 1. There were also "no [psychiatric] symptoms at this time" noted at D.S.'s following visit. *Id.* at 4.

¹¹ Two tests also found amphetamines at levels above the recommended therapeutic range. GX 33, Attachment B, at 9.

¹² The same Health History Questionnaire also lists Opana, Vickodin [sic], and MS Contin as "prescribed drugs." GX 18, at 14.

numbness, a rash on face/head, fractured left toes, sciatica, and arms and shoulder pain.” *Id.*

During this period, Registrant issued to R.H. 10 prescriptions for 90 du of hydrocodone/apap 10/325 mg; 10 prescriptions for 60 du of morphine sulfate 100 mg; 10 prescriptions for 120 du of morphine sulfate 30 mg; five prescriptions for 60 du of alprazolam 1 mg, including one which provided for two refills; and two prescriptions for 60 du of carisoprodol 350 mg, each of which provided for two refills. *Id.* at 8–10. Dr. Chambers again noted that the combination of hydrocodone, alprazolam, and carisoprodol comprise the Trinity cocktail. *Id.* at 10. He also found that on six occasions between March 11, 2011 and September 26, 2011, Registrant prescribed hydrocodone, carisoprodol and Valium (diazepam), another version of the Trinity cocktail. *Id.*

Dr. Chambers found that “[f]or the most part there are no physical exams documented in the medical records.” *Id.* He also found that “[t]here is no documentation in R.H.’s medical records demonstrating a legitimate medical justification or clinical context for prescribing this dangerous combination of controlled substances.” *Id.*

Dr. Chambers noted that R.H.’s records contain “numerous signs of possible addiction or abuse.” *Id.* at 11. These include a note (Dec. 21, 2011) in which Registrant documented that “R.H. is taking the valium three times a [day] although he is given it twice daily so he runs out early” [sic]. *Id.* Dr. Chambers also found that “R.H.’s urine drug screens also show[] a number of different problems that represent serious warnings signs of dangerous drug use and or addiction, including the presence of amphetamines and benzodiazepine[s] that [were] not prescribed by” Registrant. *Id.* Dr. Chambers further found that “[t]here are no indications in the patient records that [Registrant] addressed or resolved these red flags.” *Id.*

Based upon his review of R.H.’s patient file and prescriptions, Dr. Chambers concluded that he “was suffering from drug addiction that was not adequately diagnosed or treated.” *Id.* Dr. Chambers further concluded that Registrant “was prescribing extremely dangerous combinations of controlled substances without documenting a medical need for so doing, and [that Registrant] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.” *Id.* Dr. Chambers thus

opined that the prescriptions Registrant issued to R.H. “were not issued for any legitimate medical basis and were issued outside of the standard of care in . . . Michigan.” *Id.*

Summary of the Expert’s Findings

With respect to the UC and the three other patients, Dr. Chambers opined that:

The evidence reveals that [Registrant] has been engaged in prescribing dangerous levels and combinations of opioid and benzoid drugs to multiple patients in chronic patterns that have no legitimate medical purpose, and are not supported by the evidence base. Moreover, it is precisely these types of controlled substance patterns that are shown by a wealth of biomedical, clinical and epidemiological evidence to produce diversion and to contribute to addiction, worsening mental illness, and premature death. The case evidence suggests to various degrees that all of these outcomes have happened as a result of [Registrant’s] prescribing and clinical practices.

This prescribing was also occurring in the absence of minimally adequate practice standards of care by [Registrant], including failures to appropriately evaluate, diagnose and monitor disease processes, and treatment outcomes or treatment side effects. All 4 cases presented strong evidence that patients were suffering with mental illness and addiction of some kind when initially presenting for treatment. In 3 cases, these conditions did not change and/or worsened over time even as they were not appropriately treated, or referred elsewhere for treatment, and even as these conditions were adversely contributed to by the benzoid-opioid combination of drugs [Registrant] was prescribing.

Id. at Attachment B, at 5.

Dr. Chambers further opined that Registrant was not practicing in “good faith” as defined by Michigan Code § 333.7333(1). *Id.* This provision defines “good faith” as:

The prescribing or dispensing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual’s physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article.

