

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–26]

Samson K. Orusa, M.D.; Decision and Order

On May 31, 2019, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Samson K. Orusa (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed revocation of Respondent's DEA Certificate of Registration Number BO4959889 (hereinafter, registration or COR), the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations including the pending application for COR Number W18070589C pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's continued "registrations are inconsistent with the public interest." *Id.* (citing 21 U.S.C. 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted on September 9, 2020, October 15, 2020, and October 21, 2020, via video teleconference technology. On December 8, 2020, Administrative Law Judge Mark M. Dowd, (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD) and neither party filed exceptions. I issue the final order in this case following the RD. Having reviewed the entire record, I adopt the ALJ's Recommended Decision with minor modifications, as noted herein.*^A

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *^B

The Drug Enforcement Administration (DEA) Assistant Administrator, filed an Order to Show

*^A I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun "I" refers to myself—the Administrator.

*^B I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

Cause (OSC)¹ on May 31, 2019, the Certificate of Registration (COR), No. BO4959889, of Samson K. Orusa, M.D. (Respondent), proposing to revoke the Respondent's COR pursuant to 21 U.S.C. 824(a)(4) on the ground that the Respondent's registration is inconsistent with the public interest, as defined in 21 U.S.C. 823(f). [Omitted.]^{2,3} In its Supplemental Pre-hearing Statement (GSPHS), the Government further alleged that the Respondent made a material falsification in his renewal application of November 6, 2019, in violation of 21 U.S.C. 824(a)(1). ALJ Ex. 53, 54.⁴ A hearing was conducted in this matter on September 9, 2020, October 15, 2020, and October 21, 2020, via video teleconference technology.⁵

The issue to be decided by the Administrator is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. BO4959889, issued to Respondent should be revoked, and any pending applications for modification or renewal of the existing registration should be denied, and any pending applications for additional registrations should be denied, because his continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4) and because he materially falsified his application under 21 U.S.C. 824(a)(1).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

Overview

1. The Respondent is registered with the DEA as a Practitioner authorized to handle controlled substances in

¹ ALJ Ex. 1.

² [Omitted.]

³ [Omitted.]

⁴ Allegations brought in the OSC and Government's Prehearing Statements provide sufficient notice to the Respondent to defend against. *Jose G. Zavaleta, M.D.*, 78 FR 27431, 27439 (2013) (Where the Government did not allege material falsification on the respondent's application in the Order to Show Cause, but did raise the issue in its Supplemental Pre-hearing Statement, the respondent was on notice that the issue would be considered at the hearing).

⁵ Although in his Posthearing Brief, the Respondent suggests the hearing was "truncated", there was nothing abbreviated or shortened as to the proceeding, which is now over 18 months and counting, or as to the hearing. Neither party was limited as to their time for presentation or number of witnesses. The hearing ended on October 21, 2020, at 4:30 p.m., with 90 minutes remaining in the day. I did inform the parties that we would be finishing the hearing within the month of October, and to make their arrangements accordingly.

Schedules II–V under DEA registration number BO4959889 at 261 Stonecrossing Drive, Clarksville, Tennessee 37042. His DEA COR BO4959889 expired by its terms on December 31, 2019.

2. On July 6, 2018, the Respondent submitted an application (Application Control No. W18070589C) to the DEA for a new DEA COR (the "Application"). This application seeks a new DEA COR under his Kentucky medical license at 316 Pappy Drive, Oak Grove, Kentucky 42262.⁶

3. Presently, the Respondent is licensed in the State of Tennessee as a medical doctor with license number 28275. The Respondent's Tennessee medical license expires by its own terms on March 31, 2020. The Respondent is also licensed in the State of Kentucky as a physician with license number 33408. The Respondent's Kentucky medical license expires by its own terms on February 29, 2020.

4. As a licensed medical doctor in Tennessee, the Respondent is subject to TENN. CODE ANN. 63–6–6214(b)(12) through (14), as those provisions pertain to "dispensing, prescribing, or otherwise distributing" controlled substances. Specifically, section 63–6–214(b)(12) prohibits a physician from prescribing controlled substances "not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition." Accordingly, section 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person "addicted to the habit of using controlled substances "without" making a bona fide effort to cure the [patient's] habit." To determine a violation of these provisions, the Tennessee Board of Medical Examiners uses a non-exhaustive list of guidelines ("the guidelines") found in TENN. COMP. R. & REGS. 0880–02–.14(6)(e). The guidelines require that a physician (1) take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate "assessment and consideration of the [patient's] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance." TENN. COMP. R. & REGS.

⁶ See ALJ Ex. 65, Order Granting the Government's Motion for Partial Summary Disposition (June 18, 2020).

0880-02-.14(6)(e)(3)(i). Additionally, Rule 0880-02-.14(6)(e) requires physicians to create a “written treatment plan tailored for the individual needs of the patient” that considers the patient’s “pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.” It also requires the physician to “discuss the risks and benefits of the use of controlled substances,” do a “documented periodic review of the care . . . at reasonable intervals,” and “keep [c]omplete and accurate records of the care.” *Id.* at 0880-02-.14(6)(3)(ii)-(v).

5. On October 3, 2017, the Respondent issued a prescription for 42-ten milligram tablets of oxycodone to UC, a Tennessee state law enforcement officer working in an undercover capacity. The Respondent issued this prescription following a brief meeting with UC, during which he performed a cursory and inadequate physical examination and reviewed medical records which did not justify the prescribing of oxycodone in the amount and dosage which he prescribed. He also failed to: (1) Take an adequate medical history; (2) assess the patient’s pain, physical and psychological function; (3) assess the patient’s history

and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone. The Respondent further failed to create a legitimate written treatment plan for the patient’s individual needs or discuss the risks and benefits of the use of oxycodone with the patient.

6. Additionally, on October 18, 2017, the Respondent’s office provided UC with a prescription which the Respondent signed and dated October 18, 2017, for 84-ten milligram tablets of oxycodone. This occurred after UC paid \$377 for an office visit during which no physical examination occurred and virtually no medical information was obtained or communicated. Additionally, on November 20, 2017, the Respondent’s office provided UC with a prescription which he signed and dated November 20, 2017, for 84-ten milligram tablets of oxycodone. This occurred after UC paid for another office visit during which no physical examination occurred and no medical information was obtained or communicated.

7. With respect to the prescriptions the Respondent issued to UC, he issued these prescriptions without: (1) Taking a medical history or performing a minimally sufficient physical examination; (2) assessing the patient’s pain, physical and psychological

function; and (3) assessing the patient’s history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone. The Respondent further failed to create and follow a legitimate written treatment plan for the patient’s individual needs or discuss the risks and benefits of the use of oxycodone with the patient. Also, by falsely indicating that UC was physically examined on October 18 and November 20 of 2017, he violated TENN. COMP. R. & REGS. 0880-02-.14(6)(e)(3)(v).

8. In addition to the medical records for UC, medical records for more than 20 of the Respondent’s patients were reviewed by a qualified medical expert (“reviewing expert”) who concluded that the Respondent’s continued prescribing of controlled substances to these patients was without a legitimate medical purpose and/or outside the usual course of professional practice. Below are examples of some of the patient records which were reviewed:

a. *Patient M.H.:* From August 2014 through February 2018, the Respondent regularly issued prescriptions for large quantities of alprazolam, carisoprodol, oxycodone, and oxymorphone to M.H. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
1.3.17	Alprazolam	.5 mg	120
1.4.17	Oxycodone	30 mg	84
1.4.17	Oxymorphone	15 mg	56
2.3.17	Alprazolam	.5 mg	112
2.6.17	Carisoprodol	350 mg	56
2.6.17	Oxycodone	30 mg	84
2.6.17	Oxymorphone	15 mg	56
3.3.17	Alprazolam	.5 mg	112
3.6.17	Oxycodone	30 mg	84
3.6.17	Carisoprodol	350 mg	56
3.6.17	Oxycodone	30 mg	84
3.6.17	Oxymorphone	15 mg	56
4.3.17	Alprazolam	.5 mg	112
4.4.17	Carisoprodol	350 mg	56
4.4.17	Oxycodone	30 mg	84
4.4.17	Oxymorphone	15 mg	56

According to the reviewing expert, the Respondent diagnosed M.H. with “chronic pain syndrome” even though he made no attempt to diagnose a specific pain etiology. The reviewing expert found that the Respondent failed to obtain diagnostic studies and current medical records from M.H.’s other medical providers and that the results of the Respondent’s physical examination and medical history did not justify the

continued prescribing of controlled substances. The reviewing expert also noted that he ignored a major surgical intervention that occurred in September 2016 as well as an abnormal drug screen. As such, the reviewing expert concluded that much of the medical record for M.H. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The

Respondent also documented that the patient provided “informed consent,” when no informed consent document could be located. The expert also found that, in some cases, the Respondent failed to repeat certain physical exams after his initial encounter with M.H., despite the fact he provided him with prescriptions for controlled substances for more than three years.

b. *Patient C.F.*: From August 2014 through August 2018, the Respondent regularly issued prescriptions for oxycodone and alprazolam to C.F. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
1.4.17	Alprazolam	.25 mg	28
1.6.17	Oxycodone	15 mg	84
1.30.17	Alprazolam	.25 mg	28
2.3.17	Oxycodone	15 mg	84
2.3.17	Oxycodone	7.5 mg	28
3.1.17	Alprazolam	.25 mg	28
3.1.17	Oxycodone	7.5 mg	28
3.4.17	Oxycodone	15 mg	84
3.13.17	Alprazolam	.25 mg	28
3.14.17	Oxycodone	15 mg	28
3.14.17	Oxycodone	7.5 mg	28
4.25.17	Alprazolam	.25 mg	28
4.28.17	Oxycodone	15 mg	21
4.28.17	Oxycodone	7.5mg	7
5.8.17	Oxycodone	15 mg	84
5.8.17	Oxycodone	7.5 mg	28

The reviewing expert found that no credible physical examination had been performed on C.F. and that the exam results, as well as medical history, did not justify the continued prescribing of controlled substances. The expert further found that no meaningful follow-up physical exam was repeated, that supported diagnostic studies were not ordered, and that the Respondent

failed to determine a chronic pain etiology. The expert also found that he ignored suspicious drug screen results which indicated illegal drug use. The reviewing expert concluded that much of the medical record for C.F. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The Respondent also

documented that the patient provided “informed consent” when no informed consent document could be located.

c. *Patient M.P.*: From September 2016 through April 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone and oxymorphone to M.P. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
10.21.16	Oxycodone	30 mg	84
10.21.16	Oxymorphone	7.5 mg	56
11.18.16	Oxycodone	30 mg	84
11.18.16	Oxymorphone	7.5 mg	56
12.16.16	Oxycodone	30 mg	84
12.16.16	Oxymorphone	7.5 mg	56
11.22.17	Oxycodone	30 mg	84
11.22.17	Oxymorphone	7.5 mg	56
12.18.17	Oxycodone	30 mg	84
12.18.17	Oxymorphone	7.5 mg	56
1.19.18	Oxycodone	30 mg	84
1.19.18	Oxymorphone	7.5 mg	56
2.16.18	Oxycodone	30 mg	84
2.16.18	Oxymorphone	7.5 mg	56
3.16.18	Oxycodone	30 mg	84
3.16.18	Oxymorphone	7.5 mg	56

The reviewing expert found that he failed to request and obtain past medical records, he failed to order any radiographic studies, and that his physical examinations of M.P., including follow-up exams, were substandard and not credible. The expert found that he failed to document any evidence to support a pain etiology and that he failed to properly address M.P.’s substance abuse disorder despite

the fact that she suffered a heroin overdose in his waiting room. As a result, the expert found no objective findings to justify the continued prescribing of oxycodone and oxymorphone. The reviewing expert also concluded that much of the medical record for M.P. was fabricated and seemed to be copied from records of other patients whose records contained identically worded

assessments. He also documented that the patient provided “informed consent” when no informed consent document could be located.

d. *Patient B.C.*: From August 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone, oxymorphone, alprazolam, and carisoprodol to B.C. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
4.10.18	Alprazolam	1 mg	84
4.16.18	Oxycodone	30 mg	84
4.21.18	Oxymorphone	30 mg	56
4.27.18	Alprazolam	1 mg	84
5.14.18	Oxycodone	30 mg	21
5.21.18	Oxymorphone	30 mg	14
5.22.18	Oxycodone	30 mg	84
5.26.18	Oxymorphone	30 mg	56
6.12.18	Alprazolam	1 mg	5
6.12.18	Alprazolam	1 mg	84
6.19.18	Oxycodone	30 mg	21
6.22.18	Oxycodone	30 mg	84
6.22.18	Oxymorphone	30 gm	56
6.22.18	Carisoprodol	350 mg	56
7.9.18	Alprazolam	1 mg	84
7.25.18	Carisoprodol	350 mg	56
7.25.18	Oxycodone	30 mg	84
7.25.18	Oxymorphone	30 mg	56

The reviewing expert found that the physical examination and medical history did not justify the continued prescribing of controlled substances. The expert found that he failed to: (1) Obtain the patient’s past medical records; (2) order radiologic and other studies that would support the treatment; (3) adequately address the fact that B.C. lied about his scheduled

medications during his initial encounter; and (4) pursue a specific pain diagnosis. The expert also found that he failed to document the patient’s response to the medication which he prescribed. The reviewing expert also concluded that much of the medical record for B.C. was fabricated and seemed to be copied from records of

other patients whose records contained identically worded assessments.

e. *Patient M.W.*: From January 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities and dosages of oxycodone, oxymorphone, alprazolam, and carisoprodol to M.W. A representative sample of those prescriptions follows below:

Date written	Drug	Dosage	Quantity (number of tablets)
4.3.17	Alprazolam	2 mg	56
4.4.17	Carisoprodol	350 mg	28
4.4.17	Oxycodone	30 mg	56
4.4.17	Oxycodone	15 mg	56
4.28.17	Alprazolam	2 mg	56
5.2.17	Oxycodone	30 mg	56
5.26.17	Alprazolam	2 mg	56
7.7.17	Alprazolam	2 mg	56
7.31.17	Oxycodone	30 mg	56
8.4.17	Alprazolam	2 mg	56
10.18.17	Alprazolam	2 mg	56
12.12.17	Alprazolam	2 mg	56
1.19.18	Alprazolam	2 mg	56
2.12.18	Alprazolam	2 mg	56
3.30.18	Oxymorphone	15 mg	56
4.6.18	Alprazolam	2 mg	56
4.27.18	Oxycodone	30 mg	28
4.27.18	Oxymorphone	15 mg	56
5.15.18	Alprazolam	2 mg	56
5.29.18	Oxycodone	30 mg	28
5.29.18	Oxymorphone	15 mg	56
6.15.18	Alprazolam	2 mg	56
7.2.18	Oxycodone	30 mg	56
7.2.18	Oxymorphone	15 mg	56
8.29.18	Alprazolam	2 mg	56
8.29.18	Oxycodone	30 mg	56

With respect to M.W., the reviewing expert found that the initial physical examination and medical history did not justify the continued prescribing of controlled substances and the subsequent physical examinations did

not meaningfully evidence any chronic pain condition. The expert also found that he failed to: (1) Order and obtain diagnostic studies; and (2) adequately address numerous instances in which the patient had abnormal drug screens

indicating possible diversion, abuse, and/or use of illegal controlled substances. The reviewing expert also concluded that much of the medical record for M.W. was fabricated and seemed to be copied from records of

other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided “informed consent” when no informed consent document could be located.

9. With respect to the Respondent’s treatment of M.H., C.F., M.P., B.C., and M.W. (“the five patients”), the prescriptions for controlled substances which he issued were not issued in the course of professional practice inasmuch as he failed to: (1) Take an adequate medical history; (2) perform a sufficient physical examination; and (3) perform an adequate “assessment and consideration of the [patients’] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.” The Respondent also failed to create a “written treatment plan tailored for the individual needs” of each of the five patients which considered each of the patient’s “pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.” He also failed to: (1) “Discuss the risks and benefits of the use of controlled substances” with patients M.H., C.F., M.P., B.C., and M.W.; (2) do a “documented periodic review of the [ir] care . . . at reasonable intervals in view of the individual circumstances” of each patient; and (3) keep “[c]omplete and accurate records of the care provided.” As such, his conduct violated TENN. CODE ANN. § 63–6–214(b)(12) and TENN. COMP. R. & REGS. 0880–02.14(6)(e)(3)(i)–(v).

10. With respect to C.F., M.P., and M.W., the Respondent failed to address substantial evidence that the patients were engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. § 63–6–214(b)(13).

11. The prescriptions the Respondent issued to UC, M.H., C.F., M.P., B.C., and M.W. failed to comply with Tennessee state law in that they did not conform to accept and prevailing medical standards in Tennessee, and thus, were issued outside the usual course of professional practice. His conduct, viewed as a whole, “completely betrayed any semblance of legitimate medical treatment.” *Jack A. Danton, D.O.*, 76 FR 60,900, 60,904 (2011). By issuing these prescriptions for controlled substances, he failed to take reasonable steps to guard against diversion of controlled substances. See *David A. Ruben, M.D.*, 78 FR 38,363, 38,382 (2013); *Beinvenido Tan, M.D.*, 76

FR 17,673, 17,689 (2011); *Dewey C. Mackay, M.D.*, 75 FR 49,956, 49,974 (2010); *Physicians Pharmacy, L.L.C.*, 77 FR 47,096 (2012).

12. Even a single act of knowing diversion is sufficient for the Agency to revoke a registration. See *Dewey C. Mackay*, 75 FR at 49,977. Detailed above are numerous acts of alleged unlawful prescribing, any one of which could independently establish the sort of intentional diversion on the part that would justify the revocation of his DEA registration and the denial of his pending application as inconsistent with the public interest. See 21 U.S.C. 824(a)(4), 823(f).

13. In addition to the legal authorities cited above, the following cases and Final Orders provide a summary of the legal basis for this action: *United States v. Moore*, 423 U.S. 122, 135, 143 (1975); *Randall L. Wolff, M.D.*, 77 FR 5,106 (February 1, 2012); *Jack A. Danton, D.O.*, 76 FR 60,900 (September 30, 2011); *Robert F. Hunt, D.O.*, 75 FR 49,995 (August 16, 2010); *Linda Sue Cheek, M.D.*, 76 FR 66,972 (2011); *Kathy A. Moral*, 69 FR 59,956 (2004); *Rebecca Sotelo*, 70 FR 28,580 (2005); *Patrick W. Stodola, M.D.*, 85 FR 20,727 (2009); *Bob’s Pharmacy and Diabetic Supplies*, 74 FR 19,599 (2009); *Nirmal Saran, M.D.*, 73 FR 78,827 (2008).

14. With regard to the Respondent’s application for a new DEA COR in Kentucky, there are additional grounds for denying his application insofar as he lacks state authority to handle controlled substances in that state. On January 15, 2019, the Commonwealth of Kentucky, Board of Medical Licensure, issued an Emergency Order of Restriction prohibiting him from “prescribing, dispensing, or otherwise professionally utilizing controlled substances.” See 201 KY. ADMIN. REGS. 9:240 1 and 3. Thus, he is currently without authority to handle controlled substances in the Commonwealth of Kentucky, the state in which he has applied for a new DEA COR. Consequently, the DEA must deny his application for a DEA COR based on his lack of authority to handle controlled substances in the Commonwealth of Kentucky. 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b). See e.g., *Kenneth C. Beal, Jr., D.D.S.* 83 FR 34,877 (2018); *Mehdi Nikparvarfard, M.D.*, 83 FR 14,503 (2018); *Leia A. Frickey, M.D.*, 82 FR 37,113 (2017); *Alaaeldin A. Babiker, M.D.*, 81 FR 50,723 (2016); *James Dustin Chaney, D.O.*, 81 FR 47,416 (2016); *Irwin August, D.O.*, 81 FR 3,158 (2016); *Wayne D. Longmore, M.D.*, 77 FR 67,669 (2012); *Jovencio L. Raneses, M.D.*, 75 FR 11,563 (2010); *John B. Freitas, D.O.*, 74 FR 17,524

(2009); *Worth S. Wilkinson, M.D.*, 71 FR 30,173 (2006).

Material Falsification

In its Supplemental Prehearing Statement, the Government alleged that, on November 6, 2019, the Respondent made a material falsification on his renewal application for his Tennessee-based DEA COR, #59889. Specifically, the Government alleged that in response to liability question three, the Respondent answered “no”, which he knew or should have known to be a false response. GX 26. Liability question three queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. The Government alleged that an affirmative answer to Question Three would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered “No” to question 3. A false “no” answer can result in an improperly issued registration. GX 26.

In support, the Government cites to the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties, see GX 29, an order from the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part 3, reversing Stay with Conditions. GX 27. The Government contends that as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay. The Government also cites an Agreed Order with the State of Tennessee, GX 27, in which the Respondent was required to surrender his Pain Management Certificate, a professional license, in 2018, and prior to his application for registration in November, 2019. GX 26; GX 28. The Government alleges that, although GX 28 related to the surrender of the pain clinic license, and GX 26 was the Respondent’s personal application, as the Respondent applied for the pain clinic license himself, it constitutes a surrender of his own license, warranting an affirmative response to Question Three of his DEA application. GX 26.⁷

The Hearing

Government’s Opening Statement

The Government characterized the Respondent as a willing enabler of drug

⁷ The surrender is signed by the Respondent individually.

abuse and diversion. Tr. 20. Rather than maintaining medical records lacking in detail, the Respondent's records, although detailed, were fabricated. The Government's expert reviewed twenty-four patient charts and discovered identical language throughout. Some phrases were repeated more than 100 times. Undercover⁸ will testify that tests described in his chart were not performed. Test results were repeated during three visits in which he was not seen by the Respondent. The same identical test results were repeated in other patient charts. The Government's expert will testify that the Respondent prescribed controlled substances without a legitimate medical purpose and outside the usual course of professional practice, on the basis of the subject medical charts. He will further testify that the charts reveal multiple red flags of abuse and diversion, which were largely ignored by the Respondent. Rather, he created records which were deceptive, dishonest, and in some cases, dangerous. Tr. 20.

Respondent's Opening Statement

Samson Orusa contends that he is a fine physician, who cares deeply about his patients. Tr. 24. He spends a lot of time getting to know his patients to insure he understands their issues relating to pain management. His system is to use a number of documents, which the patients fill out prior to the Respondent seeing them, in order to get a full picture of each patient. These include the initial visit sheet, and a 41-page pain management physical exam sheet. He would go through these documents with the patient painstakingly. These forms take hours to fill out and to review.

The undercover agent presented himself to the Respondent under false colors, under an assumed identity, and with an MRI, which the Respondent could not confirm. He claimed to be from Missouri, a state without a PDMP. He reported he had used over-the-counter medications to treat his pain, and falsely claimed he had previously been prescribed Schedule II controlled substances, painting the picture that he needed Schedule II pain medications from the Respondent. The evidence will fail to show that the Respondent has done anything outside the bounds of normal medical practice.