Mich. Code § 333.7333(1). Dr. Chambers thus concluded that “rather than providing legitimate medical care, [Registrant] was actually using the guise of medical practice . . . to deal addictive drugs to patients with untreated addictions and mental illness.” GX 33, Attachment B, at 5.

Dr. Chambers also evaluated the evidence in light of the Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain. Dr. Chambers explained that the

Guidelines “set forth six key components of legitimate medical practice that should be observed in the use of controlled substance for the treatment of pain,” to “include appropriate:

- (1) Evaluation (history taking and physical examination, psychiatric screening);
- (2) Treatment Planning;
- (3) Informed consent (discussion of risks and benefits of medications . . .);
- (4) Periodic Review (evaluate and monitoring of treatment progress);
- (5) Consultation; and
- (6) Medical record keeping.”

Id. at 5–6.

Dr. Chambers opined that “there are 2 other key aspects of the evidence that highlight the particularly malignant nature of [Registrant’s] practices and prescribing pattern.” *Id.* at 6. First, Dr. Chambers concluded that the “evidence suggest[s] that Registrant deliberately acted to obscure, in the medical record, the dangerousness of his practice, to cover-up the degree to which it was a drug dealing operation, instead of a legitimate medical practice.” *Id.* As he further explained, the evidence “show[s] that [Registrant] is padding the medical record with initial PDMP evaluations and UDS testing that he never acts on regardless of what these data show, as if the point is to create the appearances of maintaining standards and adequate monitoring in the medical record without actually doing so.” *Id.* Second, Dr. Chambers explained that the evidence shows that “[h]e not only engages in little history taking and no physical examination of the patient, but he falsely documents examination findings that do not exist, in an examination that was never performed, in order to justify the continuing prescription of controlled drugs.” *Id.*

Dr. Chambers thus concluded that “this evidence shows that [Registrant] is performing well below the standard of care, and is a danger to [h]is patients and the public at large with respect to his prescribing of controlled substances. The evidence is highly suggestive that he is providing prescriptions for addictive substances, not in ‘good faith’ consistent with medical norms, but as a distribution business, *i.e.* as a drug dealing operation under the guise of legitimate health care.” *Id.* I agree.

Discussion

In its Request for Final Agency Action, the Government seeks revocation on two independent grounds. First, it argues that revocation is warranted because Registrant lacks authority under state law to dispense controlled substances. RFAA, at 6 (citing 21 U.S.C. 824(a)(3)). Second, it

argues that Registrant has committed acts which render his registration inconsistent with the public interest because he unlawfully distributed controlled substances in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). *Id.* at 9. I agree that the Government is entitled to an order of revocation on both grounds.

Lack of State Authority

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823, “upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” Moreover, DEA has held repeatedly 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., Calvin Ramsey*, 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988). *See also Frederick Marsh Blanton*, 43 FR 27616 (1978).

Here, while the Michigan Board’s Consent Order suspended Registrant’s

medical license for 15 months, the Board’s Order further provides that “reinstatement shall not be automatic,” and that Registrant must petition for reinstatement by demonstrating, “by clear and convincing evidence,” that he: (1) Is of “good moral character”; (2) has “the ability to practice the profession with reasonable skill and safety”; (3) has satisfied “the guidelines on reinstatement adopted by the Department”; and (4) “that it is in the public interest for the license to be reinstated.” Consent Order, at 2. Thus, it is far from certain that Registrant will be able to satisfy these conditions and be reinstated to the practice of medicine.

More importantly, this Agency has held that even where a State has imposed a suspension of finite duration of a practitioner’s medical license, revocation is nonetheless warranted because the controlling question is not whether a practitioner’s license to practice medicine in the State is suspended or revoked; rather, it is whether the Registrant is currently authorized to handle controlled substances in the State. *Hooper*, 76 FR at 71371 (citing *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)). Because one cannot obtain a practitioner’s registration unless one holds authority under state law to dispense controlled substances, and because where a registered practitioner’s state authority has been revoked or suspended, the practitioner no longer meets the statutory definition of a practitioner, DEA has held repeatedly 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 both obtaining and maintaining a practitioner’s registration. *See Blanton*, 43 FR 27616 (1978) (revoking registration based on one-year suspension of medical license); *Hooper*, 76 FR at 71371 (same).