Furthermore, the Government's case relies solely on the opinion of its expert, Dr. Kennedy, who we maintain is not an expert in the field of pain management, and whose qualifications are limited to family practice. He holds himself out to

be a diplomat with the American Academy of Pain Management, which is a defunct organization. He has never completed a fellowship in pain management. He is not board-certified in pain management, and would not be qualified in the State of Tennessee to be a medical director of a pain clinic. The Respondent maintains Dr. Kennedy's opinion testimony should be afforded no weight in these proceedings.⁹ Tr. 24

Government's Case-in-Chief

The Government presented its case-in-chief through the testimony of four witnesses. First, the Government presented UC. Secondly, the Government presented the testimony of Dr. Gene Kennedy. Thirdly, the Government presented the testimony of a DEA Special Agent assigned to this matter. Finally, the Government presented testimony of a DEA Diversion Investigator assigned to this matter.

Undercover

[UC testified regarding his education, credentials, and employment background with the Tennessee Bureau of Investigation].^{*C} He has conducted approximately twenty to thirty investigations as the lead case agent in cases involving allegations of fraud, physicians prescribing narcotics without medical necessity, and physicians prescribing outside the scope of professional practice. Tr. 31–32. [Omitted.]¹⁰ He provided lower back pain as a false symptom in this case, specifically because he has "absolutely no back pain whatsoever." Tr. 112–11.

Undercover was contacted by a Special Agent (SA) with the United States Department of Health, Office of Inspector General (SA–DOH) who asked him to make an appointment with the Respondent in the late summer of 2017. Tr. 34; 98.¹¹ The initial goal in these types of cases is to get an appointment to see the doctor. Tr. 34. The ultimate goal is to see if the physician will write the undercover agent a prescription for a controlled substance. Tr. 34, 101.

In this particular investigation, UC contacted the Respondent's office and

spoke with the receptionist over the phone, who told him that he would be scheduled for a new patient visit and was required to bring certain items on that day including; (1) an MRI report, (2) the last three chart notes from a previous physician, (3) the discharge summary from his previous pain management clinic, and (4) a printout of the last three months from his pharmacy. Tr. 35. UC already had some of the items, such as the MRI report, but there were other items he needed to put together. Tr. 34–35. The MRI that UC had was authentic, as it was his actual MRI that was performed on September 2, 2016. Tr. 35–37, 106. The only thing he altered was the ordering physician and patient name of "Chris Rutledge." Tr. 35–37.

The patient records that he presented to the Respondent were fabricated. Tr. 37–38. DOH–SA and another SA consulted with a nurse practitioner who worked for TBI and instructed the agents to generate medical records that would be indicative of someone who was seeing a nurse practitioner for pain. Tr. 38, 108; GX 6. UC then provided his personal information including his date of birth and his medical complaints for the agent to create a medical record. The only medical record provided to the Respondent's office was signed by "S.C.," who was not practicing medicine at that time. Tr. 38, 133.

UC visited the Respondent's office on October 3, 2017, and recorded video and audio of the visit. Tr. 40; 42–43.¹² He set up an appointment for 8:00 a.m. and was told to bring the necessary documents. Tr. 40. UC showed up for the appointment at approximately 8:00 a.m.¹³ and gave the documents he had to the receptionist, and explained why he was missing two documents.¹⁴ Tr. 38–40, 108; GX 4.¹⁵ The receptionist gave him about twenty pages of paperwork and asked him to sit in the waiting room to fill it out. At some point he was called up by one of the

¹² At this point, Government offered Government Exhibit 3. The time stamp for the video of the October 3, 2017 visit is 5:05:42. Tr. 74.

¹³ UC noted that he did not present in any "unusual way" to show that he had a disability, limp, change or change his gait. Tr. 46.

¹⁴ As discussed *supra*, UC was asked to bring in a discharge summary, which is a report that a pain management clinic creates when the clinic releases a patient. Tr. 38–39, 108. He ultimately did not provide this document to the Respondent's office, stating that he was unable to obtain it. Tr. 39. He also stated that did not provide the printout showing the last three months of pharmaceutical history, because he was unable to get it. Tr. 39–40.

¹⁵ No one asked for these records after his visit and he never produced the pharmacy records. Tr. 55.

⁹ The Respondent's written motion to exclude the testimony of Dr. Kennedy was carried until the Government offered Dr. Kennedy as an expert witness at the hearing. Tr. 24–25, 26. The Respondent's Motion to Exclude was denied on its merits in conjunction with his objection to having Dr. Kennedy qualified as an expert witness. Tr. 201, 211–12. Contrary to the Respondent's claims, the motion was not denied as untimely.

^{*C} In this section, I have omitted some biographical and investigation-related information to protect the identity and methodology of UC.

¹⁰ [Omitted original text in which footnote appeared.]

¹¹ He is familiar with the DEA Physician's Manual. Tr. 98.

⁸ [Omitted for privacy.]

employees¹⁶ who made a comment about one of the pages in UC's medical record appeared to be "whited out" and the employee then made a statement that there are "people that are trying to bring down [the Respondent]" and the Respondent would therefore "be reluctant to write any medications." Tr. 41; GX 3. The receptionist then told UC to have a seat and he would be called back for triage to get his vitals. Tr. 41–42, 44. UC paid for this visit with \$311 of cash. Tr. 49, 110.¹⁷

UC filled out a pain disability index and ranked his pain level as a nine out of ten, which was not a truthful response to how he felt at the time. Tr. 47, 101, 109–10, 123. As to his goals, his second goal was to "sleep through the night" but he did not check the box for insomnia. Tr. 134–35, 139. Despite this contradiction, no one in the office asked about this. Tr. 139.¹⁸ He also filled out a Zung Self-Rating Depression Scale, selecting random answers. Tr. 102. He also filled out a drug use questionnaire regarding his drug history with the intention of presenting a picture of a person who is in pain. Tr. 102–03. He also filled out an agreement for opioid maintenance therapy and for cancer and non-cancer patients. Tr. 103. He also filled out an American Chronic Pain Association form including a chronic problem list and reported that he was only taking Advil, an over-the-counter, anti-inflammatory and pain medication of three pills, three times a day, with the understanding that if he was performing well with the over-the-counter medicine, a doctor would likely not give him a prescription. Tr. 103–105, 123. He also filled out a multi-page pain management physical form, which was blank¹⁹ in his seized medical record. Tr. 105, 128. He could not recall if the Respondent went through every form with him, but did remember the Respondent asking him a couple questions. Tr. 105. He also recalled telling the Respondent that he had taken prescription hydrocodone in the past and it had helped him. Tr. 123.

At one point, a female wearing scrubs took his blood pressure, asked about his

weight, provided him a specimen cup, and instructed him to go into the bathroom located inside the waiting room. Tr. 44–45. UC then produced a urine sample. Tr. 45.

The time that passed from when UC spoke with the employee about his "fabricated" records with the "white-out" page until he met with the Respondent, was about seven hours, only leaving the office for approximately forty-five minutes to get lunch. Tr. 48–49, 100.

[Omitted to protect law enforcement techniques]. UC told the Respondent where his pain was located and if it hurt he would respond that he had pain in that area, but did not make any face or wince. There was less than sixty seconds of any kind of physical touching between himself and the Respondent, which he testified was brief compared with other physicians.

The Respondent asked what his previous diagnosis was and he responded with arthritis and degenerative disk disease. Tr. 105–06.²⁰ During this visit, UC learned that the office staff had tried to contact his pharmacy and was unable to do so. Tr. 108–09. UC explained to the Respondent that he would try to get a hold of them and the Respondent's stated that his office would make another attempt. Tr. 109. They also discussed the alternative treatment of injections for UC's back pain, but UC refused to get the injections. Tr. 117, 127. UC told the Respondent that he had fallen off a truck sometime in 2013, was seeing Dr. Chapman in Pierce City, Missouri, and he moved to Tennessee about one month prior to his first visit on October 3, 2017. Tr. 117–18. None of these statements were true. Tr. 117–18. UC also shared a story about his aunt breaking her hip and him going to the clinic to obtain records, that he was unable to do so because the clinic was shut down, and that his aunt still lived in Missouri. Tr. 118. None of these statements were true. Tr. 118. UC admitted that he stated all of these lies in order to achieve his stated goal to get a prescription from this visit and also noted that "[u]ndercover operations inherently rely upon some falsehoods in all aspects of law enforcement." Tr. 119–21.²¹

²⁰ In fact, a physician had previously told UC that he may have arthritis, UC was not given a diagnosis of degenerative disk disease. Tr. 106–107.

²¹ At this point in the testimony, on cross-examination, the Respondent's counsel made a comparison to an undercover agent purchasing heroin from a dealer and the Tribunal inquired of the Respondent's counsel as to the relevance of his questioning. Tr. 121. The Respondent's counsel asserted that UC had lied to the Respondent to

He received a prescription for 42 oxycodone 10-milligram tablets, thirty minutes after he left the exam room, from one of the receptionists, despite not asking for oxycodone. Tr. 56–57; GX 18. He also received prescriptions for Meloxicam and flexeril. Tr. 57–58; GX 18.²² He filled the oxycodone prescription, but not the other prescriptions. Tr. 57, 58.²³

UC went back to the office for a second visit on October 15, 2017, which was supposed to be his well-care visit between receiving his two narcotic prescriptions. Tr. 58–59. He did not make an appointment. He showed up at the office, and made a \$25 payment to the receptionist. Tr. 59. He was called back to the triage room where the nurse asked him his weight, to which he replied, "210," and if his blood pressure was ok, to which he responded, "yes." The nurse then directed him back to the waiting room. He was later called to the exam room.

This visit was recorded in the same manner as the visit on October 3, 2017. Tr. 59–60; GX 4 at 4.²⁴ When he entered

achieve his goal of getting a prescription. Tr. 121. The Tribunal asserted that "in principle this is an undercover operation. [That is] the whole point of it." Tr. 122.

²² UC confirmed that this Government Exhibit 18 was a fair and accurate copy of the prescription he received on October 3, 2017.

²³ UC asserted that he did not expect to get controlled substances on this first visit, as he usually does not expect to get them, but from what he had "been told regarding the clinic, it [did not] shock him." Tr. 125. If he had not received prescriptions that first visit, it would not have deterred him from making future appointments as it usually takes several appointments to build up to the point where the undercover agent receives controlled substances. Tr. 125. There is no set number for visits, but in cases where he has been the case agent, he has looked for a progression from other modalities of treatment first being offered and then elevating to drugs like hydrocodone to oxycodone, elevating the dosage or the quantities over time. Tr. 126–27.

²⁴ UC stated that Government Exhibit 4 is a transcript of his interaction with the Respondent on that date and is a fair and accurate representation of their encounter. Tr. 60; GX 4 at 4. The transcript reflects that the video was difficult to hear. The Respondent's counsel objected to the video being put into evidence if the video could not be properly played before the Tribunal. Tr. 64–66. The Tribunal noted the objection and allowed the Government's counsel to proceed. The video was replayed and UC asserted that he was able to hear the tape. The Tribunal overruled the objection and noted that the Respondent's counsel could cross examine UC. The Government later moved Government Exhibits 4 and 17 into the record. Tr. 69. The Tribunal admitted pages 1, 2, and 3 of Exhibit 4 and part of Government Exhibit 17, but noted that it was "not convinced that [the] audio is intelligible, fully audible, without interference, because [it] ha[s] nothing but interference" on the Tribunal's end. Tr. 70. On Day 3 of the hearing, the Tribunal reconsidered its earlier ruling on the limited admissibility of GX 4 and 17, and admitted the exhibits in their entirety, noting that the video/audio (GX 4) was played successfully at the hearing to all participants, except the Tribunal and court

¹⁶ At this point in the testimony, Judge Dowd stated that UC was not allowed to read from his report directly. UC clarified that although he "did have it open," he had not "looked at it yet." Tr. 41.

¹⁷ At this point in the testimony, the Government played a video. Tr. 51; GX 4. Judge Dowd instructed the court reporter not to transcribe the audio of the video, as the recording itself is the best evidence. UC confirmed that the transcript of the proceedings was a fair and accurate representation of the recording. Tr. 55; GX 4.

¹⁸ UC had noted that he may have stated that he did not sleep well because he was awakened by his pain.

¹⁹ UC noted that there were several forms that were blank in the copies he had.

the room, the Respondent asked if it was UC's first well visit or primary care visit and UC affirmed it was. Tr. 71. The Respondent asked if UC was taking other medications and he stated that he was not taking medications other than pain medications. The Respondent asked whether UC was sleeping well and he responded "not really." The Respondent then stated that he would write him a prescription for pain medications to help him sleep. UC asked what it was, and the Respondent stated, "amitriptyline." That marked the end of the encounter. Tr. 71. There was no further medical examination or physical examination of his lower back, of any of his extremities, or an examination to determine if he had muscle pain. Tr. 71–72.

UC had a third visit on October 18, 2017, when he was scheduled to get the refills for his narcotic medications. Tr. 75. He went to the Respondent's office and first attempted to pay with cash, but had to secure a debit card. Tr. 75–76. He wrote his name on a clipboard, paid the \$377 fee for the office visit, and about an hour later his name was called and he got his prescription. Tr. 76. He was at the clinic for approximately two and half hours and was not examined by any medical personnel nor did he provide any medical records. Tr. 77. He received a prescription for eighty-four tablets of ten milligrams of oxycodone. Tr. 78, GX 18 at 3, 4. This dosage was less than the Lortab of four times a day. He also received the "euphoria drug" of Xanax that he had falsely claimed he was receiving in Missouri. Tr. 112.

Upon reviewing the medical records, UC noted that despite his records stating that "Mr. Rutledge . . . has had a history of insomnia and anxiety for several years," he did not report anxiety symptoms of shortness of breath, of having palpitations, sweating, dizziness, or shaking. Tr. 79–80; GX 5. The medical record also reflects that he had a headache that day, despite the fact that UC did not report having a headache, dizziness, nausea, or vomiting. Tr. 80; GX 5. No one questioned UC as to whether he had abdominal pain, diarrhea, and constipation. Tr. 80–81. UC reviewed Government Exhibit 5 and noted that he was not asked about any of these symptoms. Tr. 81. He also assumes that the office accessed and checked the Tennessee controlled substance data bank on his first visit as this was in his medical records, but he was not

reporter, which the Tribunal attributed to a VTC issue and not to a defect in the DVD itself. [I have reviewed the contents of the DVD and find that the videos play successfully.]

specifically informed of it. Tr. 110. He also believes that the UC's assumed identity has never had a controlled substance filled in Tennessee. Tr. 111. He also believes there was no Missouri prescription database at that time, where he asserted he was from, so the office could not obtain information from there. And the fact that Missouri did not have a state-controlled prescription monitoring program in Missouri was a factor as to why the persona of UC's assumed identity was somebody from Missouri. Tr. 110–11.

At the appointment on October 17, 2017, UC did not have his blood pressure checked, was not weighed, did not have his chest examined, and did not have his breathing measured or evaluated. Tr. 82. On October 18, 2017, UC did not discuss muscle pain, back pain, nor a Review of Systems (ROS). Tr. 82–83. No one examined his chest, or his breathing. Tr. 83.

UC had another visit on November 15, 2017, which was another well-visit. Tr. 84. He paid \$25, waited for some time, was called back and asked about his weight and if his blood pressure was okay. He specifically asked the nurse if he was dismissed and after she said yes, he left. He did not receive any prescriptions that day. Tr. 85. Despite what the medical records say regarding this visit, there was no medical examination conducted on that day, including of his chest, or breathing. Tr. 86, 90; GX 5.

UC had another visit on November 20, 2017, for a medication visit. Tr. 87; GX at 10. UC walked in, put his name on a clip board, paid some money, waited a certain amount of time for his name to be called, and went to the window to obtain his prescriptions. Tr. 88. On this particular day, he was asked to provide a urine sample. Tr. 88, 92. He received a cup from the nurse, went into the bathroom for his unsupervised urine test, and provided a urine sample. He had brought a vial of a substance that would cause him to test positive for Oxycodone, put that in the urine sample, and returned the sample to the nurse as instructed. Tr. 88, 92; GX 3. He believes that, despite the added substance, his urine drug screen came back negative *D and the Respondent never discussed this screen with UC nor did anyone else at the practice. Tr. 91–

*D The Government did not fully explain this portion of its case which I find to be immaterial. Ultimately, inconsistent UDS results were not relevant to Dr. Kennedy's opinion that the prescriptions issued to UC were issued outside of the standard of care nor were they relevant to my findings in this decision.

92; GX 3.²⁵ He received a prescription for oxycodone for eighty-four tablets of ten milligrams from one of the receptionists, who provided the prescription to him as well as several others. Tr. 89. GX 18 at 4. UC did not meet with the Respondent that day. The medical records say ROS, but none of the systems were examined during this visit. Tr. 91.

Besides verbalizing and writing down that his pain was nine out of ten, UC did not do anything to indicate that his pain was actually that level. Tr. 94–95; GX 3, 18. He did not present any falsified records showing he had a history of filling controlled substance prescriptions in any state²⁶ and never produced pharmacy records showing his prescription history. Tr. 133. In UC's experience of working with people who abuse drugs or obtain drugs to sell them, he has found that these people are pretty savvy about filling out their forms when they go to the doctor. Tr. 133–34.

Dr. Gene Kennedy

Dr. Kennedy, who is licensed in Georgia, is a family practitioner by training and has treated patients for pain since being licensed. Tr. 202. Dr. Kennedy was offered, and qualified, as an expert in the field of pain management. Tr. 201, 211–12, 216. Although not board certified in pain management, he has been treating people for pain full-time since 2004 or 2005, when he opened his own pain management clinic. Tr. 178–80, 202–03, 427.²⁷ He has treated all types of pain patients: Patients suffering acute post-surgical pain; patients suffering from back pain; cancer patients; and patients referred by other pain management physicians. Tr. 180–81, 355. He has prescribed assorted controlled substances, including opioids to treat pain, including Schedule I. Tr. 181. He treats patients over 120 MME. He noted only UC and C.F. were being treated below 120 MME. Tr. 427–28. He has

²⁵ Although the Respondent objected to Government Exhibit 3 being offered into evidence based on hearsay, the Tribunal overruled the objection finding that any hearsay statements in this exhibit have been properly authenticated. Tr. 94. The Tribunal also noted that UC could be cross-examined regarding his report.

²⁶ UC noted in the Patient Pain History form that he had previous medications including hydrocodone between November 2016 and September 2017, Xanax from approximately August 16, 2016 through September 2017, and oxycodone from August 2017 to September 2017.

²⁷ Although not dispositive in this setting, Dr. Kennedy's credentials would not permit him to be a director of a pain clinic in Tennessee, without annually consulting with a board certified pain management specialist. Tr. 204–05, 428–30.

prescribed benzodiazepines. He performs pain injections. Tr. 357.

He has previously been qualified as an expert witness in administrative hearings of the Alabama Medical Board, the Georgia Medical Board, DEA, FBI and DOJ. On thirteen occasions he has testified regarding whether a physician has properly prescribed controlled substances. GX 24. He has served as an adjunct lecturer regarding the proper prescribing of controlled substances to DEA, at the National Advocacy Center, and on behalf of the DOJ. Tr. 185. He estimated over half of his income comes from the work and lectures given to Government agencies. Tr. 359. In 2018, he estimates he was paid over \$100,000 by the Government. Tr. 432. For the instant case, he is being paid \$450 per hour for an estimated forty hours of preparation plus courtroom hours. Tr. 434–36. He has also lectured regarding the PDMP to medical residents and physicians and taught a course to pharmacists in Tennessee regarding legitimate prescribing. Tr. 185. He is familiar with Tennessee law pertaining to prescribing controlled substances, and has relied on the following sources in developing his opinions herein: Tennessee Pain Clinic Guidelines, the Federation of State Model Policy, AMA Guidelines, the DEA Practitioner's Manual. Tr. 183, 360–62. He was hired by the DEA to offer an expert opinion on the Respondent's prescribing and of the medical practice, on the basis of material the government provided him. This material included approximately twenty charts, surveillance videos, and pharmacy reports. The surveillance videos involved undercover encounters between UC and the Respondent. Tr. 184; GX 8–23.

Dr. Kennedy is familiar with the standard of care for a physician prescribing controlled substances in Tennessee. This standard requires an adequate medical history, including all the historical information helpful in developing a diagnosis, course of treatment and in understanding the risks involved. Tr. 189, 195. The standard requires diagnostic testing, if indicated. Tr. 196. The standard requires the physician to perform a physical exam. Tr. 190, 200–01. The standard requires a physician to maintain medical records for patients to whom controlled substances are prescribed. Tr. 196. These medical records should contain a pain history, a history of drug abuse and termination by other physicians, a physical exam pertinent to the patient's complaint, efforts at obtaining state pharmacy reports, the physician's thoughtful assessment of the patient's condition,

and an individualized treatment plan. Tr. 196–98. Dr. Kennedy noted the importance of maintaining complete and accurate patient records. Tr. 353. With patients sometimes on high doses of potentially dangerous controlled substances, the charts must be accurate and honest, so any practitioner who views the charts can make an accurate assessment of the patient's conditions. Tr. 353–54.

In reviewing the subject medical records, Dr. Kennedy recognized indications of possible abuse and diversion, including patients unable to produce past medical records, a cloudy history of drug abuse. Tr. 191–92. Dr. Kennedy noted that the Tennessee standard precludes a physician from prescribing controlled substances to a patient with a habit of improperly using them, without first making a bona fide effort to cure the patient's addiction. Tr. 199. When a benzodiazepine and an opioid are prescribed in combination, the physician would have a heightened sense of vigilance, which would need to be documented within the chart. Tr. 190. Urine drug screening (UDS) is a common practice in pain management treatment. Tr. 192. It can reveal whether a patient is taking a medication he is prescribed and whether he is taking medications or illegal drugs he is not prescribed. Tr. 193–94. The standard of care would require, at minimum, that the physician document in the records the inconsistent UDS, and describe his plan of action. Tr. 194–95.

Dr. Kennedy reviewed the chart and the undercover videos for Patient UC, who was the undercover agent. Tr. 216–17, 363; GX 6. Dr. Kennedy acknowledged that in scheduling the first visit, the Respondent's staff instructed UC to bring certain medical records to his first visit: The previous three physician notes, his discharge summary, the record of the previous three months prescriptions and an MRI, an appropriate protocol in Dr. Kennedy's opinion. Tr. 364–65; GX 3 at 1. Dr. Kennedy did not believe the medical chart justified the prescribing of controlled substances. Tr. 230–31, 240; GX 18 at 1, 3. Although an actual MRI report of UC, Dr. Kennedy found the MRI report internally inconsistent, which did not justify controlled substance medication. Tr. 387–94, 483–86. UC was being treated for complaints of back pain. However, Dr. Kennedy opined that the physical exam detailed in the chart was not sufficient under Tennessee standards, and the exam performed revealed a normal back.*E Tr.