Thus, because Registrant is no longer currently authorized to dispense controlled substances in Michigan, the State in which he is registered with the Agency, I find that he is not entitled to maintain a DEA registration in the State. Accordingly, I will order the revocation of his existing registration on this ground. *See* 21 U.S.C. 824(a)(3).

The Public Interest Analysis

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 misconduct. *Jayam Krishna—Iyer, M.D.*, 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).

Even in a non-contested proceeding, the Government has the burden of producing substantial evidence to support the allegations and its proposed sanction. *See Gabriel Sanchez*, 78 FR 59060, 59063 (2013); 21 CFR 1301.44(e). In this case, I find that the Government’s evidence with respect to Factors Two and Four¹³ establishes that Registrant

¹³ In its Request for Final Agency Action, the Government states that Factors I, III and V do not weigh in favor of or against revoking Registrant’s registration. RFAA at 8, fn. 4 (citing 21 U.S.C §§ 823(f)(1), (3) and (5)). As explained above, with

“has committed such acts as would render his registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

Factors Two and Four—Registrant’s Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

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). *See also* Mich. Comp. Laws § 333.7333(1) (“As used in this section, ‘good faith’ means the prescribing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual’s physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article.”); *id.* § 333.7401 (“A practitioner licensed by the administrator under this article shall not dispense, prescribe, or administer a controlled substance for other than a legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice of the practitioner . . .”).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” *See United States v. Moore*, 423 U.S. 122, 142–43 (1975); *United States v. Lovern*, 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States v. Smith*, 573 F.3d 639, 657 (8th Cir. 2009); *see also* 21 CFR 1306.04(a) (“An order

respect to Factor One—the Recommendation of the State Board—the Board made no recommendation to the Agency in this matter. More importantly, as discussed above, the Board has suspended his medical license thus rendering him ineligible to maintain his registration.

With respect to Factor Three, I acknowledge that there is no evidence that Respondent has been convicted of an offense under either Federal or Michigan 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 at 822. 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.*

The Government makes no argument that Factor Five is implicated in this matter.

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 relating to controlled substances.”).

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 *Moore*, 423 U.S. 122, 135, 143 (1975)).

Both this Agency and the federal courts have held that establishing a violation of the prescription requirement “requires proof that the practitioner’s conduct went ‘beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.’” *Laurence T. McKinney*, 73 FR 43260, 43266 (2008) (quoting *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006)). However, as the Sixth Circuit (and other federal circuits have noted), “[t]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of the evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.” *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992) (citations omitted) (quoted in *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995)).

Thus, in *Moore*, the Supreme Court held the evidence in a criminal trial was sufficient to find that a physician’s “conduct exceeded the bounds of ‘professional practice,’ ” where the physician “gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” “took no precautions against . . . misuse and diversion,” “did not regulate the dosage at all” and “graduated his fee according to the number of tablets desired.” 423 U.S. at 142–43.

However, as the Sixth Circuit has explained, “[o]ne or more of the foregoing factors, or a combination of them, but usually not all of them, may be found in reported decisions of prosecutions of physicians for issuing prescriptions for controlled substances exceeding the usual course of professional practice.” *United States v. Kirk*, 584 F.2d 773, 785 (6th Cir. 1978).