*E Dr. Kennedy testified that an adequate back exam would have required Respondent to look “for

217, 231, 237, 396–97, 440. On rebuttal, Dr. Kennedy reiterated this assessment after listening to the Respondent's explanation. Tr. 651–52. After filling out extensive paperwork, the initial examination by the Respondent consisted of observing the UC, touching his back and causing the patient to lift his leg. Tr. 217–18, 359–60; GX 6 at 6. Dr. Kennedy did not believe UC's chart reflected the Respondent maintained a truthful and accurate record of the treatment. Tr. 232; GX 3; 4. Dr. Kennedy noted the taking of vital signs and a general exam within the chart, however he observed that from viewing the video of this visit, such exam was not performed as described, or not performed at all. Tr. 218–19, 232–33, 379–81; GX 6 at 4. The prior medical history reported by UC, was facially suspicious and constituted a red flag. Tr. 238. UC reportedly, came from a clinic, which has since shut down, and provided medical records from a Nurse Practitioner, whose license has been suspended. Tr. 238. Dr. Kennedy opined that UC's obfuscation, false and misleading statements to the Respondent and staff, did not relieve the Respondent's obligation to investigate any suspicious circumstances. Tr. 375–78, 382.

Dr. Kennedy noted that the physical exam included in this first visit by UC was repeated verbatim in most of the 20 or so charts he reviewed. Tr. 220; GX 7 at 65 (M.B.), GX 9 at 69 (M.W.). Dr. Kennedy noted UC's chart identified him with a “long-standing history of insomnia and anxiety,” however the chart contained no examination, which would support such findings. Tr. 233–34; GX 5 at 4. Additionally, the reported symptoms of the anxiety finding, “palpitations, sweating, dizziness, shaking” was repeated almost universally throughout the medical records reviewed as to patients diagnosed with insomnia and anxiety. Tr. 233–34. Although UC reported his pain level at 9 or 10, the exam results do not support that, nor did the video of this encounter. Tr. 234–35, 238. Similarly, the visit of October 17, 2017, by UC contains extensive medical findings, although the video of that visit does not support those findings. Tr. 235–37; GX 5 at 5. The video does reveal the Respondent asking UC, “how is your sleep,” to which UC responds, “not good.” Tr. 236. The Respondent

something that is out of place, muscle spasms, . . . perform lumbar range of motion maneuvers where the patient essentially bends at the waist in various directions. Additionally, . . . a straight leg raised test, . . . neurologic exam, which makes comment on their motor deficits and their sensorium as pertains to their complaint of low back pain.”

then prescribed Elavil, also called amitriptyline. Tr. 236. Dr. Kennedy made a similar observation as to extensive medical findings on subsequent visits, in which UC was not seen by the Respondent. Tr. 235–37; GX 5 at 3–5. Although the medical records reflect physical examination took place at the level one visits, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28. Dr. Kennedy disagreed, noting that it is never permissible for charts to reflect examination results, when no exam occurred. Tr. 652–53.

On the basis of the deficient physical exam, Dr. Kennedy opined that prescribing controlled substances to UC was not justified.^{*F} Although the Respondent prescribed a much lower MME than UC had purportedly been on previously, it was not consistent with the Tennessee standard, which would include observation, looking for spasms, lumbar range of motion maneuvers, straight leg raise test, neurologic exam and motor deficits. Tr. 221–25, 239, 382–83; GX 5 at 6. Other deficiencies in the records that caused the controlled substance prescriptions for UC to be unjustified included the deficiency in the prior medical records provided by UC Tr. 228. UC's chart revealed an exploration of alternate treatment, by prescribing Meloxicam. Tr. 228–29. However, UC's chart did not include an adequate treatment plan. Tr. 229. The records reveal a deficient discussion regarding the risks and benefits of controlled substance medication. Tr. 231. Dr. Kennedy deemed the diagnosis of degenerative disc disease unjustified on the basis of the chart and MRI. Tr. 240–42; GX 5 at 2, 6; GX 6 at 12.

Dr. Kennedy prepared reports or charts containing his review of the relevant medical evidence in this case. His findings accurately reflect the original medical records, which are in evidence. His chart was admitted as a

^{*F} Dr. Kennedy actually offered several bases for his opinion that all of the controlled substances Respondent prescribed to C.R. were issued outside the usual course of professional practice. Tr. 239. Specifically, Dr. Kennedy identified Respondent's failures to perform a sufficient physical examination; to adequately assess the patient's pain, physical, and psychological function; to sufficiently examine the patient's history; to assess a recognized medical indication for the use of oxycodone; to create or follow a legitimate written treatment plan; to discuss the risks and benefits of using oxycodone with the patient; to maintain truthful and accurate medical records; or to resolve red flags arising from the medical records C.R. provided, which stated that C.R. had been treated at a clinic that had closed by a nurse practitioner, whose license had been suspended. Tr. 237–39.

chart of voluminous records under Fed. R. Evid. 1006. Tr. 225–28; GX 6 at 2.

Patient M.W.

Dr. Kennedy identified his “chart review” for M.W. Tr. 243–44; GX 9, 10. M.W. was diagnosed with low back pain, yet Dr. Kennedy opined that the records did not support such diagnosis. Tr. 245–46; GX 9 at 14; GX 10 at 3. The notes did reference back to M.W.'s initial encounter. Tr. 441. There were no findings in the record which would support a chronic pain condition and justify prescribing controlled substances. Tr. 246–47. Dr. Kennedy found no credible physical exam to justify the diagnosis. Tr. 247, 265. The Respondent did not assess M.W.'s pain level, physical and psychological functioning, history, potential for drug abuse, or coexisting diseases. Tr. 265. The Respondent did not follow a legitimate treatment plan. Tr. 265. The physical exam findings were generally normal findings, except for limited range of motion at the lumbar spine. Tr. 247; GX 10 at 7. M.W. reported a pain level, at worst, at 10 of 10, and at best, 6 of 10. Tr. 248–49; GX 9 at 19; GX 10 at 8. M.W.'s reported pain level was inconsistent with the generally normal results of the physical exam. Tr. 249–50.

The electronic medical record for this visit does not contain the handwritten information recorded in GX 10 at 8. Tr. 250–51; GX 10 at 9. Instead, the results of the physical exam mirror those findings made for UC, rendering M.W.'s chart not credible. Tr. 251–52. Additionally, the record contained “wildly abnormal”^{*G} UDS results that were “not meaningfully addressed.” Tr. 252–55; GX 9 at 2–4, 9–11, 84, 96, 102. After a series of inconsistent UDS, the Respondent noted in M.W.'s chart that M.W. was dismissed from pain management with one month notice. Tr. 258; GX 9 at 84. Yet, at the same visit in which he had been notified he would be dismissed, the history of present illness (HPI) reports patient is compliant and consistent. Tr. 258. Dr. Kennedy deemed the chart not credible, accordingly. Tr. 259. However, despite being dismissed, M.W. continued to be seen for months afterwards, without any further explanation. Tr. 259–60. Dr. Kennedy later conceded that M.W. was reinstated consistent with the

^{*G} For example, regarding the UDS at GX 9, 2–4, M.W. was prescribed oxycodone, carisoprodol, alprazolam, and oxymorphone. GX 9, 2–4. The drug screen results were negative for the prescribed drugs alprazolam and carisoprodol and, as Dr. Kennedy testified, positive for non-prescribed substances including “morphine, positive for hydromorphone, positive for oxymorphone, . . . positive for THC. . . .” Tr. 251–52.

Respondent's office protocol. Tr. 449–50. The Respondent continued to prescribe him Alprazolam, amitriptyline, oxycodone, oxymorphone and Soma. Regarding the Alprazolam prescription, Dr. Kennedy found it unjustified based on the information supporting the anxiety diagnosis. Tr. 260–61, 442–44; Tr. 261; GX 9 at 85. Dr. Kennedy noted the indications for anxiety were not supported by the findings within the chart, and mirrored those in the charts for UC and the other patients. Tr. 261–62. Although Dr. Kennedy opined M.W. should have been physically examined “on a regular basis” during his treatment, the charts suggest he was not examined again following his first examination.^{*H} Tr. 262. Dr. Kennedy further opined that as M.W. was a 25 year-old diagnosed with degenerative disc disease, the Tennessee standards would require diagnostic testing, such as an MRI to confirm the diagnosis. Tr. 262, 447–48. Dr. Kennedy found M.W.'s chart “not credible and fabricated.” Tr. 263–64, 266; GX 10 at 5, 23. He noted that of 93 of 98 total visits shared the identical findings for the physical exams and ROS. Tr. 264. Similarly, Dr. Kennedy found the diagnosis of insomnia not credible. Tr. 264. A finding of drug abuse and chemical dependency would have been supportable, but such indications were not sufficiently addressed by the Respondent. Tr. 264–65. The credible findings within M.W.'s chart did not support the prescribing of controlled substances,^{*I} and the subject prescriptions were issued without medical justification and outside the usual course of professional practice. Tr. 266–68.

Patient C.F.

Dr. Kennedy identified the summary chart he prepared on Patient C.F. Tr. 268; GX 12. C.F. was being treated for chronic pain due to trauma, unspecified inflammatory polyarthropathy. C.F. had suffered stab wounds to the chest requiring open heart surgery, which can cause long-term neuropathic pain. Tr. 451–53. Dr. Kennedy opined the history,

^{*H} Dr. Kennedy testified that the little documentation there was suggesting a physical exam could have been performed was “not credible” because it was “repeated documentation that we have described before.” Tr. 262.

^{*I} Specifically, Dr. Kennedy testified that Respondent failed: To perform a sufficient physical examination; to adequately assess the patient's pain, physical, and psychological function; to sufficiently examine the patient's history and potential for substance abuse; to identify a recognized medical indication for the use of the controlled substance prescriptions; to create or follow a legitimate written treatment plan; and to adequately address M.W.'s exhibited evidence of drug abuse. Tr. 264–66.

physical exams, the pain and physical and psychological functioning, the potential for substance abuse, written treatment plan, and alternate treatment considerations were inadequate, and did not justify the controlled substance prescriptions. Tr. 269–70, 285, 455; GX 11 at 106; GX 12 at 7. The Respondent did not discuss the risks and benefits of controlled substance medications [and did not keep accurate records of the care he provided.] Tr. 285–86. The physical exam notes revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language often duplicated in the records, is included. Tr. 272. There were no credible follow up physical exams, supporting studies, and no reasonable pain etiology. Tr. 272; GX 12 at 5, 6. The ROS indications were identically repeated in other charts. Tr. 272–73. Dr. Kennedy noted that the language in the general exam, “patient is alert and oriented” is similarly repeated 102 times throughout the records. Dr. Kennedy reported an inconsistent UDS for C.F., collected on July 2, 2018, and many thereafter. Tr. 273–80, 282; GX 11 at 9, 23, 24, 25, 28, 33, 44, 47, 54, 69, 78, 111, 117; GX 20. C.F.’s UDS result was negative for all of the medications he was prescribed. Tr. 275–77. C.F. also tested positive for cocaine and marijuana. Tr. 277, 280. An inconsistent drug screen on July 26, 2017, is not mentioned in the medical records. Tr. 288–89. Although the records repeatedly noted that, “patient counseled at length on unsatisfactory UDS,” this was insufficient under Tennessee standards in addressing C.F.’s drug abuse and diversion [because it did not document “anything specific.”] Tr. 280, 284. On May 3, 2017, C.F. tested positive for buprenorphine, a medication typically used for opioid use disorder. Tr. 281–82. The Respondent had not prescribed it [and failed to investigate or address the issue.] Tr. 282. Dr. Kennedy opined that the Respondent continued to improperly prescribe controlled substance without making a bona fide effort to cure C.F.’s addiction. Tr. 284. The Respondent prescribed alprazolam for anxiety and insomnia. Tr. 286; GX 11 at 39. However, the supporting indications are identical to the other patients who were diagnosed with anxiety and insomnia. Tr. 286–87. The Respondent did not maintain complete and accurate records for C.F. Tr. 286. Dr. Kennedy concluded that the controlled substance prescriptions to C.F. were outside the

usual course of professional practice. Tr. 287.

Patient B.C.

Dr. Kennedy identified his summary chart for B.C. Tr. 289–90; GX 13; GX 14. B.C. was being treated for chronic pain syndrome. B.C. was referred from the Clark County Jail, a potentially challenging patient. Tr. 458–59. The Respondent did not take an adequate medical history. Tr. 304. Although documentation of some physical exam was evident, it was insufficient and non-supportive to justify prescribing the medications prescribed.*^J Tr. 290–91, 304; GX 13 at 169; GX 14 at 7; GX 22. He did not make an adequate assessment of pain, physical and psychological function, history of substance abuse, coexisting diseases and conditions, written treatment plan, or alternate treatments. Tr. 304–06. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 306. There were no radiologic studies ordered. Tr. 303. There were no prior medical records ordered or obtained, yet the records did include hospital records. Tr. 303, 459–60. Dr. Kennedy noted indications from the ROS were duplicated throughout the records. Of 141 encounters, the ROS language was duplicated 140 times, while the physical exam language was duplicated 134 times. Tr. 291–92. He did not maintain accurate and complete records. Tr. 306. B.C. had serious health issues, including Hodgkins lymphoma, a cancer of the lymphatic system. Tr. 293. Dr. Kennedy identified a document in the chart indicating B.C. had been dismissed from a prior physician, a clear red flag [for which there was no “evidence in the medical record that [the] red flag was investigated.”] Tr. 293–94; GX 13 at 188.

Dr. Kennedy noted that B.C.’s pain level was left blank in the medical record for nine consecutive encounters, suggesting [“that [the] information is not actually being obtained and that the documentation is simply being inserted in the chart.”] Tr. 294–95; GX 13 at 159; GX 14 at 8. One entry reveals, “patient

*^JDr. Kennedy testified that the documented physical exam was insufficient, because “there are no positive objective physical findings that rise to the level of requiring medications prescribed.” Tr. 291. He further testified, that based on B.C.’s known medical problems, “[it is] not impossible that this patient had a chronic pain condition. But I would note that over the course of 140 encounters the chart does not mention, . . . on a single occasion where [we are] consistently talking about what specific pain the patient is experiencing.” Tr. 305. Accordingly, Dr. Kennedy testified, the medical record did not support a recognized medical indication for the use of the prescribed controlled substances. *Id.*

lied about his prescriptions,” an alarming red flag left unaddressed by the Respondent. Tr. 296; GX 13 at 169. Despite noting that the “patient lied,” the Respondent issued controlled medications and “held” up UDS for a month. Tr. 297. Dr. Kennedy opined that this prescribing was outside the usual course of professional practice. B.C. continued to have inconsistent UDS results, which were insufficiently addressed by the Respondent.*^K Tr. 297–98; GX 13 at 33, 79, 150, 155, 156, 158, 164, 165. The information contained in B.C.’s chart did not justify the controlled medications prescribed by the Respondent, nor support that they were issued in the usual course of professional practice. Tr. 307–08.

Patient M.H.

Dr. Kennedy identified his summary chart for Patient M.H. Tr. 309; GX 15; GX 16. M.H. was being treated for chronic pain syndrome. GX 15 at 62, 63. The physical exam indications are identical to those repeated throughout the medical records. Tr. 311. The indications do not support any chronic pain diagnosis. Tr. 311. The records reveal M.H. suffered a gunshot wound in 2008, and although serious, would not in itself justify pain medication eight years later. Tr. 323. Dr. Kennedy assessed the Respondent’s treatment as outside the scope of acceptable medical practice.*^L Tr. 312. He did not make an adequate assessment of pain, and physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan or alternate treatments. Tr. 326–28. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 328. M.H. had inconsistent UDS. Tr. 314–20; GX 15 at 36, 39, 40, 47, 49, 53, 56, 63. Although several inconsistent UDS were noted in the chart, they were not typically mentioned. The Respondent failed to adequately address the UDS. Tr. 314–20.

During his treatment with the Respondent, M.H. underwent a serious and complex spinal surgery, a major surgery. Tr. 320–22, 462–63. GX 15 at 26; GX 16 at 9. M.H. was seen by the Respondent the day after his release

*^KAccording to Dr. Kennedy, the medical records say “the patient is counseled at length, but again, [there is] nothing specific about what the counseling entailed or any decision made based on it.” Tr. 301.

*^LMy findings in this matter are based solely on Respondent’s prescribing of controlled substances, not Respondent’s prescribing of non-controlled substances or his overall treatment of patients.

from the hospital. GX 15 at 48. Despite his recent, major surgery, there is no mention of the surgery in the encounter notes.^{*M} Tr. 322–23. The encounter notes are identical to all the other encounter notes reviewed. Tr. 323; GX 15 at 48. There is no updated physical exam, as would be required by the standard of care. Tr. 324. The PE and HPI notes are the same as those the 4 months prior to the spinal surgery, which is not credible. Tr. 324–25, 491–92; GX 15 at 49, 51. The Respondent did not maintain accurate and complete records as to M.H. Tr. 328. Dr. Kennedy reviewed the prescriptions issued. Tr. 325; GX 19 at 1–13. He opined that the chart, including the number of inconsistent UDS, reveals that there was “a significant probability” that M.H. was addicted to the habit of using controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction. Tr. 325. The subject prescriptions were issued outside the usual course of professional practice. Tr. 329–30, 493.

Patient M.P.

Dr. Kennedy identified his summary chart for Patient M.P. Tr. 331; GX 8. M.P. was being treated for low back, neck, hip and shoulder pain. She was later diagnosed with degenerative disc disease and right shoulder pain. Although a physical exam was performed, it was inadequate to substantiate the diagnoses. Tr. 331–34, 339–40, 343; GX 7 at 2. A mechanical shoulder exam and range of motion back and neck exam should have been performed. Tr. 335. He did not make an adequate assessment of pain, nor physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan nor alternate treatments. Tr. 349–51. He did not conduct any periodic reviews, nor discuss the risks and benefits of the use of controlled substances. Tr. 349–50. Her employment as a server, working forty to sixty-five hours per week is inconsistent with her “occupational disability” score of 9 or 10, which Dr. Kennedy described as a significant conflict. Tr. 344–45; GX 7 at 3, 9, 10. Dr. Kennedy noted the hand-written exam notes did not appear in the electronic

^{*M}Dr. Kennedy opined that the “spinal surgery . . . definitely supported being on scheduled medications. [But] [t]hat’s not even referenced in the medical record.” Tr. 328. Accordingly, Dr. Kennedy opined that Respondent failed to document a “recognized medical indication for the use of the controlled substances, which were prescribed.” *Id.*

medical records, Tr. 325–36; GX 7 at 68, rather, the medical records reflected the same PE notes duplicated throughout the medical records for all of the patients at issue. Tr. 336, 351. The pain level is reported as 9, which is inconsistent with the PE indications. Dr. Kennedy indicated notes generated at the initial visit appeared to be a reminder to obtain certain prior medical records from Dr. M. Tr. 337, 468; GX 7 at 1, 68. Those same notes appear in the record repeatedly thereafter. Tr. 337; GX 7 at 59. Other than the requested pharmacy report, the prior records were never obtained. Tr. 338–39. The Respondent did not maintain accurate and complete records as to M.P., [and the chart contained language that was verbatim as other medical charts.] Tr. 350–51.

At M.P.’s initial visit, a UDS was performed revealing inconsistent results, which were never addressed in the records. Tr. 338; GX 7 at 19, 68. Notes reveal M.P. had been terminated from a prior physician, which is a red flag. Tr. 343. The records did reveal a monitoring of the Tennessee PDMP, and a successful pill count. Tr. 470. There were emergency room notes, which revealed she was admitted on April 17, 2018, and released on April 18 for apparent heroin overdose, which occurred in the Respondent’s waiting room. Tr. 340–41; GX 7 at 25. [Dr. Kennedy testified that, aside from the ER records, “there is not a note in the chart that specifically refers to this patient overdosing or going unresponsive in the waiting room.” Tr. 341.] At the next encounter, the Respondent discontinued the previous prescriptions for controlled substances, discussed drug rehab with M.P., which she declined to pursue, and prescribed buprenorphine, an opioid abuse treatment. Tr. 342. Dr. Kennedy viewed this course of action as dangerous and outside the standard. Tr. 342, 371–73, 465–66. As the patient was shown to be on heroin, a UDS would be necessary to determine if she had heroin in her system before prescribing buprenorphine, which in conjunction with heroin could result in permanent withdrawal. Tr. 343. There were inconsistent UDS in the records for M.P. Tr. 346; GX 7 at 48, 59.

Dr. Kennedy reviewed the prescriptions issued. Tr. 348–49; GX 21. He opined that the chart, including the number of inconsistent UDS, reveals that [Respondent should have been concerned that M.P. had a habit of being] addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the

addiction, until after she overdosed on heroin. Tr. 348. The subject prescriptions, as well as those prescribed to the other charged patients, were dangerous^{*N} and were issued without medical justification and outside the usual course of professional practice. Tr. 352, 488–89.

DEA Special Agent (SA1)

SA1 is a Special Agent with the Drug Enforcement Administration, and has been for ten years. Tr. 498. He attended the Special Agent Academy in 2009. Tr. 498. He has been involved in three or four investigations surrounding prescriptions. Tr. 498. He served as case agent for the current investigation. The first search warrant was executed on February 27, 2018, at the clinic and at the Respondent’s residence in Clarksville, Tennessee, where paper records, patient files, financial records and digital evidence from several computers were seized. Tr. 500. The second warrant was served on the Respondent’s clinic in Millersville, Tennessee in September, 2018. Tr. 500. SA1 authenticated GX 5 as seized from the Respondent’s clinic. Tr. 502–03. SA1 noted that some medical documents provided by UC to the clinic were not found during the searches. Tr. 503–04. SA1 authenticated GX 7 as medical records of M.P. seized from the Respondent’s clinic. Tr. 505. SA1 authenticated GX 9, as the medical records of M.W. seized from the Respondent’s clinic. Tr. 506. SA1 authenticated GX 11 as medical records of C.F. seized from the Respondent’s clinic. Tr. 507. SA1 authenticated GX 13, as the medical records of B.C. seized from Respondent’s clinic. Tr. 508. SA1 authenticated GX 15, as the medical records of M.H. seized from the Respondent’s clinic. Tr. 509–10. These complete records were supplied to the Government’s medical expert, Dr.

^{*N}Dr. Kennedy went on to testify that all of the controlled substances prescribed to the individuals at issue (other than the undercover) were “dangerous.” Tr. 352. He stated, “[c]ontrolled substances are dangerous. . . . [In the] context that we’re talking about, because of the abnormal drug screens that were essentially ignored, and the documentation about the patient’s status was not done. In the face of sometimes very alarming patient red flags, I would say that it was clearly dangerous.” *Id.* Dr. Kennedy further opines, “none of the medical records are credible and . . . maintaining a patient on scheduled medications . . . sometimes at high dosages, without having honest, accurate, complete medical records is dangerous.” Tr. 352–53. This is because, according to Dr. Kennedy, “those medical records will instruct other people who look at them as to what the motivation was for the treatment . . . [a]nd if what is documented in the medical record simply doesn’t make sense or is something that is in conflict . . . [t]hat can . . . present a dangerous situation.” Tr. 353.

Kennedy. Tr. 511–12. Additionally supplied to the expert were PDMP reports, the missing records supplied to the clinic by UC and the video of the undercover encounters. Tr. 512.

DEA Diversion Investigator (DI)

DI is a Diversion Investigator with the Drug Enforcement Administration. Tr. 519–20. She has been with DEA for ten years. She has been involved in 15–20 investigations involving physicians prescribing controlled substances. As part of the current investigation, she collected relevant prescriptions, and processed the documents in support of the Order to Show Cause. Tr. 520. She identified the Respondent's DEA Registration. GX 1. She authenticated GX 18, which include the prescriptions the Respondent issued to UC, which she obtained from various pharmacies. Tr. 521–22. She authenticated GX 19, which are the prescriptions the Respondent issued to M.H., which DI obtained from various pharmacies. Tr. 523–24. She authenticated GX 20, which are the prescriptions the Respondent issued to C.F., which DI obtained from various pharmacies. Tr. 524–25. She authenticated GX 21, which are the prescriptions the Respondent issued to M.P., which DI obtained from various pharmacies. Tr. 526. She authenticated GX 22, which are the prescriptions the Respondent issued to B.C., which DI obtained from various pharmacies. Tr. 527. She authenticated GX 23, which are the prescriptions the Respondent issued to M.W., which DI obtained from various pharmacies. Tr. 528. She authenticated the Respondent's application for renewal of his DEA Registration for the State of Tennessee, # 59889, which was submitted on November 6, 2019. Tr. 529–30; GX 26.

She explained the significance of Question Three on the application, a “liability” question. It queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. Tr. 530–31. An affirmative answer to Question Three would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered “No” to Question Three. Tr. 531; GX 26.

She also authenticated GX 29, the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties. Tr. 531–32. She also authenticated GX 27, an order from the Chancery Court for the State of

Tennessee, 20th Judicial District, Davidson County, Part 3, reversing Denial of Stay, but Accompanying Stay with Conditions. Tr. 532–33. DI noted that as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay. Tr. 533–34. DI authenticated GX 28, An Agreed Order with the State of Tennessee, in which the Respondent was required to surrender his Pain Management Certificate, a professional license, in 2018, and prior to his application for registration in 2019. Tr. 534–35; GX 26; GX 28. DI authenticated GX 25, an Emergency Order of Restriction from the Commonwealth of Kentucky board of License, issued on January 15, 2019, which again predates his subject DEA application, and is a further restriction on a professional license. Tr. 537–39.²⁸ DI explained that although GX 28 related to the surrender of the pain clinic license and GX 26 was the Respondent's personal application, as the Respondent applied for the pain clinic license himself, it constitutes a surrender of his license, warranting an affirmative response to question 3 of his DEA application. Tr. 542–43; GX 26. Additionally, the surrender is signed by the Respondent individually. Tr. 545.

Respondent's Case-in-Chief

The Respondent presented his case-in-chief through the testimony of one witness, the Respondent, Samson K. Orusa, M.D.

Samson K. Orusa, M.D.

Dr. Orusa was born in Bayelsa, Nigeria. Tr. 547. Dr. Orusa finished his medical education at a fully accredited medical school in Benin City, Nigeria and worked for a year in Nigeria. Tr. 548. He completed a one-year rotational internship in internal medicine, pediatrics, surgery and OBGYN at the University of Port-Harcourt Teaching Hospital. Tr. 549–50. He then spent a year doing outpatient care at a rural primary healthcare center. Thereafter, he entered private practice in Lagos, Nigeria in 1989. In 1992, Dr. Orusa immigrated to the United States to advance his medical training. He

²⁸ Although relevant testimony herein, the January 15, 2019 restriction as to the Respondent's Kentucky license does not constitute a ground for the material falsification allegation. It was neither charged in the OSC or the Government's Pre-hearing Statements. Nor was it noticed by the Government at the time of its offering as a proposed additional charge under the principle of “litigation by consent.” Where the Government has not provided notice of a particular charge yet produces evidence on that charge, and does not argue that the issue was litigated by consent, the charge cannot form the basis for revocation. *Cove Inc., d/b/a Allwell Pharmacy*, 80 FR 29,037, 29,039 (2015).

completed a three-year residency program in internal medicine at Columbia University, College of Physicians and Surgeons in 1996. Tr. 551. He obtained his Tennessee medical license, and with his certification in internal medicine, he was hired at a clinic in Clarksville, Tennessee. Tr. 552, 555. He was admitted to practice at Memorial Hospital. In 1997, he opened his own clinic in Clarksville, where he had a general medical practice. In 2004, he began concentrating on pain management. Tr. 553. In 2017, he was board certified by the American Board of Interventional Pain Physicians as a specialist in interventional pain medicine. Tr. 553, 555. His extensive training involved the use of deep injections, spinal nerve blocks, nerve injections, foraminal blocks, and epidural injections. Tr. 553–54. By 2018, he held sufficient certification to operate his own pain clinic in Tennessee. Tr. 555.

From 1998 to 2017, the clinic transitioned from primary care to pain management, but even by 2017, he still had primary care patients. Tr. 557–58. Initial visits required appointment, which were scheduled for the first thing in the morning. Returning pain patients were permitted to walk in without appointments. Tr. 558. He has had a staff of ten, including a nurse practitioner and physician's assistant. Tr. 559. By 2017, his pain management practice included deep tissue injections, cervical, lumbar and thoracic nerve blocks, sacroiliac joint injections, and bursitis injections. Tr. 60. In 2018, the frequency of injections increased as the Respondent began performing injections under fluoroscopy. Tr. 560.

The Respondent had a protocol for new pain patients. Tr. 561. Some of these protocols were in writing, but not produced at the hearing. Tr. 620. They were required to bring a referral letter or letter of dismissal from their previous physician, any imaging reports, records from their last three medical visits and their pain medication. Tr. 561–62, 572. If the patient did not produce the materials, the clinic staff would attempt to obtain them. Tr. 564–66. The initial visit typically takes all day, as the patient must fill out extensive documentation (twenty pages with 252 questions), which is necessary for diagnosis and selection of treatment. Tr. 566–67. Seventy-five questions relate strictly to pain. It includes pain disability index, depression assessment, drug-use history and social history. There is a pain management agreement. Tr. 571–72. The staff explains the side effects, the addiction process and the

resources to help with addiction. Tr. 572.

The charts often contained the exact same language for indications of anxiety and insomnia. Tr. 633–34. The Respondent explained that the language was often identical as anxiety patients typically share the same symptoms. Tr. 634–36.

Undercover

The Respondent took a medical history, a condition-specific physical exam for low back pain, reviewed the MRI (GX 6) of UC. Tr. 575–80. The Respondent noted that his physical exam of UC was not captured by the video of the encounter. The camera was pointed at the wall. Tr. 581–82. The Respondent spent no more than fifteen minutes with UC in the examination room. Tr. 621. The Respondent performed the required assessments related to pain, physical and psychological function, and history and potential for drug abuse. Tr. 582. This involved the paperwork UC filled out, authenticating that paperwork, the triage of UC by staff, UDS, and a final review of the paperwork by the Respondent with the patient. Tr. 583, 584. Although UC's chart contains an entry that his pharmacy printout was reviewed, the Respondent conceded that no pharmacy printout was reviewed and that such entry was in error. Tr. 631–32; GX 5 at 6. UC was a challenge as the clinic he reported had been closed, and he could not obtain the pharmacy information, so the Respondent could not verify that source. Tr. 583–85.

The Respondent expected his patients to be honest and truthful with him, consistent with the DEA Physician's Manual, which requires patients to be honest with their doctors. Tr. 586–87. The Respondent explained that a patient's pain is very subjective. After reviewing his paperwork, including the MRI, examining UC, and speaking with him, the Respondent had no reason not to treat him as someone who had genuine pain. Tr. 588. UC's statement that he had used controlled substances for his pain and that ibuprofen was not working supported the conclusion that his pain was long-standing, and warranted a Schedule II medication. As UC's prior medical records could not be confirmed, the Respondent prescribed a dosage appropriate to a patient just starting opioid treatment. Tr. 589–90. The Respondent testified that he prepared a written treatment plan with appropriate treatment goals and therapy. Tr. 590–91.

The Respondent explained that his electronic medical record often referred to other records. For example under

history of present illness (HPI), he would often reference the initial encounter paperwork as included in the electronic record. Tr. 592. He also explained that he performed a physical exam at the initial visit of each of his patients, as required by the Tennessee pain management guidelines. Tr. 594. Physical exams thereafter are at the discretion of the physician. Tr. 594. Although UC had five visits to the clinic, only two involved encounters with the Respondent. The other three visits were "level one" visits, in which UC met with the Respondent's staff only. Tr. 622–28, 645–50. Although the medical records reflect a physical examination took place at the level one visits, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28.

Patient M.W.

M.W. was first seen in January 2013. Tr. 595. M.W. was a gunshot victim to whom the Respondent prescribed alprazolam. This was based on the history and physical exam. Tr. 593. Tr. 635–36; GX 9 at 69. The Respondent obtained a medical history, conducted a physical exam, performed an adequate pain, physical, and psychological assessment, history and potential for substance abuse. Tr. 596. The evaluation of the patient's potential for drug abuse is an ongoing evaluation with UDS, involving both office screens, confirmatory lab screens, and pill counts. Tr. 596–98, 600. Once an inconsistent UDS is discovered, the Respondent initiates a dismissal process. Tr. 598–600. The Tennessee pain management guidelines leave it to the physician's discretion on the handling of confirmed inconsistent UDS results. Tr. 598–99. The Respondent gives the patient a month to come into compliance. Tr. 600. If he has a consistent UDS within the month, the patient is permitted to remain in treatment. Tr. 601. The Respondent was able to bring M.W. back into compliance through counseling; however, the chart only documents that the patient was counseled as to the inconsistent UDS. Tr. 637–38. The Respondent prepared a written treatment plan. Tr. 601.

Patient C.F.

Patient C.F. had a stab wound to the chest, requiring heart surgery, resulting in residual chronic pain. Tr. 601. The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse. Tr.

601–02. The Respondent noted that he had the benefit of confirmatory records from Vanderbilt University Medical Center. Tr. 602. The Respondent explained that the MED prescribed to C.F. was a relatively low dose of 82.5, noting the 120 MED threshold in which primary care physicians in Tennessee must consult with pain management specialists. Tr. 603–05.

Patient B.C.

Patient B.C. was referred from jail on December 19, 2012. The Respondent noted the pain management guidelines have changed since then. Tr. 605. The Respondent explained why he kept pharmacy printouts in his records because they are easier and quicker to obtain than medical records. Tr. 606. The pharmacy printout informs how long the patient has been prescribed medications, changes in dosage, and the prescriber. Tr. 607. Each of the Respondent's patient records contained the instruction, "rule out doctor shopping," which was a prompt to review the Tennessee PDMP to determine if the patient was obtaining controlled substances from multiple physicians. Tr. 608.

The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated his history and potential for substance abuse, and prepared a written treatment plan. Tr. 608. Although the Respondent described the extensive forms each patient is required to fill out at the initial visit, some of the described forms, which were referenced in B.C.'s chart, were missing from the Respondent's records as relates to B.C. Tr. 628–29; GX 13 at 5. The Respondent explained that some records were lost in 2014. Tr. 630. The missing records were not recreated as B.C. was a long-term patient. Tr. 630.

Patient M.H.

Patient M.H. presented with a post gunshot wound to the abdomen and chronic low back pain secondary to degenerative disc disease. Tr. 608. He had already been treated for pain management. He had a history of extensive spinal surgery at Vanderbilt University Medical Center, including a laminectomy. Tr. 609–11. The Respondent prescribed a lower MME than the surgeon prescribed post-operative at Vanderbilt. Tr. 611. The Respondent's medical findings as to Patient M.H. for the visit just prior to M.H.'s major back surgery are the same as the Respondent's findings for the visit the day after the surgery. Tr. 637–38; GX 15 at 48–50. The Respondent

explained that the subject findings were based on history. Tr. 638.

The chart reports M.H. has been “compliant,” however, on the next page of the chart, it reports M.H. had an inconsistent UDS. Tr. 638–40; GX 15 at 48–49. The Respondent explained that the inconsistent UDS related to the point of care test, not the confirmatory lab test, so the chart was accurate. Tr. 640. M.H.’s chart contains apparently inconsistent findings of long-term insomnia, but with an entry of sleeping well. Tr. 640–41; GX 15 at 47–48. The Respondent conceded these were inconsistent entries. Tr. 641.

Patient M.P.

Patient M.P. was being managed for chronic pain. In her initial visit, she reported conflicting information regarding whether she had been in drug rehab treatment. Tr. 641–42; GX 7. The Respondent explained that he could only rely on the information provided. Tr. 642. Initially, in September of 2016, the Respondent requested dismissal records, an X-ray and an MRI from Dr. M. Tr. 642–44; GX 7 at 48. Yet, eighteen months later, the Respondent still had not received the requested records. Tr. 644; GX 7 at 59.

Ultimately, she came to the clinic overdosing on heroin. Tr. 611–12. She had to be resuscitated until EMS was able to reverse the effects of heroin with Narcan. Tr. 612. In the post-overdose notes the Respondent took an extensive history again regarding her drug use. He directed she cannot be on pain management but must be on opioid abuse treatment. So, the Respondent started her on Suboxone. Tr. 613. The Respondent explained his understanding of Suboxone induction. The first type of induction therapy is by observation. You give the patient Suboxone and observe them until they reach the point of withdrawal. The other form of induction is to give the patient Suboxone and send her home without observation by the physician. Tr. 612–14. M.P. was initially receptive to drug treatment, but later changed clinics. Tr. 615.

The Respondent took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse, and prepared a written treatment plan. Tr. 615–17. Following the heroin overdose, the determination was made that she needed treatment of Suboxone and no further opioid prescriptions. Tr. 616.

The Facts

Stipulations of Fact

The Government and the Respondent have agreed to 1, 2 in part, 3, 4, 5, 6, 7 stipulations, which I recommend be accepted as fact in these proceedings:

1. The Respondent is registered with the DEA as a Practitioner authorized to handle controlled substances in Scheduled II–V under DEA COR No. BO4959889 at 261 Stonecrossing Drive, Clarksville, Tennessee 37042. DEA COR. No. B04959889 expires by its terms in December 31, 2019.*^o

2. On July 6, 2018, the Respondent submitted an application (No. W18070589C) for a new DEA COR at 316 Pappy Drive, Oak Grove, Kentucky 42262. On January 15, 2019, the Commonwealth of Kentucky, Board of Medical Licensure, issued an Emergency Order of Restriction prohibiting Respondent from “prescribing, dispensing, or otherwise professionally utilizing controlled substances.” See 201 KY. ADMIN. REGS 9:240 Section 1 and 3. Thus the Respondent is currently without authority to handle controlled substances in the Commonwealth of Kentucky.

3. Soma is a brand name of carisoprodol, a Schedule IV controlled substance.

4. Percocet is a brand name for oxycodone, a Schedule II controlled substance.

5. Oxycodone is a Schedule II controlled substance.

6. Oxymorphone is a Schedule II controlled substance.

7. Alprazolam is a Schedule IV controlled substance.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

The Government’s case was largely based on (1) several undercover visits to Respondent’s medical office by UC; (2) the medical charts and prescriptions pertaining to UC as well as to five other patients, M.H., M.W., C.F., B.C. and M.P.; and (3) the testimony of Gene Kennedy, M.D., the Government’s expert.

The Undercover Operation

1. UC is currently an Assistant Special Agent in Charge with the Tennessee

*^o According to Agency records, this application is pending renewal and has not expired.

Bureau of Investigation. Tr. 30. [Omitted to preserve identity of UC.]

2. UC testified that he was contacted by a Special Agent with the United States Department of Health and Human Services, Office of the Inspector General, to conduct an undercover operation at Respondent’s clinic. Tr. 33–34. In preparation for this operation, UC contacted Respondent’s clinic to set up an appointment. Tr. 34. He was told to bring several items to the appointment, including an MRI report, prior “chart notes” from his previous physician, a discharge summary from his previous physician, and documentation showing his last three months of prescriptions. Tr. 35.

October 3, 2017 Visit

3. UC testified he arrived at Respondent’s office on October 3, 2017, at approximately 8:00 a.m. Tr. 40. He testified that he paid \$311 for this appointment. Tr. 49. He recorded portions of the visit on a “covert video camera device embedded” in a cell phone case. Tr. 42–43. Upon arrival, he provided an MRI report from September 2, 2016, that he testified was “authentic in the sense that it was my physical MRI.” However, the physician’s name on the report had been altered. Tr. 35, 37; GX 6 at 8–9. UC also provided “fabricated” medical records which appeared to be signed by a nurse practitioner in Missouri. This nurse practitioner, according to UC, was no longer practicing in October 2017. Tr. 37–8; GX 6 at 10–11. UC did not provide a discharge summary or any prescription information. Tr. 39–40; 133. Nor did he provide any documents to show he had undergone a prior physical examination. Tr. 133.

4. After providing the materials, UC was given what he estimated to be approximately twenty pages of paperwork to fill out, none of which was included in his medical file seized later by DEA. Tr. 40; GX 5. However, UC took photographs of the forms before turning them in. Tr. 100. When asked to state his pain level, UC testified he told the clinic staff that it was “9” out of “10” (“9/10”), but when he was examined, he exhibited no overt indications of pain. Tr. 47, 56, 95. In fact, on one of the forms, he listed his quality of life as nine out of ten. Tr. 131–32. On another form, he rated his pain disability as only two out of ten. Tr. 132. On one form, he also denied he suffered from insomnia, Tr. 132–33, but wrote on another form that he sought to work without pain and sleep through the night. Tr. 135. No one questioned him about these contradictions. Tr. 139. UC acknowledged that he filled out

forms at his first appointment on October 3, 2017, and took photographs of the forms. Tr. 100. The completed documents, however, were not part of the Respondent's medical file seized by DEA and were not offered as exhibits by either party. Tr. 100; GX 5.

5. UC testified that one of the Respondent's employees apparently questioned the authenticity of the records he provided, stating that people are trying to "bring down Dr. Orusa." Tr. 41–42. This employee was not named, but was identified as the person depicted in GX 30. UC testified that, after providing the paperwork, his vital signs were recorded, including his blood pressure. He was also asked about his weight and asked to give a urine sample. Tr. 44–45.

6. UC described the October 3, 2017 visit as follows. He testified that he made no attempt to demonstrate that he had a disability. He did not limp or change his gait. Tr. 45–46. Though UC arrived at the clinic at approximately 8:00 a.m., he did not meet with Respondent until approximately 4:00 p.m. Tr. 47–48. During UC's encounter with Respondent, UC informed Respondent that the last "pain clinic" he visited was "Dr. Chapman in Pierce, City, Missouri, and had recently "closed down." GX 4 at 1. He also told Respondent that the person who ordered his MRI was "Dr. Morgan," a fictitious person. Tr. 37; GX 4 at 2. There was also a discussion about UC providing "pharmacy information." GX 4 at 3. UC told Respondent he would "get those records if I need to" but did not know the pharmacy's phone number.

7. UC testified that he did not produce any additional records. Tr. 55. UC testified that, during his meeting with Respondent, he saw Respondent "going through some forms on the counter," but could not determine what Respondent was reviewing. Tr. 105. UC testified that he told Respondent he fell while unloading a truck in 2013. Tr. 117; GX 1. He told Respondent that he was managing his pain with over-the-counter medications. Tr. 104. Though he told Respondent that he could "barely function," he did not "elaborate" and there was no further discussion about this statement. Tr. 124; GX 2; GX 17. UC testified that, in response to Respondent's question about a previous diagnosis, he told Respondent that a previous medical provider told him he had degeneration of some sort and "some arthritis." Tr. 105–06; GX 1.

8. UC testified that Respondent performed a cursory physical exam described as "less than 60 seconds of

any kind of physical touching." Tr. 56. He testified that Respondent instructed him to remain seated and UC "just told [Respondent] where the pain was. If he did something and asked me if it hurt I would respond that I felt pain in that area." Tr. 56. He testified that he made no "faces" and did not "wince" when touched. Following the exam, Respondent inquired about UC's past pharmacy records. UC told Respondent. "I'll get those records if I need to." Tr. 108–09; GX 3. UC testified that Respondent wanted to do "injections," but UC refused. Tr. 117. According to the transcript of the meeting, UC told Respondent that he hated needles. GX at 3.

9. Approximately 30 minutes after he left the exam room, UC received a prescription for 42 tablets of 10 mg oxycodone, even though he never asked for oxycodone. GX 18 at 1; Tr. 57. During the encounter with Respondent, UC said that he had previously been given hydrocodone, Xanax (alprazolam) and "oxys." GX 4 at 2. He also told Respondent that he was currently managing his pain with "Advil this past month" and had been "miserable." *Id.* UC testified that he also received two other prescriptions for non-controlled substances, including Flexeril (cyclobenzaprine) and meloxicam. Tr. 58.

10. When asked why, he told Respondent he had lower back pain as opposed to pain in some other area, UC testified that, due to his exercise schedule, which including running five to seven miles each day, a practitioner might find objective evidence to justify complaints of knee, ankle, or shoulder pain. Here, he testified, he had "absolutely no back pain whatsoever." Tr. 114–15. He testified that, if Respondent's clinic had been "doing their job," he would "not expect to walk out with a prescription." Tr. 105. Also, in his experience as an undercover operative, he testified that "more often than not" he has been refused prescriptions for controlled substances on the first visit. Tr. 123–24.

11. A video recording of UC's meeting with Respondent was played during the hearing. GX 17. UC testified that the video portion was a fair and accurate recording of his "entire encounter with" Respondent on October 3, 2017. Tr. 55. UC also testified that the transcript of that encounter (GX 4) was an accurate representation of the recording. Both the recording and the transcript were accepted into the official record. GX 4, 17; Tr. 70–71, 187–88.

October 17, 2017 Visit

12. UC testified that, in order to receive more "narcotic prescriptions," he was required to come in for a "well-care" visit before making an appointment during which he would receive narcotics. Tr. 57–58. On October 17, 2017, he returned to the clinic and paid \$25 for the visit. Tr. 57–59; GX 4, GX 17. He was then called back to a "triage room" and asked about his weight and blood pressure. Tr. 59.*P He saw the Respondent for "about one minute," during which Respondent asked him if he slept well. When he responded, "not really," Respondent wrote him a prescription for amitriptyline. Tr. 59; GX 4. This encounter was also recorded. GX 17. UC testified that, during this visit, no physical exam was performed. Tr. 71–72. He testified that no one examined his lower back, extremities, or checked his muscles. Tr. 72.