See also United States v. Hooker, 541 F.2d 300, 305 (1st Cir. 1976) (affirming conviction under section 841 where physician “carried out little more than cursory physical examinations, if any, frequently neglected to inquire as to past medical history and made little to no exploration of the type of problem a patient allegedly” had, and that “[i]n light of the conversations with the agents, the jury could reasonably infer that the minimal ‘professional’ procedures followed were designed only to give an appearance of propriety to [the] unlawful distributions”); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1139 (4th Cir. 1994) (holding evidence sufficient to find physician prescribed outside of professional practice, in that “in most cases the patients complained of such nebulous things as headaches, neckaches, backaches and nervousness, conditions that normally do not require . . . controlled substances,” physician was “aware that some of the[] patients were obtaining the same drugs from other doctors,” “[m]ost of the patients were given very superficial physical examinations,” and patients were not “referred to specialists”); *United States v. Bek*, 493 F.3d 790, 799 (7th Cir. 2007) (upholding convictions; noting that the evidence included “uniform, superficial, and careless examinations,” “exceedingly poor record-keeping,” “a disregard of blatant signs of drug abuse,” “prescrib[ing] multiple medications having the same effects . . . and drugs that are dangerous when taken in combination”); *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006) (“[T]he *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.”); *United States v. Joseph*, 709 F.3d 1082, 1104 (11th Cir. 2013) (upholding conviction of physician where “record establishe[d] that [physician] prescribed an inordinate amount of certain controlled substances, that he did so after conducting no physical examinations or only a cursory physical examination, that [physician] knew or should have known that his patients were misusing their prescriptions, and that many of the combinations of prescriptions drugs were not medically necessary”).¹⁴

¹⁴ However, as the Agency has held in multiple cases, “the Agency’s authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.” *Bienvenido Tan*, 76 FR 17673, 17689

The evidence shows that Registrant unlawfully distributed controlled substances by issuing prescriptions to the UC on multiple occasions outside the usual course of professional practice and for other than a legitimate medical purpose, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). *See also* Mich. Comp. Laws § 333.7401(1) (“A practitioner . . . shall not . . . prescribe . . . a controlled substance for other than legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice of the practitioner.”); *id.* § 333.7405(1)(a) (a licensed practitioner shall not “distribute, prescribe, or dispense a controlled substance in violation of section 7333”).

The Michigan Guidelines set forth the applicable standards of professional practice for the prescribing of controlled substances in the State. GX 28. The Guidelines provide that:

when evaluating the use of controlled substances for pain control . . . [a] complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.

GX 28. The Guidelines also state that the physician is to keep “accurate and complete records” of the forgoing and other aspects of medical care. *Id.*

The Government’s evidence shows that Registrant dispensed controlled substances to the UC on multiple occasions, notwithstanding his failure to conduct an adequate evaluation, including any physical examination to support a finding that the prescribing of both hydrocodone and the Xanax was medical necessary to treat the UC. GX 3–4, 6–7, 9–10. Dr. Chambers explained that Registrant failed to do a proper evaluation of the UC’s substance use even though he admitted to significant alcohol use, did not properly evaluate his psychiatric symptoms even though he said he was using Xanax and the

PMP report showed that he had obtained this drug from multiple providers, failed to perform a physical examination of the [UC] at any point, and failed to perform adequate treatment planning. Dr. Chambers further explained that Registrant falsified the medical record by fraudulently documenting in it that the UC denied drinking, as well as by making physical exam findings such as “[l]imited motion, spasm, tenderness, weakness, atrophy, abnormal reflexes,” when he did not perform the tests necessary to make these findings. GX 33, Attachment B, at 22.

Moreover, on the pain questionnaire, the UC did not circle any of the descriptors, did not rate his pain, nor indicate whether his pain interfered with various life activities listed on the form. Yet Registrant made no inquiry as to why the UC left most of the form blank.

Most significantly, during his visit with Registrant, the UC never complained of anything more than back stiffness, made no complaint that he suffered from anxiety and stated that he took Xanax because it kept him from drinking too much on the weekends. Here again, Registrant falsified the medical record by documenting: “Today [the UC] is complaining mostly of [] some level of anxiety.” Dr. Chambers further concluded that there was no basis for the various diagnoses which Registrant documented in the UC’s record, including anxiety and muscle spasms; he also noted that Registrant made no diagnosis of pain and that opioids are not indicated for muscle spasms.

The UC’s second visit with Registrant lasted all of three and a half minutes. As Dr. Chambers explained, the most substantial questions Registrant asked the UC for evaluating his need for the (hydrocodone and alprazolam, were: “Doing OK?” and “Med went well?” Moreover, Registrant did not perform a physical exam during the visit and yet, he again falsified the medical record by noting various exam findings.