October 18, 2017 Visit

13. UC testified that, on October 18, 2017, he returned to the clinic for refills of narcotic medications. Tr. 74. Because the clinic would no longer accept cash, he secured a debit card to pay for the appointment, which cost \$377. Tr. 75–76. During the October 18, 2017 appointment, UC waited approximately two and a half hours. He was not examined and he met with medical personnel only for the purpose of paying the fee and receiving his prescription. There was no discussion about his medical condition and he provided no medical records. Tr. 76–77. At the end of this visit, he received a prescription for 84 tablets of 10 mg oxycodone, twice as much as he received 15 days earlier. Tr. 78; GX 18 at 3–4.

November 15, 2017 Visit

14. UC testified that, on November 15, 2017, he returned to the clinic for a fourth time. On this visit, he testified that he paid \$25, "waited for some amount of time," was "asked" about his weight and blood pressure, and was dismissed. Tr. 83–84.

November 20, 2017

15. UC testified that, on November 20, 2017, he returned to the clinic for a fifth time. He described this as a "medication visit." Tr. 87. UC testified that, during this visit, he wrote down his name on

*P This section of the Recommended Decision included several superscript numbers in the body of the text without any corresponding text in footnotes. As I believe that the superscript text was likely the result of a scrivener's error, I have deleted them throughout this section without further demarcation.

a clipboard, “paid a certain amount of money,” and waited a “certain amount of time” before he was given his prescriptions. Tr. 87–8. UC testified that he was asked to provide a urine sample to which he added “a vial of a substance that would cause me to test positive for oxycodone.” Tr. 88. At this visit, he received another prescription for 84 tablets of 10 mg oxycodone. GX 18 at 4; Tr. 89.

Falsified Medical Records

16. UC identified numerous entries in his medical record that indicated his medical chart had been fabricated. For instance, on October 17, 2017, Respondent wrote that UC exhibited a number of “[a]nxiety symptoms” such as shortness of breath, “palpitations, sweating, dizziness, [and] shaking.” GX 5 at 5. UC testified that he never reported any of these symptoms. Tr. 79–80. Respondent also wrote that UC reported “no headache, no dizziness, no nausea, no vomiting, no abdominal pain, no diarrhea, no constipation, no [shortness of breath], no chest pain, [and] no palpitations.” GX 5 at 5. UC testified that he was never asked about any of these symptoms. Tr. 80–81. UC was also asked about a notation for October 17, 2017, where his weight and blood pressure were recorded. GX 5 at 5. He testified that he was neither weighed, nor did anyone measure his blood pressure on that day. Also, on October 17, 2017, Respondent wrote “Chest: no deformities, no asymmetry, no rales, no wheezes, normal vesicular breath sounds.” GX 5 at 5. UC testified that no one ever examined his chest or evaluated his breathing. Tr. 81–82.

17. Regarding the medical records for October 18, 2017, Respondent’s entries for this appointment were identical to those made the day before. Again, he wrote “ROS for MSS is positive for muscle pain, back pain, joint pain, and body aches and pain.” GX 5 at 4. Respondent again repeated the same notations about UC’s chest and breathing. However, all of this was created on a day when UC did not see the Respondent. Nor was UC examined by anyone else at the clinic that day. Tr. 82–83.

18. With respect to the November 15, 2017 visit, Respondent repeated the same notations even though, as UC testified, no exams were performed and Respondent was not there to see him. Nevertheless, Respondent wrote out a list of symptoms in the section marked “HPI,” GX 5 at 4, which correspond to the visit on November 15, 2017. Again, UC testified that none of these symptoms were ever discussed and no examination was performed. Tr. 86.

Likewise, with respect to Respondent’s notes in the section marked “PE” (physical exam),” UC testified that no one examined his chest or breathing. Tr. 86–87.

19. Finally, regarding the November 20, 2017 visit, Respondent wrote, as he had four times previously, that UC was “positive for muscle pain, back pain, joint pain and body aches.” GX 5 at 3. UC testified that no physical exam was performed on this day. Tr. 90–91. Respondent also, for the fifth time, described a physical examination (section “PE”) that was never performed. GX 5 at 3; Tr. 91.

20. UC also testified about the results of his urine drug screening. He noted that, despite adding an oxycodone solution to his urine on November 20, 2017, his records showed “UDS ALL NEG.” Tr. 91–92; GX 5 at 3. UC also testified that there was no discussion about this result. Tr. 92.

Expert Review

21. Dr. Kennedy testified as the Government’s expert. Dr. Kennedy owns a pain management clinic on St. Simons Island, Georgia; has treated more than 1000 patients, but his current practice involves fewer than 100 patients. Tr. 143–46. He testified that he has treated patients with post-surgical issues, patients with cancer pain, and patients with back pain. Tr. 178–80. Most of his patients, he testified, need to have their medications “managed.” Tr. 143–44. Dr. Kennedy testified that he has been practicing pain management for approximately 15 years. Tr. 145, 179–80. He is licensed to practice medicine in Georgia and runs a “state licensed pain management clinic.” Tr. 146; GX 24. Dr. Kennedy is not board certified. Tr. 373.

22. Dr. Kennedy testified that, in his practice, he prescribes controlled substances, including opioids such as oxycodone and hydrocodone. Tr. 181. He has treated insomnia and/or anxiety with benzodiazepines, such as lorazepam, diazepam, and alprazolam. Tr. 181–82. He has also prescribed muscle relaxants such as carisoprodol. Tr. 181–82.

23. Dr. Kennedy has also lectured on controlled substances “numerous times” at the DEA training facility in Quantico. He has taught at the National Advocacy Center, and at various DEA and Department of Justice (“DOJ”) “venues” around the country. Tr. 184–85. He also taught a course for pharmacists in Tennessee. Tr. 185.

24. Dr. Kennedy testified he has served as an expert witness in numerous cases, including those involving physicians alleged to have improperly

prescribed controlled substances. Tr. 182. He estimates he has testified 13–14 times. *Id.*

25. As the Government’s expert, Dr. Kennedy reviewed the medical charts for patients UC (GX 5), M.P. (GX 7), M.W. (GX 9), C.F. (GX 11), B.C. (GX 13), and M.W. (GX 15). He also reviewed the prescriptions for these patients (GX 18–23), the undercover video created by UC, the transcripts (GX 17 and 4) of that video, and UC’s reports of his undercover visits (GX 3). Tr. 183–84, 186–89; 213–16.

26. Dr. Kennedy explained that, according to the minimal standard of care for prescribing controlled substances in Tennessee, a physician must: (1) Take an adequate medical history; (2) perform a physical examination; (3) obtain past medical records; (4) order diagnostic testing if indicated; [and (5) maintain complete and accurate medical records.] Tr. 189–90, 195–96, 353.

27. Dr. Kennedy testified that, according to the minimal standard of care, a physician’s medical records should contain the following: (1) past medical records or attempts to obtain past medical records; (2) a “pain history” or “collection of statements pertaining directly” to the patient’s pain history; (3) history of “drug abuse, chemical dependency, [or] alcoholism;” (4) records of a physical examination “that is specific and pertinent to the problem;” (5) patient assessment; (6) treatment plan; and (7) efforts to obtain state pharmacy reports. Tr. 197. He also testified he was familiar with Tennessee regulations requiring a physician to keep accurate and complete medical records. Tr. 201.

28. Dr. Kennedy testified that, in cases where physicians prescribe opioids in combination with benzodiazepines, a physician must have a “heightened sense of vigilance managing the patient” and this should be noted in the medical record. Tr. 190–91.

29. Dr. Kennedy testified that there are indications of possible drug abuse and/or diversion in patients whose medical histories are “difficult to obtain” as well as patients with “cloudy histories of drug abuse.” Tr. 191–92. He discussed urine drug screening (“UDS”) and how a physician must respond if a patient’s UDS result shows an “abnormality, it’s not simply enough to just to say a patient’s urine is positive for cocaine or positive for methamphetamine. The physician also has an obligation to say that the patient is positive for this substance, and I discussed it with the patient, and I’m going to do this if it happens again or I’m going to adjust the medications or

not adjust the medications. And it has to be something that is utilized as a diagnostic treatment.” Tr. 194. Dr. Kennedy further testified that the above information should be documented in the medical record. *Id.*

30. Dr. Kennedy testified that, prior to testifying in this matter, he reviewed Tennessee regulations pertaining to the prescribing of controlled substances. He confirmed that these regulations included requirements that a physician must (1) take the patient’s documented medical history; (2) perform a physical examination; (3) perform an adequate assessment and consideration of the patient’s pain, physical, and psychological function; And (4) take a history for the potential of substance abuse.*Q Tr. 200. Dr. Kennedy also testified that he was familiar with rules prohibiting a physician from prescribing controlled substances to a person addicted to the habit of using controlled substances without making a bona fide effort to the cure the patient’s habit. Tr. 199.

31. Based on his qualifications and expertise, his knowledge of Tennessee regulations and statutes, and his experience as an operator of a pain management clinic, Dr. Kennedy was accepted as an expert in pain management qualified to give an expert opinion regarding Respondent’s prescribing of controlled substances. Tr. 211–12; 216.

Undercover

32. With respect to the undercover officer, Dr. Kennedy testified he reviewed the video recording UC made during his visits to Respondent’s clinic on October 3 and October 17 of 2017 (GX 17); UC’s investigative reports for all five of his visits to Respondent’s clinic; the patient medical file pertaining to patient UC; and the prescriptions issued to UC by the Respondent. GX 3, 5, 17–18; Tr. 184–86, 216, 239.

33. Dr. Kennedy testified that, based on his review, UC was being treated for back pain. He testified that the physical exam was inadequate, describing it as “cursory in that it consisted of essentially observing” UC, “touching his back, and having him lift his leg once.” Tr. 217. Dr. Kennedy testified that a minimally adequate exam would

include “observing the patient’s back, looking for muscle spasms, performing “lumbar range of motion maneuvers where the patient . . . bends at the waist in various directions,” doing a neurologic exam, and doing a “straight leg raised test having the patient laying supine on the table.” Tr. 224–25. Dr. Kennedy concluded that, based on the medical records, there were no “positive findings on physical examination.” Tr. 226. In other words, he testified, Respondent’s “physical exam findings” failed to support a “pain ideology” and certainly could not justify a reported pain level of 9/10. Tr. 226–27, 234. With respect to the Respondent’s diagnosis (GX 5 at 2) of “[d]egeneration of [l]umbar [i]ntervertebral [d]isc . . . [l]umbar [s]pondylosis . . . , and [i]nsomnia,” Dr. Kennedy noted that even the MRI failed to mention degenerative disc disease and Dr. Kennedy could identify no other findings to justify that diagnosis. Tr. 240–42. And though spondylosis could be severe enough to “be causing symptoms,” Dr. Kennedy testified that there was no evidence that these symptoms existed. Tr. 242. Dr. Kennedy also testified that neither UC’s MRI report, nor the prior medical records, justified the prescribing of controlled substances. Tr. 228, 230.

34. Looking at Respondent’s medical record for patient UC, Dr. Kennedy further concluded that the record was rife with fabrications as the following testimony indicates: “. . . if you look it says on the second line, chest, no deformities, no asymmetry. The only way to determine [this] is to look at them with their shirt off. And this patient was not required to disrobe . . . there is also no indication . . . that the heart and lungs were evaluated. But there are heart and lung evaluations as well as the chest appearance . . . you couldn’t see everything, but clearly listening to the audio, I didn’t hear any breathe in, breathe out, anything that would indicate to me that there was a physical exam that included these things.” Tr. 218–19. Dr. Kennedy further noted that the description of UC’s general exam in the section marked “PE” (GX 5 at 6) was not only inaccurate, but was identical to language he found in more than 20 medical charts he reviewed for other patients. Likewise, Dr. Kennedy disputed the truth of the information supposedly used to support a finding that UC suffered from insomnia. Tr. 233. This was further confirmed by UC’s testimony, in which he testified that he neither reported nor manifested any of the listed “insomnia” symptoms. Tr.

79–80, 134–35, 139. Dr. Kennedy also testified that the physical exam depicted in the video (GX 17) as well as UC’s subsequent encounters could not possibly support the repeated findings corresponding to visits on October 17 and 18, as well as the visits on November 15 and 20. GX 5 at 3–5; Tr. 235–37.

35. Dr. Kennedy testified that UC, as an undercover patient, also manifested various “red flags” for possible drug abuse and/or diversion. Tr. 230. He noted that UC’s prior medical records showed only a “single office visit” (GX 6 at 10) from a provider in another state and documentation from the encounter showed a “completely normal physical exam with no positive findings at all.” Tr. 220–31. Dr. Kennedy testified that a patient who comes from a clinic that has closed and provides medical records from a practitioner whose license has been suspended are red flags for diversion. He further noted that none of these red flags was “significantly” addressed by Respondent prior to prescribing oxycodone. Tr. 238.

36. In summary, Dr. Kennedy testified that, with respect to UC, Respondent: (1) Failed to discuss the risks and benefits of the use of oxycodone; (2) failed to maintain truthful and accurate medical records; (3) failed to assess the patient’s pain, physical and psychological function; (4) failed to assess the patient’s history and potential for substance abuse; (5) failed to assess any co-existing diseases, conditions in the presence of a recognized medical indication for the use of oxycodone; and (6) failed to create and follow a legitimate written treatment plan for the patient’s individual needs. Tr. 231–32, 237–38. Dr. Kennedy further concluded that Respondent’s prescribing of controlled substances to UC was outside the usual course of professional practice. Tr. 239. Additionally, Dr. Kennedy concluded that the prescriptions issued to UC lacked a medical justification. Tr. 239; *see also* GX 6 (Dr. Kennedy’s expert report on patient UC), 18 (prescriptions issued to UC).

Patient M.W.

37. Dr. Kennedy testified that Respondent treated M.W. for lower back and limb pain. Tr. 245. M.W. was prescribed alprazolam, carisoprodol (Soma), oxycodone, and oxymorphone. GX 23. In his review, Dr. Kennedy stated that there was nothing that meaningfully supported a chronic pain condition. *Id.* Dr. Kennedy discussed a form in M.W.’s file titled “Pain Management Physical Exam.” (GX 9 at 14/GE 10 at 7). He testified that the form

*QI find that Dr. Kennedy credibly testified that the applicable standard of care in Tennessee is as described in Finding of Fact Nos. 26–27 *supra*. The requirements of the Tennessee regulations are clearly components of and incorporated into the standard of care set forth by Dr. Kennedy at Finding of Fact Nos. 26–27. TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(i). Further, Dr. Kennedy’s expert testimony is un rebutted in this proceeding.

indicated only “normal findings” and “acute findings.” Tr. 247. Yet, the patient reported a pain level of 10/10. Tr. 248–49; GX 9 at 19; GX 10 at 8. As Dr. Kennedy testified, in order to support such a high pain level, there would have to be “very, very significant findings on lumbar exam.” For instance, he testified, he would not expect to see a patient whose “gait is normal.” Tr. 250. Dr. Kennedy also testified that it would be unusual to see a 25 year old patient with degenerative disc disease. In that case, he testified, he would expect Respondent to order radiologic studies to confirm the diagnosis. Tr. 262–63; GX 10.

38. Dr. Kennedy also found nothing in M.W.’s medical chart to justify the continuing prescribing of alprazolam. Tr. 260–62. Rather, he found “identical language [to] that [which] was used to diagnose insomnia” for UC. Tr. 261; *see also* GX 9 at 84 (“HPI” entry); *compare to* GX 5 at 5 (same). There was no evidence, Dr. Kennedy testified, that M.W. suffered from insomnia. Tr. 264.

39. Dr. Kennedy also testified that there were numerous red flags in M.W.’s medical chart for abuse and/or diversion. Specifically, M.W.’s chart showed a “wildly abnormal” drug screen in which M.W. tested positive for morphine, hydromorphone, and THC in March 2016. He was also negative for carisoprodol and alprazolam, two drugs he was being prescribed and was supposed to be taking. Tr. 251–52; GX 9 at 2–4. Based on the medical record, Dr. Kennedy testified that this abnormal result was not “meaningfully addressed.” Tr. 252. Elsewhere in the chart, there were other examples of abnormal drug screens. On March 28, 2016, Respondent wrote “UDS pos for oxy-unsat.” GX 9 at 102. Then, according to an UDS lab report dated May 11, 2017, M.W. tested negative for four controlled substances he had been prescribed, including oxycodone, oxymorphone, alprazolam, and carisoprodol (Soma). GX 9 at 10. Inexplicably, six days before M.W. provided the specimen, Respondent wrote that M.W. was negative for all prescribed drugs. GX 9 at 85. On May 31, 2017, Respondent wrote that M.W. is “dismissed” with “one month notice,” but noted *on the same day* that M.W. was “compliant and consistent.” GX 9 at 83–84. However, less than a month later, the “dismissal [was] reversed.” GX 9 at 83. Dr. Kennedy said, “[i]f the patient is negative for the medication and its metabolites of essentially everything that’s prescribed, there’s a problem.” Tr. 260. Dr. Kennedy testified that this was evidence of drug

abuse, which Respondent failed to adequately address. Tr. 265.

40. With respect to M.W.’s medical records, Dr. Kennedy again cited numerous inconsistencies that questioned Respondent’s credibility. For instance, he testified that the findings on the handwritten physical exam form (GX 9 at 14) did not match those listed in Respondent’s electronic medical record (GX 10 at 9). Instead, Dr. Kennedy found the same language in M.W.’s chart that was present in UC’s medical chart and in the charts for other patients he reviewed. Tr. 250–51. Dr. Kennedy noted that, out of 98 different encounters, Respondent repeated the same notes 93 times. Tr. 264. This, he testified, rendered the medical file “not credible.” Tr. 251. Dr. Kennedy also cited the fact that Respondent described M.W. as “compliant and consistent” the same day he tested negative for all the controlled drugs he was supposed to be taking. Tr. 258–59. Again, he described the inconsistency as “simply not credible.” Tr. 259.

41. In summary, Dr. Kennedy testified that, with respect to M.W., Respondent: (1) Failed to perform an adequate physical examination; (2) failed to assess the patient’s pain, physical, psychological function; (3) failed to assess the patient’s history and potential for substance abuse, coexisting diseases and conditions; and (4) failed to create a legitimate written treatment plan for the patient’s individual needs. Tr. 265. He further testified that Respondent failed to maintain a truthful and accurate medical record for M.W. Tr. 265–66. Dr. Kennedy testified that the controlled substances in GX 23 were prescribed to M.W. outside the usual course of professional practice. Tr. 266–68. Lastly, Dr. Kennedy testified that his opinions applied to all the prescriptions in GX 23. Tr. 266.

Patient C.F.

42. Dr. Kennedy testified that patient C.F. was treated for “chronic pain due to trauma, unspecified inflammatory polyarthropathy.” Tr. 269. However, he testified that C.F.’s physical examination did not support the controlled substances prescribed. *Id.* Dr. Kennedy noted that, while C.F. had scars, her muscle strength was normal as well as her tendon reflexes, and her fine touch sensation. Also, he testified that C.F.’s “[l]eg raise tests were normal bilaterally” and her gait was normal. Tr. 270; GX 11 at 106. Dr. Kennedy also testified that the findings in Respondent’s “Pain Management Physical Exam” (GX 11 at 106) were not accurately reflected in Respondent’s electronic medical record. Tr. 271.

Rather, he testified, that portion of Respondent’s medical record contained findings “present in the other charts that we’ve already discussed.” Tr. 271–72; GX 11 at 69. Dr. Kennedy also testified that he could find no evidence of any credible follow-up physical exams being performed even though C.F. remained a patient for nearly four years. Tr. 272. Nor did he find any evidence that Respondent ordered any supporting studies. *Id.*

43. Dr. Kennedy testified regarding the long term prescribing of alprazolam to C.F. He testified that there was no justification for this since the objective findings to support a diagnosis of insomnia and/or anxiety were identical to those found in medical records for other patients, including those pertaining to UC. GX 11 at 39; Tr. 286–87.

44. Dr. Kennedy testified he also found evidence of possible abuse/diversion that Respondent never adequately addressed. In GX 11 at 117, a laboratory report dated July 9, 2018, shows that C.F. tested negative for prescribed controlled medications, a result that Respondent himself labeled as “Unsat.” GX 11 at 117; Tr. 274. According to Respondent’s own records, this test was taken just three days after C.F. was prescribed alprazolam, oxycodone, and oxymorphone. GX 11 at 9; Tr. 274–75. Pursuant to a report dated July 7, 2017, C.F. tested negative for alprazolam and positive for hydrocodone. GX 11 at 111; Tr. 275. On June 30, 2017, Respondent’s records showed C.F. was prescribed alprazolam, but hydrocodone is not listed. GX 11 at 25; Tr. 275–76. Dr. Kennedy testified that, according to notes from a subsequent visit on July 26, 2017, the abnormal drug screen result is never mentioned. GX 11 at 23; Tr. 288–89.

45. Additionally, Dr. Kennedy testified that, according to a lab report dated July 13, 2014, C.F. tested positive for a diazepam metabolite, negative for alprazolam, and positive for cocaine, oxycodone, oxymorphone, and THC. GX 11 at 79; Tr. 276–278. However, at the next visit on August 11, 2014, Respondent’s medical records made no reference to these abnormal results. GX 11 at 69; Tr. 278–79.

46. Regarding C.F.’s multiple unsatisfactory drug screens, Dr. Kennedy testified that it is insufficient for a physician to simply document that the patient was counseled. Rather, he testified, the doctor needs to document how the abnormalities are “going to affect treatment.” Tr. 283–84. Dr. Kennedy testified that “repeating over and over that the patient was counseled. . . leads to the impression

. . . that it's not making any difference to the prescriptions for schedule medications that are being provided." *Id.*

47. Regarding C.F.'s medical record, Dr. Kennedy testified that Respondent's description of his review of systems ("ROS") was repeated throughout C.F.'s chart and found in numerous other charts. Tr. 272–73. Likewise, the section labeled "Gen exam" was repeated 102 times and also found in other charts. Tr. 273. Also, as stated above, Respondent's description of the physical exam failed to reflect the actual handwritten notes but rather mirrored what had been written about other patients, including UC.

48. In summary, regarding patient C.F., Dr. Kennedy testified that Respondent: (1) Failed to take an adequate medical history; (2) failed to perform an adequate physical examination; (3) failed to perform an adequate assessment in consideration of the patient's pain, physical, and psychological function; (4) failed to take an adequate history and evaluate the potential for substance abuse; (5) failed to create a written treatment plan tailored for the individual needs of the patient; (6) failed to consider the patient's pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities, (7) failed to discuss the benefits and risks of the use of controlled substances; (8) failed to conduct a documented periodic review of the care at reasonable intervals in view of the individual circumstances of each patient; (9) failed to keep complete and accurate records of the care provided; and (10) continued to issue prescriptions for controlled substances without making a bona fide effort to cure the patient's habit. Tr. 284–86.

49. Dr. Kennedy further testified that, for the reasons in Finding of Fact no. 48 and given C.F.'s numerous abnormal drug screen results, the issuing of prescriptions for controlled substances to C.F., including those in GX 20, were issued "outside the scope of acceptable medical practice." Tr. 287.

Patient B.C.

50. Dr. Kennedy testified that B.C. was treated for "chronic pain syndrome." Tr. 290. He testified that he found no handwritten notes reflecting a physical exam and that the electronic records showed results that were "non-supportive" of a chronic pain condition. Tr. 290–91. Dr. Kennedy explained that the electronic records, in the category of "systems review," reflected 141 encounters with Respondent and the

"system review documentations was repeated 140 times." He also testified that the "physical exam documentation was repeated "approximately 134 times." According to Dr. Kennedy, this same documentation was found, verbatim, in other charts. Tr. 292.

51. Though Dr. Kennedy acknowledged that B.C. seemed to have serious medical "problems," such as Hodgkin's lymphoma, a cancer of the lymphatic system, Respondent's notes, inexplicably, failed to reflect those problems. Dr. Kennedy noted, for instance, that the review of systems for B.C. showed, among other things, that B.C.'s "endocrine" was "negative." Tr. 292–93; *see, e.g.*, GX 13 at 169. Dr. Kennedy also took issue with the fact that Respondent, after repeatedly reporting a nonsensical pain level of "/10" over the course of nine sequential encounters," began to record a pain level of 10/10 without medication and 8/10 with medication. Tr. 295–96. Dr. Kennedy testified that, despite B.C. being dismissed from another physician, there was also no attempt to obtain prior medical records. Tr. 304.

52. Dr. Kennedy testified that there were numerous red flags in B.C.'s chart for abuse and/or diversion. First, B.C. had been dismissed from a previous physician, GX 13 at 188, Tr. 293–94, an issue that was not investigated. Tr. 294. Respondent also noted that B.C. lied about his prescriptions at the first encounter—another issue that does not appear to have been addressed. Tr. 296; GX 13 at 169. In fact, Dr. Kennedy testified that the record, despite evidence of B.C.'s untruthfulness, appears to show that Respondent prescribed controlled substances to B.C. without ordering a UDS screen, something that "is outside the course of usual medical practice." Tr. 297; GX 13 at 169. Dr. Kennedy testified that there were also abnormal drug screen results. On February 20, 2013, B.C. was positive only for oxycodone when he was also prescribed alprazolam. Tr. 298; GX 13 at 166. A note dated March 26, 2013, indicated "unsatisfactory benzo only UDS." Tr. 298–99; GX 13 at 165. On August 19, 2013, B.C. was positive for opioids only, another unsatisfactory result. Tr. 299; GX 13 at 158. Dr. Kennedy identified more abnormal results, including one where B.C. testified positive only for benzodiazepines when he was also being prescribed oxycodone. Tr. 299; GX 13 at 156–57. In another note, B.C. tested positive only for oxycodone when he was also being prescribed alprazolam. GX 13 at 155–65 (October 6, 2014 entry); Tr. 300. On December 22, 2014, Respondent noted that B.C. was

negative for all drugs, another unsatisfactory result. Tr. 300–01; GX 13 at 150. And though the record indicates the patient was counseled, Dr. Kennedy testified that there was "nothing specific about what the counseling entailed or any decisions" made as a result. Tr. 301.

53. Dr. Kennedy also testified that B.C. had been in jail, another red flag. Tr. 301–02. Dr. Kennedy testified that, in this case, a "reasonable physician would provide documentation that supports that this was addressed and taken into account in pursuing a treatment plan." Tr. 302–03.

54. Dr. Kennedy noted numerous instances where the medical chart, instead of recording an actual pain level, listed a nonsensical pain level of "/10." Tr. 294–95.

55. In summary, Dr. Kennedy testified that Respondent's examination of B.C. did not support a chronic pain condition. He testified that Respondent: (1) Failed to take an adequate medical history; (2) failed to perform a sufficient physical examination; (3) failed to perform an adequate assessment in consideration of the patient's pain, physical and psychological function; (4) failed to take an adequate history for the potential for substance abuse, coexisting diseases and condition; (5) failed to show the presence of a recognized medical indication for the use of a dangerous drug or controlled substance; (6) failed to create a written treatment plan tailored to the individual needs of the patient; (7) failed to adequately address the need for further testing, consultation, referrals or other treatment modalities; (8) failed to discuss the risks and benefits of the use of controlled substances; (9) failed to do a documented periodic review of his care at reasonable intervals in view of the individual circumstances; and (10) failed to keep complete and accurate records of the care provided. Tr. 304–06. Dr. Kennedy testified that, in his view, there was no medical justification for issuing prescriptions for controlled substances to B.C. and, as a result, the prescriptions were issued outside the usual course of professional practice. Tr. 307–08; GX 22.

Patient M.H.

56. Dr. Kennedy testified that M.H. was being treated for "chronic pain syndrome." Tr. 309. He testified that Respondent performed a physical exam; however, the findings were identical to those for other patients. *See* GX 15 at 62–63 (sections marked "PE" for February 4, 2015, and April 1, 2015); Tr. 310–11. Moreover, Dr. Kennedy testified that these findings did not support a chronic pain condition and that the

treatment was “outside the scope of acceptable medical practice.” Tr. 311–12. Dr. Kennedy also testified about an “extremely” unusual situation in which M.H. underwent extensive spinal surgery and was discharged from the hospital on October 4, 2016. However, the medical chart entry dated October 5, 2016, shows no mention of the surgery and no evidence that a physical exam was performed. Tr. 320–22, 323–24; GX 15 at 26 (hospital notes), at 48 (encounter note for October 5, 2016). Dr. Kennedy described the situation as follows: “this whole thing is about scheduled medications to begin with. This is ostensibly a chronic pain patient. He has been discharged from the hospital the day before this encounter after having had a major, major spinal surgery. And not only it is not mentioned in this encounter note, but essentially this encounter note is normal and identical to all the other encounter notes.” Tr. 322–23. Dr. Kennedy also found no justification for the continued prescribing of alprazolam. As with the other patients, the factual findings related to insomnia/anxiety were identical to the findings found in charts of the other patients discussed during the hearing. GX 15 at 49 (section marked HPI).

57. Dr. Kennedy testified that he also found evidence of abnormal drug screens, even on M.H.’s initial visit. Tr. 313–14; GX 15 at 63. On some occasions, M.H. tested positive for illicit substances. See GX 15 at 56 (positive for THC, cocaine, PCP); GX 15 at 53 (positive for amphetamines); Tr. 314–15. In other cases, he tested negative for drugs that had been prescribed. GX 15 at 51 (positive for opiates and oxycodone when patient also prescribed alprazolam and carisoprodol); GX 15 at 49 (same); GX 15 at 47 (same); GX 15 at 40 (UDS negative for all drugs while patient was prescribed oxycodone oxymorphone, alprazolam, and carisoprodol); GX 15 at 39 (UDS negative for all drugs); GX 15 at 36 (UDS positive only for oxycodone). In these cases, Dr. Kennedy testified, there was no evidence that Respondent addressed the abnormalities other than to order repeat tests. Tr. 313–20.

58. Dr. Kennedy also reviewed the prescriptions for M.H. identified as GX 19. These included alprazolam, oxymorphone, carisoprodol, and oxycodone. Tr. 325–27.

59. Dr. Kennedy testified that, in his view, Respondent prescribed controlled substances to M.H. despite evidence that M.H. may have been addicted to the habit of using controlled substances. Tr. 327. He testified that Respondent made no effort to cure M.H.’s habit. *Id.* Dr.

Kennedy further testified that Respondent: (1) Failed to perform an adequate assessment in consideration of the patient’s pain, physical and psychological function; (2) failed to evaluate the patient’s history and potential for substance abuse; (3) failed to determine a recognized medication indication for the use of controlled substances; (4) failed to create a written treatment plan tailored for the individual needs of the patient; (5) failed to consider the need for further testing, consultation, referrals, or use of other treatment modalities; (6) failed to discuss the risks and benefits of the use of controlled substances; (7) failed to do a documented periodic review of the patient’s care at reasonable intervals in view of the individual circumstances of each patient; and (8) failed to keep complete and accurate records of the care provided to M.H. Tr. 327–29.

60. Dr. Kennedy testified that the controlled substances issued to M.H. were not issued in the usual course of professional practice. Tr. 329.

Patient M.P.

61. Dr. Kennedy testified that M.P. was being treated for low back, neck, hip, and shoulder pain. Tr. 331. Dr. Kennedy testified that the physical exam used to justify prescribing controlled substances for M.P. was inadequate. Tr. 334. As he explained, M.P. was diagnosed with degenerative disc disease and right shoulder pain. To determine whether M.P. had shoulder pain, Dr. Kennedy testified, a physician would have to test the patient’s “range of motion as far as extension, flexion, abduction . . . tenderness to palpation specific to the shoulder.” Tr. 335. With respect to degenerative disc disease, Dr. Kennedy testified that Respondent should have found, for example, that the “dorsal lumber and C-spine range of motion” was “decreased in all directions.” *Id.* Dr. Kennedy testified he saw no such findings in Respondent’s medical record. Tr. 334–35. Dr. Kennedy also testified that M.P.’s pain level was inconsistent with other information in the record.

62. Dr. Kennedy also testified that, throughout M.P.’s medical records, Respondent expressed a need to obtain M.P.’s prior medical records, but Respondent never followed through. GX 7 at 1, 59, 68; Tr. 337–38. This included obtaining M.P.’s x-rays, MRI report, and the dismissal form from her prior physician. *Id.*

63. Dr. Kennedy testified that M.P. manifested signs of abuse/diversion which were not adequately addressed. Initially, M.P. tested positive for buprenorphine, benzodiazepines,

oxycodone, and THC. GX 7 at 68. According to the pharmacy report, which was part M.P.’s medical chart, buprenorphine had never been prescribed. Tr. 338–39; GX 7 at 19. Dr. Kennedy also discussed that there was mention of “termination paperwork from a previous physician,” another red flag for abuse and/or diversion. Tr. 342. Dr. Kennedy pointed out “highly conflicting” information in M.P.’s medical chart. Tr. 345. For instance, M.P. listed her occupational disability as both “9” and “10,” but stated she works “45–60 hours weekly” as a waitress. GX 7 at 9–10. Dr. Kennedy also questioned M.P.’s truthfulness when she denied that she had ever been in a drug treatment program (GX 7, 13). However, following a heroin overdose, she told Respondent that she refused to go into such a program because she had tried drug treatment *before*. GX 7 at 57 (section marked “HPI”). Dr. Kennedy also pointed out several abnormal drug screen results. In GX 7, page 58, there is a reference to a positive test for THC, opioids, and benzodiazepines, none of which had been prescribed. Tr. 347.

64. M.P. overdosed on heroin in Respondent’s waiting room. GX 7 at 25; Tr. 340–41. However, according to Dr. Kennedy, Respondent incorrectly treated M.P. with Suboxone (buprenorphine).

65. Dr. Kennedy testified that Respondent repeatedly issued prescriptions for controlled substances to M.P. despite the fact she was addicted to the habit of using controlled substances. Tr. 348. Also, up until the point M.P. overdosed on heroin, Respondent made no effort to cure M.P.’s habit. Tr. 348–49. Dr. Kennedy also testified that, with respect to M.P., Respondent: (1) Failed to perform a sufficient physical examination; (2) failed to perform an adequate assessment in consideration of the patient pain, physical and psychological function; (3) failed to record an adequate history of potential substance abuse; (4) failed to determine a recognized medical indication for the use of controlled substances; (5) failed to create a written treatment plan tailored for the individual needs of the patient; (6) failed to take a pertinent medical history and perform a physical examination as well as perform further testing, consultation, referrals. And the use of other treatment modalities; (7) failed to discuss the risk and benefits of the use of controlled substances; (8) failed to do a documented periodic review of M.P.’s care at reasonable intervals in view of the individual circumstances; and (9) failed to keep

complete an accurate medical records of the care provided to M.P. Tr. 348–50.

66. Dr. Kennedy also testified that the prescriptions issued to M.P., including those in GX 21, were issued outside the usual course of professional practice, and that Respondent lacked a medical justification for issuing the prescriptions. Tr. 352.

67. With respect to patients, B.C, C.F., M.H., M.W., and M.P., Dr. Kennedy testified that the prescribing of controlled substances to these patients was dangerous. Tr. 352. As a basis for that opinion, he cited: (1) Abnormal drug screens that were “essentially ignored,” (2) the lack of documentation about the patients’ status; (3) medical records that were not credible; (4) and maintaining patients on scheduled medications, sometimes at high dosages “without having honest, accurate, complete medical records.” Tr. 352–53. He testified that “[b]ecause medical records will instruct other people who look” at the patients later, a medical record that “simply doesn’t make sense or [has] something that is in conflict,” can “present a dangerous situation.” Tr. 353.

Respondent’s Falsification

68. DI testified that Respondent submitted an application to renew his DEA COR (No. BO4959889) on November 6, 2019. Tr. 529; GX 26. She testified that Respondent answered “no” to the third liability question on the application. Specifically, the question sought to determine whether Respondent had ever “surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation.” Tr. 530.

69. DI introduced a document outlining an administrative action against Respondent, titled “Notice of Charges and Memorandum for Assessment of Civil Penalties,” submitted May 1, 2019, by the Tennessee Department of Health. GX 29; Tr. 531. As the document states, Respondent was charged with, among other things, prescribing “narcotics and other medications and controlled substances in amounts and/or duration that were not medically necessary, advisable, or justified for a diagnosed condition.” GX 29 at 5.

70. DI introduced a document from the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part III (“Chancery Court”), staying the proceedings brought by the Tennessee Department of Health, [omitted] and imposing restrictions on Respondent’s license as conditions of the stay. Those restrictions included

prohibiting Respondent from: (1) Writing prescriptions; (2) supervising or collaborating with any mid-level practitioners for the writing of prescriptions; and (3) providing direct patient care including but not limited to diagnosing, treating, operating on or prescribing for any person. GX 27 at 2–3; Tr. 533–34. The order is dated May 17, 2019, approximately three months before Respondent submitted his renewal application. GX 27 at 4.

71. DI introduced a document, titled Agreed Order, dated August 21, 2018. GX 28. DI testified that the Order provided that Respondent must surrender his Tennessee Pain Management Clinic Certificate (“Pain Clinic Certificate”), No. 246, as a result of violations related to the prescribing of controlled substances. *Id.* at 5–7.

72. DI testified, as a result of having surrendered his Pain Clinic Certificate and the restrictions placed upon his medical license by the Chancery Court, that Respondent did not answer truthfully on his renewal application. Tr. 536.

Analysis

Findings as to Allegations

The Government alleges that the Respondent’s COR should be revoked, and any applications should be denied, because the Respondent [has committed such acts as would render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4); 21 U.S.C. 823(f) and in particular the Government relies on Public Interest Factors Two (the Respondent’s experience conducting regulated activity) and Four (the Respondent’s compliance with state and federal laws related to controlled substances)]. ALJ Ex. 1.²⁹ In the adjudication of a revocation of a DEA COR, the DEA bears the burden of proving that the requirements for such revocation are satisfied. 21 CFR 1301.44(e). Where the Government has sustained its burden and established that a respondent has committed acts that render his registration inconsistent with the public interest, to rebut the Government’s *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 FR 20,727, 20,734 (2009).

Acceptance of responsibility and remedial measures are assessed in the context of the “egregiousness of the violations and the [DEA’s] interest in deterring similar misconduct by [the]

²⁹In its GPHB, the Government argues Factors Two and Four should be combined for a joint analysis.

Respondent in the future as well as on the part of others.” *David A. Ruben, M.D.*, 78 FR 38,363, 38,364 (2013).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008).

The Agency’s conclusion that “past performance is the best predictor of future performance” has been sustained on review, *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency’s consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie v. DEA*, 419 F.3d 477, 482–83 (6th Cir. 2005); *see also Ronald Lynch, M.D.*, 75 FR 78,745, 78,754 (2010) (holding that the Respondent’s attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.*, 74 FR 17,529, 17,543 (2009) (finding that much of the respondent’s testimony undermined his initial acceptance that he was “probably at fault” for some misconduct); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009) (noting, on remand, that despite the respondent’s having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Medicine Shoppe-Jonesborough*, 73 FR 364 at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).^{*R}

Tennessee Law

As a licensed medical doctor in Tennessee, the Respondent was subject to TENN. CODE ANN. § 63–6–214(b)(12) through (14),³⁰ as those provisions

^{*R}Remaining text omitted for brevity and clarity.

³⁰T. C. A. § 63–6–214. License denial, suspension, or revocation; grounds; examination; investigations; abstract of record; report; standard of care; disclosure of records; screening panels; hearings; orders

(a) The board has the power to: (1) Deny an application for a license to any applicant who applies for the same through reciprocity or otherwise; (2) Permanently or temporarily withhold issuance of a license; (3) Suspend, or limit or restrict a previously issued license for such time and in such manner as the board may determine; (4) Reprimand or take such action in relation to

pertain to “dispensing, prescribing, or otherwise distributing” controlled substances. Specifically, section 63–6–214(b)(12) prohibits a physician from prescribing controlled substances “not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.” Additionally, section 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person “addicted to the habit of using controlled substances” without “making a bona fide effort to cure the [patient’s] habit.” To determine a violation of these provisions, the Tennessee Board of Medical Examiners uses a nonexhaustive list of guidelines (“the guidelines”) found in TENN. COMP. R. & REGS. 0880–02–14(6)(e).³¹ The guidelines require that a physician: (1) Take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate “assessment and consideration of the [patient’s] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.” TENN. COMP. R. & REGS. 0880–02–14(6)(e)(3)(i). Additionally, Rule 0880–02–14(6)(e) requires physicians to create a “written treatment plan tailored for the individual needs of the patient” that considers the patient’s “pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or

disciplining an applicant or licensee, including, but not limited to, informal settlements, private censures and warnings, as the board in its discretion may deem proper; or (5) Permanently revoke a license.

(b) The grounds upon which the board shall exercise such power include, but are not limited to: . . . (12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition; (13) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient; (14) Dispensing, prescribing or otherwise distributing any controlled substance, controlled substance analogue or other drug to any person in violation of any law of the state or of the United States; . . . (emphasis added).

³¹Tenn. Comp. R. & Regs. 0880–02–14 SPECIALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE. [Omitted text of guidelines for brevity.]

use of other treatment modalities.” It also requires the physician to “discuss the risks and benefits of the use of controlled substances,” complete a “documented periodic review of the care . . . at reasonable intervals,” and “keep [c]omplete and accurate records of the care.” *Id.* at 0880–02–14(6)(e)(3)(ii)–(v).

Exclusion of the Respondent’s Testimony

The Government objected to the Respondent’s testimony^{*S} because prior to the hearing Respondent identified that he may testify regarding the material falsification allegation, but said he would not testify regarding the prescribing allegations as he has another matter pending. However, at the hearing, the Respondent sought to present testimony regarding the allegations surrounding his prescribing. He did not offer testimony regarding the material falsification allegation. [The ALJ permitted all portions of the Respondent’s testimony that could have been reasonably anticipated by the Government and I have considered Respondent’s testimony in reaching my decision. I find it unnecessary to reach any further conclusions and have omitted the remainder of the ALJ’s analysis for brevity, as the Government did not take exception to the ALJ’s ultimate decision.]^{32 33}

Accurate and Complete Medical Records

The Government alleges that the Respondent failed to maintain accurate and complete medical records for each of the subject patients, as mandated by the relevant Tennessee regulations and standard of care. The medical records contain the results of physical examinations and other tests, which did not occur on the reported dates. The records are rife, across all of the subject patients, with identical findings, suggesting the subject examinations either did not take place, or the results were not reported accurately.

In explaining the identical anxiety and insomnia indications written in each of his patients’ charts to justify benzodiazepines, the Respondent testified that his patients exhibited the same symptoms which is common among anxiety patients. However, the fact that UC’s chart reflected that he had the same anxiety indications and other indications identical to the other five patients, despite the fact that he testified

credibly that he did not complain of any anxiety symptoms, greatly reduces the credibility of the Respondent’s subject explanations. Tr. 79–80. Indeed, most of the indications within UC’s chart were unreported by him.³⁴ UC reviewed Government Exhibit 5 and noted that he was not asked about any of the reported symptoms. Tr. 81. As to why individual patients had the same indications within the chart for long periods of time, the Respondent maintains that the subject record findings were carried forward from prior tests, as permitted by the Tennessee standard of care. [However, Dr. Kennedy testified, “there is no regulation anywhere that allows a physician [to] document physical exam findings that he did not perform. That’s not acceptable under any regulations.” Tr. 652.]

Similarly, the Respondent justified reporting test results when no tests occurred, as he claimed was permitted by the Tennessee standard. Prior test results were simply carried forward within the electronic medical record. I credit Dr. Kennedy’s opinion that reporting test results purported to have occurred on a particular date, which did not then occur, is contrary to the Tennessee standard of care. Even a casual review of the relevant Tennessee regulations reveals the prominence of the Tennessee physician’s obligation to accurately document. He is required to establish a “written treatment plan tailored for the individual needs of the patient” that considers the patient’s “pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.” It also requires the physician to perform a “documented periodic review of the care . . . at reasonable intervals,” and “keep [c]omplete and accurate records of the care.” *Id.* at 0880–02–14(6)(e)(3)(ii)–(v).

Common sense itself would refute the Respondent’s position. Indications and exam results carried forward, perhaps for months or even years, defeats the whole purpose of medical records, which is to inform the practitioner and other potential treating practitioners of the patient’s true and present condition, progression of disease or efficacy of treatment. [Dr. Kennedy testified that

³⁴UC noted that despite his records stating that “[UC] . . . has had a history of insomnia and anxiety for several years,” he did not report anxiety symptoms of shortness of breath, of having palpitations, sweating, dizziness, or shaking. Tr. 79–80; GX 5. The medical record also reflects that he had a headache that day, despite the fact that UC did not report having a headache, dizziness, nausea, or vomiting. Tr. 80; GX 5. No one questioned UC as to whether he had abdominal pain, diarrhea, and constipation. Tr. 80–81.

*S Text omitted for brevity.

³²[Omitted original text in which footnote appeared.]

³³[Omitted original text in which footnote appeared.]

here the documentation did not “make sense” and was “in conflict,” which “present[s] a dangerous situation” for “other people who look at [the records].” Tr. 353. Based on this testimony, one could conclude that wrong records are worse than no records at all, as they would mislead other treating practitioners. And as Dr. Kennedy testified, here “you have a medical record which shows consistently documentation . . . that did not occur, that is outside the scope of acceptable medical practice, and it does not support legitimate prescribing of scheduled agents.” Tr. 652.]

The Respondent has conceded there are factual errors in the subject records. Although UC’s chart contains an entry that his pharmacy printout was reviewed, the Respondent conceded that no pharmacy printout was reviewed and that such entry was in “error.” Tr. 631–32; GX 5 at 6. M.H.’s chart contains the inconsistent finding of long-term insomnia, but with an entry of sleeping well. Tr. 640–41; GX 15 at 47–48. The Respondent conceded they were inconsistent entries. Tr. 641. Additionally, while M.W.’s chart reflects he had been dismissed, M.W. continued to be seen for months afterwards, without any further explanation documented in the record. Tr. 259–60. And, Respondent reported a “history of insomnia for several years” for M.H.; however, this note first appears 19 months into treatment. GX 15; Tr. 49.