As for the third visit, Dr. Chambers noted that Registrant did not address the UC’s statements regarding his drinking and statements that he had run out of medication and obtained controlled substances from his neighbor. Dr. Chambers further opined that there was essentially no clinical evaluation of the UC’s symptoms, illness course or treatment response. Registrant again falsified the visit note by indicating that the UC “appears to be in mild pain” and “states he is very anxious,” as well as by making physical exam findings of “limited motion, spasm, tenderness,”

“abnormal reflexes” and “weakness/atrophy,” when he did not perform the tests necessary to make these findings.

I thus conclude that Registrant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued the prescriptions for hydrocodone and alprazolam at each of the UC’s visits. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *see also* Mich. Comp. Laws § 333.7401(1). With respect to the UC, I conclude, based on Dr. Chambers’ testimony, that Registrant failed to comply with the Michigan Guidelines in that he failed to take a complete medical history, conduct a physical examination, and document in the medical record “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.” *Michigan Guidelines*, Section II.1. Based on Dr. Chambers’ testimony, I also conclude that Registrant “essentially” failed to comply with each of the standards of the Michigan Guidelines, including developing a treatment plan which sets forth objectives for determining treatment success and considering other treatment modalities, obtaining informed consent, conducting periodic reviews, and maintaining accurate and complete records. GX 33, Attachment B, at 5–6. (Expert Declaration), at 6. I further conclude that Registrant violated Michigan Law and the CSA in that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the UC. 21 CFR 1306.04(a); *see also* Mich. Comp. Laws §§ 333.7401(1).

I also find that Registrant failed to comply with the Michigan Guidelines, and violated both Michigan Law and the CSA in that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to patients D.S., A.L. and R.H. 21 CFR 1306.04(a); *see also* Mich. Comp. Laws § 333.7401(1). As discussed above, Dr. Chambers found that there was evidence that all three patients were suffering from drug addiction which Registrant did not adequately diagnose or treat, and that Registrant’s prescribing practices contributed to their addiction. With respect to each of the chart review patients, Dr. Chambers also found that Registrant “was prescribing extremely dangerous combinations of controlled substances without documenting an appropriate medical context or justification for so

(2011) (citing *Paul J. Caragine, Jr.*, 63 FR 51592, 51601 (1998)); *see also* *Dewey C. MacKay*, 75 FR at 49974. As *Caragine* explained: “[j]ust because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify” the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601.

“Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.” *MacKay*, 75 FR at 49974; *see also* *Patrick K. Chau*, 77 FR 36003, 36007 (2012).

doing, and [that he] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.” GX 33, at 6 (D.S.), 8 (A.L.), 11 (R.H.).

With respect to D.S., Dr. Chambers found that over the two-year period between January 2014 and February 2016, there was no evidence in the patient file that Registrant performed physical exams other than to take vital signs and that his treatment plan was essentially non-existent. He also found that D.S.’s chart contained multiples notations that she was suffering from addiction but no evidence that Registrant addressed this with her. Most significantly, as Dr. Chambers observed, D.S. provided multiple aberrational drug tests which included: (1) The presence of controlled substances which he did not prescribe on six occasions, including methadone, buprenorphine, cocaine, and amphetamines; (2) the non-presence of controlled substances (oxycodone and morphine) which he had prescribed on two occasions; and (3) the presence of oxycodone above the recommended therapeutic range on four occasions. Yet there is no evidence that Registrant addressed any of these aberrational test results with D.S.

As for A.L., Dr. Chambers found that “for the most part,” Registrant did not document the performance of a physical exam and there is no documentation in the patient file to support Registrant’s prescribing of the combinations of narcotics, benzodiazepines, and carisoprodol that he did. GX 33, at 7. Moreover, A.L.’s MAPS report showed that she had seen eight other providers in the year prior to her first visit with Registrant and that she had obtained controlled substances on 50 occasions¹⁵ which included hydrocodone, oxymorphone, oxycodone, morphine, diazepam, alprazolam and amphetamine based on prescriptions issued by these providers. Moreover, at her first visit with Registrant, A.L. reported that she was taking the Trinity of oxycodone, Xanax, and Soma, and while at one point, Registrant even documented that A.L. stated that she was buying drugs off the street, Registrant did not address this aberrant behavior. Moreover, as Dr. Chambers observed, her chart is devoid of evidence that she was monitored through the use of urine drug screens. See GXs 18–20.