Additionally, there are conflicts between the Respondent’s written notes and the electronic medical records. Documents UC filled out are missing from his chart that was seized from the Respondent. The electronic medical record for a visit by M.W. does not contain the handwritten information recorded in GX 10 at 8. Tr. 250–51; GX 10 at 9. Instead, the results of the physical exam mirror those findings made for UC, rendering M.W.’s chart not credible. Tr. 251–52. The physical exam notes written for C.F. revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language that is duplicated so often in the records, appears. Tr. 272. Dr. Kennedy noted the hand-written exam notes for M.H. did not appear in the electronic medical records. Tr. 325–36; GX 7 at 68. Instead the same physical exam notes duplicated throughout the records appear. Tr. 336, 351. So, at times, verbatim records were repeatedly and inaccurately inputted into the electronic medical records

when actual, accurate indications were available.

Dr. Kennedy noted the actual pain level was left blank at nine consecutive encounters with B.C., suggesting it was being added later and that the record was being fabricated. Tr. 294–95; GX 13 at 159; GX 14 at 8.

For these reasons and those discussed below, I find the Government has sustained its burden in proving the Respondent failed to maintain accurate and complete medical records as to the subject patients, in violation of TENN. COMP. R. & REGS. Rule 0880–02–.14 (6)(e).^{*T} [I further find that each of the relevant prescriptions at issue in this matter were issued outside the usual course of professional practice and beneath the standard of care due to Respondent’s failure to maintain complete and accurate records.]

Undercover

The Government alleges the Respondent failed to perform an adequate physical exam; take an adequate medical history; assess UC’s pain, physical and psychological function; assess the patient’s history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of oxycodone; and failed to create a legitimate written treatment plan for UC’s individual needs or to discuss the risks and benefits of the use of oxycodone with UC. At three level one visits, the chart falsely reflects the results of physical exams, which did not occur. The Government alleges the Respondent’s continued prescribing of controlled substances to UC was without a legitimate medical purpose and/or outside the usual course of professional practice.

Dr. Kennedy reviewed the chart and the undercover videos for UC, the undercover agent. Tr. 216–17, 363; GX 6. Dr. Kennedy acknowledged that in scheduling the first visit, the Respondent’s staff instructed UC to bring certain medical records to his first visit, the previous three physician notes, his discharge summary, the record of the previous three months prescriptions and an MRI, an appropriate protocol in Dr. Kennedy’s opinion. Tr. 364–65; GX 3 at 1.

The Respondent testified that he took a medical history, a condition-specific physical exam for low back pain, and reviewed the MRI (GX 6) of UC. Tr. 575–80.³⁵ The Respondent agreed that he

^{*T} Omitted for brevity.

³⁵ The Respondent noted that his physical exam of C.R. was not captured by the video of the

spent no more than fifteen minutes with UC in the examination room. Tr. 621. The Respondent maintains that he performed the required assessments related to pain, physical and psychological function, and history and potential for drug abuse. Tr. 582. This involved reviewing the paperwork UC filled out, authenticating that paperwork, the triage of UC by staff, UDS, and a final review of the paperwork by the Respondent with the patient. Tr. 583, 584. UC recalled the Respondent going over his paperwork with him, but could not remember the extent of the review. According to UC, the triage by other staff was minimal, sporadic or non-existent. Tr. 59. UC cited Dr. Morgan, who did not exist, in his medical history paperwork, yet the staff did not discover that fact. None of UC’s paperwork could be authenticated, as designed. UC’s history was similarly designed to be a “dead end.” Tr. 238. [Accordingly, I find Respondent’s testimony that he authenticated UC’s paperwork to lack credibility.] There was no review of UC’s psychological functioning, although he was diagnosed with anxiety.³⁶ The Respondent’s instant claims are belied by the record.

The Respondent explained that a patient’s pain is very subjective. After reviewing his paperwork, including the MRI, examining UC and speaking with him, the Respondent claimed that he had no reason not to treat him as someone who has genuine pain. Tr. 588. UC’s statement that he had used controlled substances for his pain and that ibuprofen was not working supported the conclusion that his pain was long standing, and warranted a Schedule II medication. [Omitted for relevance.]

Dr. Kennedy opined that UC’s medical chart did not justify the prescribing of controlled substances.³⁷ Tr. 230–31, 240; GX 18 at 1, 3. Although there was an actual MRI report of UC, Dr. Kennedy found the MRI report internally inconsistent [which Dr. Kennedy testified should have caused Respondent to question the MRI.] Tr. 387–94. Dr. Kennedy opined that it

encounter. The camera was pointed at the wall. Tr. 581–82.

³⁶ Where practitioner asked his patient whether there was “any other medication he took for anxiety,” and where the practitioner made no effort to determine the extent of the patient’s symptoms before prescribing Xanax to him, the practitioner was not engaged in the legitimate practice of medicine but instead was dealing drugs. *Henri Wetselaar, M.D.*, 77 FR 57,126, 57,132 (2012).

³⁷ The Respondent cautioned that in reviewing his electronic medical record, it often referred to other records. For example, under history of present illness (HPI), he would often reference the initial encounter paperwork, as included by reference, in the electronic record. Tr. 592.

would be outside the usual course of professional practice to prescribe controlled substances based on this MRI alone.*^U Tr. 483–86.³⁸ UC was being treated for complaints of back pain. However, Dr. Kennedy opined that the physical exam detailed in the chart was not sufficient under Tennessee standards, and the exam that was performed revealed, essentially, a normal back. Tr. 217, 231, 237, 396–97, 440. On rebuttal, Dr. Kennedy reiterated this assessment after listening to the Respondent's explanation. Tr. 651–52.

The Respondent explained his treatment of UC. After the UC filled out extensive paperwork, the initial examination by the Respondent consisted of observing UC, touching his back and causing the patient to lift his leg. Tr. 217–18, 359–60; GX 6 at 6. Dr. Kennedy noted the taking of vital signs and a general exam within the chart; however, he observed that from viewing and listening to the video of this visit, such exam was not performed as described, or not performed at all. Tr. 218–19, 379–81; GX 6, 4.³⁹ The prior medical history reported by UC was facially suspicious and constituted a red flag. Tr. 238. UC reportedly came from a clinic, which had been shut down, and provided medical records from a Nurse Practitioner whose license had been suspended. Tr. 238. The Respondent conceded UC was a challenge, as the clinic he reported had been closed, and he could not obtain the pharmacy information, so the Respondent could not verify that source. Tr. 583–85. As UC's prior medical records could not be confirmed, the Respondent claimed that he prescribed a dosage appropriate to a patient just starting opioid treatment. Tr. 589–90.

The Respondent expected his patients to be honest and truthful with him consistent with the DEA Physician's Manual, which requires patients to be honest with their doctors. Tr. 586–87.⁴⁰ In his Post-hearing Brief, the

Respondent continues to complain of the use of an undercover agent, who operated under "false colors" to ensnare the Respondent, and his disappointment that the Tribunal does not share his sentiment. The fact of the matter is, there is nothing illegal or improper regarding the Government's use of undercover agents.⁴¹ Even if I shared the Respondent's sentiment, and opined that the use of undercover agents was somehow unfair, this is not a court of equity.⁴² We operate strictly by statute and regulation [and here the evidence clearly establishes that Respondent's prescribing to UC was outside the usual course of professional practice and beneath the standard of care in violation of the CSA and its implementing regulations.]

Dr. Kennedy opined that UC's obfuscation, false and misleading statements to the Respondent and staff, did not relieve the Respondent's obligation to investigate any suspicious circumstances. Tr. 375–78, 382. The Respondent misperceives his role. [Omitted for relevance.] Physicians must be wary of patients seeking controlled substances for abuse and diversion. Although the Respondent's staff was suspicious of UC's prior records, as they appeared to have been altered, their concern appeared to be that the UC was perhaps law enforcement, "try[ing] to bring the Respondent down," rather than someone attempting to divert or abuse controlled substances. UC presented as a patient with no verified history, his paperwork contained indications of alteration, he complained of pain without overt indications; yet, the Respondent opined that the record supported his conclusion that UC was legitimately in pain. Dr. Kennedy disagreed and opined that it is the practitioner's responsibility to investigate suspicious circumstances and to resolve them prior to prescribing controlled substances.

Dr. Kennedy noted that the physical exam included in this first visit by UC was repeated verbatim in most of the approximately twenty charts he reviewed. Tr. 220; GX 7 at 65 (M.B.), GX 9 at 69 (M.W.). The Respondent explained that he performed a physical exam at the initial visit of each of his patients, as required by the Tennessee pain management guidelines. Tr. 594. Physical exams thereafter are at the discretion of the physician. Tr. 594.

⁴¹ [Omitted for relevance.]

⁴² Administrative Law Judges of the DEA "lack the authority to exercise equitable powers" in determining whether a registration is consistent with the public interest. *The Main Pharmacy*, 80 FR 29,022, 29,024 (2015).

Although UC had five visits to the clinic, only two involved encounters with the Respondent. The other three visits were "level one" visits, in which UC met with the Respondent's staff only. Tr. 622–28, 645–50. Although the medical records reflect a physical examination took place at the level one visits, there was no physical exam. Instead, the Respondent explained he and his staff had carried forward results from prior examinations to later visit records with new findings added, which Dr. Kennedy opined was not permissible. Tr. 623–28; *supra* "The Analysis, Accurate and Complete Medical Records."

Dr. Kennedy noted UC's chart identified him with a "long-standing history of insomnia and anxiety," however the chart contained no examination that would support such findings. Tr. 233–34; GX 5 at 4. Additionally, the reported symptoms of the anxiety finding, "palpitations, sweating, dizziness, shaking" was repeated almost universally throughout the medical records reviewed as to patients diagnosed with insomnia and anxiety. Tr. 233–34. Similarly, the visit of October 17, 2017, by UC contains extensive medical findings, but the video of that visit does not support those findings. Tr. 235–37; GX 5 at 5. The video does reveal the Respondent asking UC, "how is your sleep" to which UC responds, "not good." Tr. 236. The Respondent then prescribes Elavil, or amitriptyline [which is not a controlled substance and is not at issue in this case.] Tr. 236. Dr. Kennedy made a similar observation as to extensive medical findings on subsequent visits in which UC was not seen by the Respondent. Tr. 235–37; GX 5 at 3–5. Although the medical records state that a physical examination took place at the level one visits when no physical examination occurred, the Respondent explained that it was permissible in medical record-keeping to carry forward results from prior examinations to later visit records, with new findings added. Tr. 623–28. Dr. Kennedy disagreed, noting that it is never permissible for charts to reflect examination results, when no exam occurred. Tr. 652–53. At UC's second visit, he was called back to the triage room where the nurse asked him his weight to which he replied, "210," and if his blood pressure was ok to which he responded, "yes." Tr. 59. He was not weighed, nor was his blood pressure taken. Dr. Kennedy did not believe UC's chart reflected the Respondent maintained a truthful and accurate record of the treatment. Tr. 232; GX 3; 4. I credit Dr. Kennedy's

*U This sentence has been modified for clarity.

³⁸ The Agency has previously found based on credible expert testimony that relying exclusively on MRI results for prescribing controlled substances is unprofessional conduct in the applicable state. *Zvi H. Perper, M.D.*, 77 FR 64,131, 64,140 (2012).

³⁹ The Agency has previously found that falsifying a patient's medical record to indicate that respondent performed a physical exam but where video/audio recordings show that a physical was never conducted demonstrate that respondent knowingly violated the CSA. *Jeri Hassman, M.D.*, 75 FR 8194, 8236 (2010); *Bernard Wilberforce Shelton, M.D.*, 83 FR 14,028, 14,042 (2018).

⁴⁰ "A practitioner who ignores the warning signs that her patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if she is merely gullible or naive." *Krishna-Iyer, M.D.*, 74 FR 460 n.3.

opinion regarding the results of non-existent tests.

On the basis of the deficient physical exam, Dr. Kennedy opined that prescribing controlled substances to UC was not justified. Although the Respondent prescribed a much lower MME than UC had purportedly been on before, it was not consistent with the Tennessee standard, which would require observation, looking for spasms, lumbar range of motion maneuvers, straight leg raise test, neurologic exam and motor deficits. Tr. 221–25, 239, 382–83; GX 5 at 6. Other deficiencies in the records that caused the controlled substance prescriptions for UC to be unjustified included the deficiency in the prior medical records provided by UC. Tr. 228. On a positive note, UC's chart revealed an exploration of alternate treatment by prescribing Meloxicam, and offering injections. Tr. 228–29.

The Respondent testified he prepared an adequate written treatment plan with appropriate treatment goals and therapy. Tr. 590–91. However, Dr. Kennedy opined UC's chart did not include an adequate treatment plan. Tr. 229. The records reveal a deficient discussion regarding the risks and benefits of controlled substance medication. Tr. 231. Dr. Kennedy deemed the diagnosis of degenerative disc disease unjustified on the basis of the chart and MRI. Tr. 240–42; GX 5 at 2, 6; GX 6 at 12. I find Dr. Kennedy's assessments credible.*^v

[In accordance with Dr. Kennedy's credible and un rebutted expert testimony, and for the reasons above, I find that the three oxycodone prescriptions Respondent issued to UC were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of UC's pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for UC's individual needs or to discuss the risks and benefits of the use of oxycodone with UC. Additionally, and in accordance with Dr. Kennedy's testimony, I find that the relevant

prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for UC.]

Allegations Common to the Five Remaining Patients

With respect to the Respondent's treatment of M.H., C.F., M.P., B.C., and M.W. ("the five patients"), the Government alleges the prescriptions for controlled substances were not issued in the course of professional practice inasmuch as the Respondent failed to: (1) Take an adequate medical history; (2) perform a sufficient physical examination; and (3) perform an adequate "assessment and consideration of the (patients') pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance." The Respondent also failed to create a "written treatment plan tailored for the individual needs" of each of the five patients that considered each of the patient's "pertinent medical history and physical examination, as well as, the need for further testing, consultation, referrals, or use of other treatment modalities." The Respondent also failed to: (1) "discuss the risks and benefits of the use of controlled substances" with patients M.H., C.F., M.P., B.C., and M.W.; (2) conduct a "documented periodic review of the [ir] care . . . at reasonable intervals in view of the individual circumstances" of each patient; and (3) keep "(c)omplete and accurate records of the care provided." As such, the Respondent's conduct violated TENN. CODE ANN. § 63–6–214(b)(12) and TENN. COMP. R. & REGS. 0880–02 .14(6)(e)(3)(i)–(v).

The Government further alleges the prescriptions the Respondent issued to M.H., C.F., M.P., B.C., and M.W. failed to comply with Tennessee state law in that they did not conform to accepted and prevailing medical standards in Tennessee, and thus, were issued outside the usual course of professional practice. The Respondent's conduct, viewed as a whole, "completely betrayed any semblance of legitimate medical treatment." *Jack A. Danton, D.O.*, 76 FR 60,900, 60,904 (2011).

By issuing these prescriptions for controlled substances, the Respondent failed to take reasonable steps to guard against diversion of controlled substances. *See David A. Ruben, M.D.*, 78 FR at 38,382; *Beinvenido Tan, M.D.*, 76 FR 17,673, 17,689 (2011); *Dewey C.*

Mackay, M.D., 75 FR 49,956, 49,974 (2010); *Physicians Pharmacy, L.L.C.*, 77 FR 47,096 (2012).

Allegations as to Specific Patients

As to the allegations regarding each of the subject patients, in his Posthearing Brief (PHB), the Respondent argues the Government's case suffers weakness by the Government's failure to present the relevant patients' testimony, testimony of relevant pharmacists, any evaluation regarding the volume of the Respondent's prescriptions in relation to other physicians, the absence of any complaints to law enforcement, and no physician testimony that the subject patients were seeking detox due to the Respondent's excessive prescribing.*^w

In the context of the allegations and evidence, none of the above constitutes necessary evidence to prove the allegations. Indeed, I struggle to see any relevance to such evidence in the context of the allegations made.

Patient M.W.

The Government alleged that the Respondent regularly and improperly issued prescriptions for large quantities and dosages of oxycodone, oxymorphone, alprazolam, and carisoprodol to Patient M.W. The Government further alleged that the initial physical examination and medical history did not justify the continued prescribing of controlled substances and the subsequent physical examinations did not meaningfully evidence any chronic pain condition. The Government alleged that the Respondent failed to: (1) Order and obtain diagnostic studies; and (2) adequately address numerous instances in which the patient had inconsistent drug screens indicating possible diversion, abuse, and/or use of illegal controlled substances. The Government further alleged that much of the medical record for M.W. was fabricated and appeared to be copied from records of other patients, whose records contained identically worded assessments. Finally, the Government alleged the Respondent documented that the patient provided "informed consent" when no informed consent document could be located. Additionally, the Government alleged the Respondent failed to address substantial evidence that M.W. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. 63–6–214(b)(13).

In support, the Government offered the testimony of its expert, Dr. Kennedy.

*^wIt is also noted that Respondent did not offer any of this testimony in an attempt to rebut the Government's case.

*^vOmitted. The ALJ found that the diagnosis of C.R. with insomnia was appropriate. The issue relevant to this case is whether or not there was a recognized medical indication for the use of oxycodone. The medication prescribed as a result of the insomnia diagnosis was not a controlled substance and was not directly at issue in this case. Accordingly, it is not necessary to determine whether the records contained sufficient evidence to support the insomnia diagnosis, because it is not relevant to the case.

Dr. Kennedy identified his “chart review” for M.W. Tr. 243–44; GX 9, 10. M.W. was diagnosed with low back pain, yet Dr. Kennedy credibly opined that the records did not support such diagnosis. Tr. 245–46; GX 9 at 14; GX 10 at 3. The notes did reference back to M.W.’s initial encounter. Tr. 441. The Respondent testified M.W. was first seen in January 2013. Tr. 595. M.W. was a gunshot victim to whom the Respondent prescribed alprazolam. This, according to Respondent, was based on the history and physical exam. Tr. 593, 635–36; GX 9 at 69. The Respondent claimed he obtained a medical history, conducted a physical exam, performed an adequate pain, physical, and psychological assessment, history and potential for substance abuse. Tr. 596. The Respondent claimed that he prepared a written treatment plan. Tr. 601.

Yet, Dr. Kennedy countered there were no findings in the record that would support a chronic pain condition and justify prescribing controlled substances. Tr. 246–47. Dr. Kennedy found no credible physical exam to justify the diagnosis. Tr. 247, 265. Dr. Kennedy testified that the Respondent did not assess M.W.’s pain level, physical and psychological functioning, history, potential for drug abuse, or coexisting diseases. Tr. 265. The Respondent did not follow a legitimate written treatment plan. The physical exam findings were generally normal findings, except for limited range of motion at the lumbar spine. Tr. 247; GX 10 at 7. M.W. reported a pain level, at worst, at 10 of 10, and at best, 6 of 10. Tr. 248–49; GX 9 at 19; GX 10 at 8. M.W.’s reported pain level was inconsistent with the generally normal results of the physical exam. Tr. 249–50. The electronic medical record for this visit does not contain the handwritten information recorded in GX 10. Tr. 250–51; GX 10 at 9. Instead the results of the physical exam mirror those findings made for UC, rendering M.W.’s chart not credible. Tr. 251–52. This finding was bolstered by “wildly” inconsistent UDS results. Tr. 252–55; GX 9 at 2–4, 9–11, 84, 96, 102. After a series of inconsistent UDS, the Respondent noted in M.W.’s chart that M.W. was dismissed from pain management with one-month notice. Tr. 258; GX 9 at 84. Yet, at the same visit in which he had been notified he will be dismissed, the history of present illness reports the patient is compliant and consistent. Tr. 258. Dr. Kennedy deemed the chart not credible, accordingly. Tr. 259. However, despite being dismissed, M.W. continued to be seen for months

afterwards without any further explanation in the medical records. Tr. 259–60.

The Respondent explained that the evaluation of the patient’s potential for drug abuse is an ongoing evaluation with UDS, involving office screens, confirmatory lab screens, and pill counts. Tr. 596–98, 600. Respondent testified that once a lab-confirmed inconsistent UDS is discovered, the Respondent initiates a dismissal process. Tr. 598–600. The Tennessee pain management guidelines leave it to the physician’s discretion on the handling of confirmed inconsistent UDS results. Tr. 598–99.⁴³ The Respondent gives the patient a month to come into compliance. Tr. 600. If he has a consistent UDS within the month, the patient is permitted to remain in treatment. Tr. 601. The Respondent claimed was able to bring M.W. back into compliance through counseling, however, the chart only documents that the patient was counseled as to the inconsistent UDS without identifying any specific information. Tr. 637–38. Dr. Kennedy later conceded that M.W. was reinstated consistent with the Respondent’s described office protocol. Tr. 459–60. The Respondent continued to prescribe him alprazolam, amitriptyline, oxycodone, oxymorphone and Soma. As noted earlier, Respondent’s documentation of these events and his handling of M.W.’s inconsistent UDS was clearly outside the Tennessee standards.

Regarding the alprazolam prescriptions, Dr. Kennedy found it unjustified based on the information supporting the anxiety diagnosis. Tr. 260–61, 442–44; GX 9 at 85. Dr. Kennedy noted the indications for anxiety were not supported by the findings within the chart, and mirrored those in the charts for UC and other patients. Tr. 261–62. In his PHB, the Respondent argued that Dr. Kennedy conceded a gunshot victim would have PTSD; however, I credit Dr. Kennedy’s opinion that the chart did not justify the alprazolam prescription.

Although Dr. Kennedy opined M.W. should have been physically examined periodically during his treatment, the charts suggest he was not examined again following his first examination. Tr. 262. Dr. Kennedy further opined that as M.W. was a 25-year-old diagnosed with degenerative disc disease, the

⁴³ The Respondent’s explanation of the Tennessee standards was admitted, not as expert testimony, as the Respondent had not been qualified as an expert to opine on the Tennessee standards, but as reflecting his understanding of the guidelines to explain why he took or declined to take certain action.

Tennessee standards would require diagnostic testing, such as an MRI to confirm the diagnosis. Tr. 262, 447–48. Dr. Kennedy found M.W.’s chart “not credible and fabricated.” Tr. 263–64, 266; GX 10 at 5, 23. He noted that of 93 of 98 total visits shared the identical findings for the physical exams and ROS. Tr. 264. Similarly, Dr. Kennedy found the diagnosis of insomnia not credible. Tr. 264. A finding of drug abuse and chemical dependency would have been supportable, but such indications were not sufficiently addressed by the Respondent. Tr. 264–65. The credible findings within M.W.’s chart did not support the prescribing of controlled substances, and the subject prescriptions were issued outside the usual course of professional practice. Tr. 267–68. I credit Dr. Kennedy’s opinions in finding the Respondent’s subject actions fell below the Tennessee standards, and the controlled substances were prescribed outside the Tennessee standards.