With respect to R.H., Dr. Chambers found that “[f]or the most part there are

no physical exams documented in the medical records” and “[t]here is no documentation in R.H.’s medical records demonstrating a legitimate medical justification . . . for [Registrant’s] prescribing” the “dangerous combination[s]” of narcotics, benzodiazepines, and carisoprodol to R.H. GX 33, at 10. Dr. Chambers also found that R.H.’s urine drug screens showed the presence of controlled substances including amphetamines and benzodiazepines that Registrant did not prescribe to him and that Registrant had also documented that R.H. was overmedicating with respect to Valium. However, R.H.’s medical record contains no indication that Registrant resolved these red flags.

Accordingly, I agree with Dr. Chambers that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he issued the various controlled substance prescriptions identified above to D.S., A.L., and R.H. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1). I also agree with Dr. Chambers that Registrant’s prescribing to D.S., A.L. and R.H. violated Mich. Comp. Laws § 333.7401(1) and did not comply with the Michigan Guidelines.

I thus conclude that Registrant’s multiple violations of 21 CFR 1306.04 (a), 21 U.S.C. 841(a)(1), and Mich. Comp. Laws § 333.7401(1) are egregious and support the conclusion that he “has committed such acts as would render his registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4).¹⁶ I therefore conclude that the Government’s evidence with respect to Factors Two and Four makes out a *prima facie* case for revoking his existing registration and denying any applications for a new registration. As Registrant has waived his right to a hearing or to submit a written statement of position, there is no evidence to refute the conclusion that his registration is inconsistent with the public interest. I will therefore order that Registrant’s remaining registration be revoked and that any pending application 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. FS6457407 issued to Bernard Wilberforce Shelton, M.D., be, and it

hereby is, revoked. I further order that any pending application of Bernard Wilberforce Shelton to renew or modify the above registration, as well as any other pending application for registration be, and it hereby is, denied. This Order is effective immediately.¹⁷

Dated: March 24, 2018.

Robert W. Patterson,
Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Angela L. Lorenzo, P.A.: Decision and Order

On December 18, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Angela L. Lorenzo, P.A. (Registrant), of Las Vegas, Nevada. The Show Cause Order proposed the revocation of Registrant’s Certificate of Registration No. ML0901985 on the ground that she lacks “authority to handle controlled substances in the State of Nevada, the State in which [she is] registered with the DEA.” Order to Show Cause, Government Exhibit (GX) A–3, at 1 (citing 21 U.S.C. 824(a)(3)).¹ For the same reason, the Order also proposed the denial of any of Registrant’s “pending applications for a new registration or for renewal.” *Id.*

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that Registrant is registered as a practitioner in schedules II through V, pursuant to DEA Certificate of Registration No. ML0901985, at the address of 811 N Buffalo Road, Suite 113, Las Vegas, Nevada. *Id.* at 1–2. The Order also alleged that this registration

¹⁷ Based on the egregious nature of Respondent’s prescribing violations, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

¹ The Show Cause Order also proposed that Registrant’s DEA registration should be revoked because she “committed acts which render [her] registration inconsistent with the public interest.” GX 3, at 1 (citing 21 U.S.C. 823(f), 824(a)(4)). However, the Government did not include evidence to support this allegation with its Request for Final Agency Action (RFFA). Instead, the Government requested “leave to supplement its [R]equest to include the grounds for revocation under 21 U.S.C. 823(f), 824(a)(4)” should Registrant “regain her Nevada state license during the pendency of this Request for Final Agency Action.” RFFA at 1 n.1. The Government has not filed a request to supplement its RFFA, apparently because Registrant has not regained her Nevada state medical license. Accordingly, I do not consider the Government’s public interest allegation.

¹⁵ In some instances, she obtained the controlled substances through a refill of a previously issued prescription. See, e.g., GX 18, at 32 (alprazolam refill); *id.* at 33–34 (refills of hydrocodone).

¹⁶ This provides a separate and independent ground from the finding that he does not currently possess state authority for revoking his registration and denying his application.