[In accordance with Dr. Kennedy’s credible and un rebutted expert testimony, and for the reasons above, I find that the twenty-six identified prescriptions for alprazolam, carisoprodol, oxycodone, and oxymorphone that Respondent issued to M.W. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy’s opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.W.’s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.W.’s individual needs. Tr. 265. In accordance with Dr. Kennedy’s testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent’s failure to maintain complete and accurate records for M.W. Tr. 265–66. Finally, in accordance with Dr. Kennedy’s testimony, I find that M.W. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent. Tr. 264–64.]

Patient C.F.

The Government alleged that from August 2014 through August 2018, the Respondent regularly issued prescriptions for oxycodone and alprazolam to C.F. The Government further alleged that no credible physical examination had been performed on C.F. and that the exam results, as well

as medical history, did not justify the continued prescribing of controlled substances. The Government further alleged that no meaningful follow-up physical exam was repeated, that supported diagnostic studies were not ordered, and that the Respondent failed to determine a chronic pain etiology. The Government further alleged that the Respondent ignored suspicious drug screen results which indicated illegal drug use. The Government alleged that much of the medical record for C.F. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. Although the Respondent documented that the patient provided “informed consent,” no informed consent document could be located. Additionally, the Government alleged the Respondent failed to address substantial evidence that C.F. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. 63–6–214(b)(13).

The Respondent explained that Patient C.F. had a stab wound to the chest, requiring heart surgery, resulting in residual chronic pain. Tr. 601. The Respondent reported he took a medical history, performed a physical exam, an adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse. Tr. 601–02. The Respondent noted that he had the benefit of confirmatory records from Vanderbilt University Medical Center. Tr. 602.

Dr. Kennedy testified that the chart revealed C.F. was being treated for chronic pain due to trauma, and unspecified inflammatory polyarthropathy. Tr. 268; GX 12. Dr. Kennedy conceded C.F. had suffered stab wounds to the chest requiring open heart surgery, which can cause long-term neuropathic pain. Tr. 451–53. Although in his PHB, the Respondent characterizes Dr. Kennedy’s criticism of the Respondent’s subject treatment as failing to order tests, Dr. Kennedy had more extensive criticism than that. Dr. Kennedy opined that the history, physical exams, the pain and physical and psychological functioning, the potential for substance abuse, written treatment plan, and alternate treatment considerations were each inadequate, and did not justify the controlled substance prescriptions.⁴⁴ Tr. 269–70,

285, 455; GX 11 at 106; GX 12, at 7. Dr. Kennedy noted the Respondent did not discuss the risks and benefits of controlled substance medications. Tr. 285. The physical exam notes revealed essentially normal findings, however the electronic records for this visit failed to include these findings. Tr. 271; GX 11 at 69. Instead, under physical exam, the same language duplicated so often in the records, is included. Tr. 272. There were no credible follow up physical exams, supporting studies, and no reasonable pain etiology. Tr. 272; GX 12 at 5, 6. The ROS indications were identically repeated in other charts. Tr. 272–73. Dr. Kennedy noted that the language in the general exam, “patient is alert and oriented” is similarly repeated 102 times throughout the records. Dr. Kennedy reported inconsistent UDSs for C.F., collected on July 2, 2018, and thereafter. Tr. 273–80, 282; GX 11 at 9, 23, 24, 25, 28, 33, 44, 47, 54, 69, 78, 111, 117; GX 20. Even more concerning, C.F.’s UDS result was negative for all of the medications she was prescribed. Tr. 275–77. C.F. also tested positive for cocaine and marijuana. Tr. 277, 280. An inconsistent drug screen on July 26, 2017, is not mentioned in the medical records. Tr. 288–89. Although the records repeatedly noted that, “patient counseled at length on unsatisfactory UDS,” Dr. Kennedy credibly testified that this was insufficient under Tennessee standards to address C.F.’s drug abuse and diversion. Tr. 280, 284. I credit Dr. Kennedy’s assessment regarding the Respondent’s deficient handling of C.F.’s ongoing drug abuse and diversion.

On May 3, 2017, C.F. tested positive for buprenorphine, a medication typically used to treat opioid use disorder. Tr. 281–82. The Respondent had not prescribed it. Although the Respondent explained that the MED prescribed to C.F. was a relatively low dose, Tr. 603–05; in light of C.F.’s continued drug abuse and diversion, Dr. Kennedy opined that the Respondent continued to improperly prescribe controlled substances without making a bona fide effort to cure C.F.’s addiction. Tr. 284. I agree.

The Respondent prescribed alprazolam for anxiety and insomnia. Tr. 286; GX 11 at 39. However, the supporting indications are identical to the other patients who were diagnosed with anxiety and insomnia. Tr. 286–87. The Respondent did not maintain complete and accurate records for C.F.

Tr. 286. Dr. Kennedy concluded that the controlled substance prescriptions issued to C.F. were outside the usual course of professional practice. Tr. 287. For the reasons detailed, I concur. I credit Dr. Kennedy’s expert opinions and find that the Respondent’s subject prescribing to C.F. was in violation of Tennessee regulations, and below the Tennessee standards.

[In accordance with Dr. Kennedy’s credible and un rebutted expert testimony, and for the reasons above, I find that the sixteen identified prescriptions for alprazolam and oxycodone that Respondent issued to C.F. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy’s opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of C.F.’s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for C.F.’s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy’s testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent’s failure to maintain complete and accurate records for C.F. Finally, in accordance with Dr. Kennedy’s testimony, I find that C.F. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent.]

Patient B.C.

The Government alleges that from August 2014 through August 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone, oxymorphone, alprazolam, and carisoprodol to B.C. The Government further alleged that no credible physical examination had been performed on B.C. and that the exam results, as well as medical history, did not justify the continued prescribing of controlled substances. The Government further alleged that no meaningful follow-up physical exam was repeated, that confirmatory diagnostic studies were not ordered, and that the Respondent failed to determine a chronic pain etiology. The Government further alleged that the Respondent ignored suspicious drug screen results which indicated illegal drug use. The Government alleged that much of the medical record for B.C. was fabricated and seemed to be copied from records of other patients whose records

⁴⁴ The Agency has previously found based on the expert testimony that where the respondent: (1) “gave inadequate examinations or none at all;” (2) ignored the results of tests; and (3) “took no precautions against misuse and diversion” of controlled substances, the evidence established that the respondent exceeded the bounds of professional

practice. *Carlos Gonzalez, M.D.*, 76 FR 63,118, 63,141 (2011) (citing *United States v. Moore*, 423 U.S. 122, 135, 142–43 (1975)).

contained identically worded assessments. Although the Respondent documented that the patient provided “informed consent,” no informed consent document could be located.

Dr. Kennedy identified his summary chart for B.C. Tr. 289–90; GX 13; GX 14. B.C. was being treated for chronic pain syndrome. B.C. was referred from the Clark County Jail, on December 19, 2012,⁴⁵ a potentially challenging patient. Tr. 458–59. Although not revealed in the chart, Respondent testified that B.C. had previously been a patient of the Respondent. The Respondent maintained that he took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated his history and potential for substance abuse, and prepared a written treatment plan. Tr. 608.

Dr. Kennedy disagreed, claiming the Respondent did not take an adequate medical history. Tr. 304. Although a physical exam was evident, Dr. Kennedy testified that it was insufficient and non-supportive to justify prescribing the medications prescribed. Tr. 290–91, 304; GX 13 at 169; GX 14 at 7; GX 22. Dr. Kennedy asserted the Respondent did not make an adequate assessment of pain, and physical and psychological function, of history of substance abuse, coexisting diseases and conditions, written treatment plan or alternate treatments. Tr. 304–06. He did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 306. There were no radiologic studies ordered. Tr. 303. There were no prior medical records ordered or obtained, but the records did include hospital records. Tr. 303, 459–60. Although the Respondent described the extensive forms each patient is required to fill out at the initial visit, some of the described forms, which were referenced in B.C.’s chart, were missing from the Respondent’s records. Tr. 628–29; GX 13 at 5. The Respondent explained that some records were lost in 2014.⁴⁶ Tr. 630. However, the missing records were not recreated despite B.C. being a long-term patient. Tr. 630.

The Respondent explained why he obtained and kept pharmacy printouts

in his records. They are easier and quicker to obtain than medical records. Tr. 606. The pharmacy printout informs how long the patient has been prescribed medications, changes in dosage, and the prescriber. Tr. 607.

Dr. Kennedy noted indications from the ROS were duplicated throughout the records. Of 141 encounters, the ROS language was duplicated 140 times, while the physical exam language was duplicated 134 times. Tr. 291–92. B.C. had serious health issues, including Hodgkins lymphoma, a cancer of the lymphatic system. Tr. 293. Dr. Kennedy identified a document in the chart indicating B.C. had been dismissed from a prior physician, a clear red flag which was not resolved. Tr. 293–94; GX 13 at 188.

Dr. Kennedy noted the actual pain level was left blank at nine consecutive encounters, suggesting it is being added later, a further indication of fabricated records. Tr. 294–95; GX 13 at 159; GX 14 at 8. Dr. Kennedy opined the Respondent did not maintain accurate and complete records. Tr. 306. One entry reveals, “patient lied about his prescriptions,” an alarming red flag left unaddressed by the Respondent. Tr. 296; GX 13 at 169. Despite noting that the “patient lied,” the Respondent issued controlled medications and “held” up UDS for a month. Tr. 297. This is outside the usual course of professional practice. B.C. continued to have inconsistent UDS results, which were insufficiently addressed by the Respondent. Tr. 297–98; GX 13 at 33, 79, 150, 155, 156, 158, 164, 165. The Respondent countered that each of the Respondent’s patient records contained the instruction, “rule out doctor shopping”, which was a prompt to review the Tennessee PDMP to determine if the patient was obtaining controlled substances from multiple physicians. Tr. 608. Although ruling out doctor shopping is appropriate and necessary action, it does not excuse the failure to adequately address B.C.’s drug abuse and other red flags. I credit Dr. Kennedy’s findings, and I find that the information contained in B.C.’s chart did not justify the controlled medications prescribed by the Respondent, nor support that they were issued in the usual course of professional practice. Tr. 307–08.

[In accordance with Dr. Kennedy’s credible and un rebutted expert testimony, and for the reasons above, I find that the eighteen identified prescriptions for alprazolam, oxycodone that Respondent issued to B.C. were issued outside the usual course of professional practice and

beneath the standard of care. The basis for Dr. Kennedy’s opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of B.C.’s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for B.C.’s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy’s testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent’s failure to maintain complete and accurate records for B.C. Finally, in accordance with Dr. Kennedy’s testimony, I find that B.C.’s records included unresolved inconsistent drug screens, a red flag that was not adequately addressed by Respondent.]

Patient M.H.

The Government alleges that from August 2014 through February 2018, the Respondent regularly issued prescriptions for large quantities of alprazolam, carisoprodol, oxycodone, and oxymorphone to M.H. The Government further alleges the Respondent diagnosed M.H. with “chronic pain syndrome” even though the Respondent made no attempt to diagnose a specific pain etiology. The Government further alleged that that the Respondent failed to obtain diagnostic studies and current medical records from M.H.’s other medical providers and that the results of the physical examination and medical history did not justify the continued prescribing of controlled substances. The Government alleged the Respondent ignored a major surgical intervention that occurred in September 2016 as well as an abnormal drug screen. As such, the Government concluded that much of the medical record for M.H. was fabricated and seemed to be copied from records of other patients whose records contained identically-worded assessments. The Respondent also documented that the patient provided “informed consent” when no informed consent document could be located. The Government alleged that, in some cases, the Respondent failed to repeat certain physical exams after the initial encounter with M.H., despite the fact the Respondent provided him with prescriptions for controlled substances for more than three years.

The Respondent explained Patient M.H. presented with a post gunshot wound to the abdomen and chronic low

⁴⁵ The Respondent noted the pain management guidelines have changed since then. Tr. 605. [It appears that Tennessee has been regulating authority for physicians to prescribe for treatment of pain since 2014. As the changes seem to have taken place well before the prescribing of the controlled substances at issue in this case, this information is not material to my decision.]

⁴⁶ I ruled the evidence of lost files in 2014 inadmissible as unnoticed and not reasonably anticipated by the Government, representing surprise.

back pain secondary to degenerative disc disease. Tr. 608. According to Respondent, he had already been treated for pain management. He had a history of extensive spinal surgery at Vanderbilt University Medical Center, including a laminectomy. Tr. 609–11. The Respondent testified that he prescribed a lower MME than the surgeon prescribed post-operative at Vanderbilt. Tr. 611.

Dr. Kennedy identified his summary chart for Patient M.H. Tr. 309; GX 15; GX 16. The chart reveals M.H. was being treated for chronic pain syndrome. GX 15 at 62, 63. The physical exam indications are identical to those repeated throughout the medical records and, in Dr. Kennedy's opinion, do not support any chronic pain diagnosis. Tr. 311. The records reveal M.H. suffered a gunshot wound in 2008, and although serious, Dr. Kennedy opined that would not in itself justify pain medication eight years later. Tr. 323. Dr. Kennedy assessed the Respondent's treatment as outside the scope of acceptable medical practice because the Respondent did not make an adequate assessment of pain, and physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan or alternate treatments. Tr. 312, 326–28. The Respondent did not conduct any periodic reviews, or discuss the risks and benefits of the use of controlled substances. Tr. 328. M.H. had inconsistent UDSs. Tr. 314–20; GX 15 at 36, 39, 40, 47, 49, 53, 56, 63. Although several inconsistent UDS were noted in the chart, there were typically no notes of discussions. The Respondent failed to adequately address the UDS. Tr. 314–20.

During his treatment with the Respondent, M.H. underwent a serious and complex spinal surgery, a major surgery. Tr. 320–22, 462–63; GX 15 at 26; GX 16, at 9. M.H. was seen by the Respondent the day after his release from the hospital. GX 15 at 48. Despite his recent, major surgery, there is no mention of the surgery in the encounter notes. Tr. 322–23. The encounter notes are identical to all the other encounter notes for M.H. Tr. 323; GX 15 at 48. The Respondent conceded his medical findings as to Patient M.H. for the visit just prior to M.H.'s major back surgery are the same as the Respondent's findings for the visit the day after the surgery. Tr. 637–38; GX 15 at 48–50. The Respondent explained that the subject findings were based on "history." Tr. 638. Put another way, Respondent carried forward the exam indications from the pre-surgery visit to the post-surgery visit.

There is no updated physical exam, as Dr. Kennedy opined would be required. Tr. 324. The PE and HPI notes are the same as those the four months prior to the spinal surgery, which is not credible. Tr. 324–25, 491–92; GX 15 at 49, 51. Dr. Kennedy opined that the Respondent did not maintain accurate and complete records as to M.H. Tr. 328. Dr. Kennedy reviewed the prescriptions issued. Tr. 325; GX 19 at 1–13. He opined that the chart, including the number of inconsistent UDS, reveals that M.H. was addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction. Tr. 325. The Respondent conceded the chart reports that M.H. has been "compliant," however, on the next page of the chart, it reports M.H. had an inconsistent UDS. Tr. 638–40; GX 15 at 48–49. The Respondent explained that the inconsistent UDS related to the point of care test, not the confirmatory lab test, so the chart was accurate in that instance. Tr. 640. However, even if the inconsistent UDS result were at the point of care, as discussed *supra*, the record discloses there were eight of them, some of which went completely unaddressed within the records. I credit Dr. Kennedy's opinion that the Respondent's failure to resolve the red flag arising from inconsistent UDS rendered the subsequent prescribing outside the Tennessee standard of care.

Dr. Kennedy opined the subject prescriptions were issued outside the usual course of professional practice. Tr. 329–30, 493. I credit Dr. Kennedy's findings, and find that the Respondent's controlled substance prescribing were in violation of Tennessee regulations and the Tennessee standards.

[In accordance with Dr. Kennedy's credible and un rebutted expert testimony, and for the reasons above, I find that the approximately fifteen identified prescriptions for alprazolam, oxycodone, and oxymorphone that Respondent issued to M.H. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.H.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.H.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice

and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for M.H. Finally, in accordance with Dr. Kennedy's testimony, I find that M.H. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent.]

Patient M.P.

The Government alleges that from September 2016 through April 2018, the Respondent regularly issued prescriptions for large quantities of oxycodone and oxymorphone to M.P. The Government alleges that the Respondent failed to request and obtain past medical records, the Respondent failed to order any radiographic studies, and that the physical examinations of M.P., including follow-up exams, were substandard and not credible. The Government alleged that the Respondent failed to document any evidence to support a pain etiology and that the Respondent failed to properly address M.P.'s substance abuse disorder despite the fact that she suffered a heroin overdose in the Respondent's waiting room. As a result, the Government alleged there were no objective findings to justify the continued prescribing of oxycodone and oxymorphone. The Government alleges that much of the medical record for M.P. was fabricated and seemed to be copied from records of other patients whose records contained identically worded assessments. The Respondent also documented that the patient provided "informed consent" when no informed consent document could be located in the medical record. Additionally, the Government alleged the Respondent failed to address substantial evidence that M.P. was engaged in abuse and/or diversion of controlled substances, a violation of TENN. CODE ANN. § 63–6–214(b)(13).

The Respondent explained Patient M.P. was being managed for chronic pain. In her initial visit, she reported conflicting information regarding whether she had been in drug rehab treatment. Tr. 641–42; GX 7. The Respondent explained that he could only rely on the information provided by the patient. Tr. 642. The Respondent claimed that he took a medical history, performed a physical exam, adequate pain, physical and psychological assessments, and evaluated her history and potential for substance abuse, and prepared a written treatment plan. Tr. 615–17.

Dr. Kennedy countered, noting he reviewed the prescriptions issued. Tr. 348–49; GX 21. He opined that the chart, including the number of

inconsistent UDS, reveals that M.P. was addicted to controlled substances, yet the Respondent continued prescribing them without making a bona fide effort to cure the addiction, until after she overdosed on heroin. Tr. 348. The subject prescriptions, as well as those prescribed to the other charged patients, were dangerous and issued outside the usual course of professional practice. Tr. 352, 488–89.

Dr. Kennedy reported M.P. was being treated for low back, neck, hip and shoulder pain. Tr. 331; GX 8. She was later diagnosed with degenerative disc disease and right shoulder pain. Although a physical exam was performed, it was inadequate to substantiate the diagnoses. Tr. 331–34, 339–40, 343; GX 7 at 2. A mechanical shoulder exam and range of motion back and neck exam should have been performed. Dr. Kennedy opined that Respondent did not make an adequate assessment of pain, nor physical and psychological function, of medical history, of history of substance abuse, coexisting diseases and conditions, periodic review of care, written treatment plan nor alternate treatments. Tr. 349–51. He did not conduct any periodic reviews, nor discuss the risks and benefits of the use of controlled substances. Tr. 349–50. Dr. Kennedy stated that M.P.'s employment as a server, working 45–60 hours per week is inconsistent with her "occupational disability" score of 9 or 10, a significant conflict. Tr. 344–45; GX 7 at 3, 9, 10. Dr. Kennedy noted the hand-written exam notes did not appear in the electronic medical records. Tr. 325–36; GX 7 at 68. Instead the PE notes duplicated throughout the records appears. Tr. 336, 351. The pain level is reported as 9, which is inconsistent with the PE indications. Dr. Kennedy indicated notes generated at the initial visit appeared to be a reminder to obtain certain prior medical records from Dr. M. Tr. 337, 468; GX 7 at 1, 68. Those same notes appear in the record repeatedly thereafter. Tr. 337; GX 7 at 59. Other than the requested pharmacy report, the prior records were never obtained. Tr. 338–39. The Respondent explained that in September of 2016, the Respondent requested dismissal records, an X-ray, and an MRI from Dr. M. Tr. 642–44; GX 7 at 48. Yet, eighteen months later, the Respondent still had not received the requested records. Tr. 644; GX 7 at 59. There is no documentary proof records were ever requested.

Dr. Kennedy concluded the Respondent did not maintain accurate and complete records as to M.P. Tr. 350. At M.P.'s initial visit a UDS was

performed revealing inconsistent results, which were never addressed in the records. Tr. 338; GX 7 at 19, 68. Notes reveal M.B. had been terminated from a prior physician, a red flag. Tr. 343. The records did reveal a monitoring of the Tennessee PDMP, and a successful pill count, both positive steps by the Respondent. Tr. 470. There were emergency room notes which revealed she was admitted on April 17, 2018 and released on April 18 for apparent heroin overdose, which occurred in the Respondent's waiting room. Tr. 340–41; GX 7 at 25.

The Respondent explained those events. He testified that M.P. came to the clinic overdosing on heroin. Tr. 342, 611–12. She had to be resuscitated until EMS was able to reverse the effects of heroin with Narcan. Tr. 612. In the post-overdose notes the Respondent took an extensive history again regarding her drug use. Following the heroin overdose, the determination was made that she needed treatment of Suboxone and no further opioid prescriptions. Tr. 616. He directed she cannot be on pain management but must be on opioid abuse treatment. So, the Respondent started her on Suboxone. Tr. 613. The Respondent explained his understanding of Suboxone induction. The first type of induction therapy is by observation. He stated that you give the patient Suboxone and observe them until they reach the point of withdrawal. The other form of induction is to give the patient Suboxone and send them home without observation by the physician. Tr. 612–14. According to Respondent, M.P. was initially receptive to drug treatment, but later changed clinics. Tr. 615.

Dr. Kennedy viewed Respondent's prescribing of Suboxone as dangerous and outside the standard of care. Tr. 342, 371–73, 465–66. As the patient was shown to be on heroin, a UDS would be necessary to determine if she had heroin in her system before prescribing buprenorphine (Suboxone), which in conjunction with heroin could result in permanent withdrawal. Tr. 343. The Respondent argues in his PHB that a successful UDS was conducted. However, I do not find a successful UDS in the record prior to the Respondent prescribing Suboxone. There were inconsistent UDS in the records for M.P. Tr. 346–; GX 7 at 48, 59. I credit Dr. Kennedy's findings. The Respondent's prescribing to M.B. was in violation of Tennessee regulations and Tennessee standards. The Suboxone prescription without determining her heroin level was dangerous and outside the course of professional practice. The Respondent's failure to timely address M.P.'s

inconsistent UDS results was outside the Tennessee standards.

[In accordance with Dr. Kennedy's credible and un rebutted testimony, and for the reasons above, I find that the sixteen identified prescriptions for oxycodone and oxymorphone and the prescription for buprenorphine that Respondent issued to M.P. were issued outside the usual course of professional practice and beneath the standard of care. The basis for Dr. Kennedy's opinion and my finding is that Respondent failed to: Take an adequate medical history including an assessment of M.P.'s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for M.P.'s individual needs and discuss the risks and benefits of using controlled substances. In accordance with Dr. Kennedy's testimony, I further find that the relevant prescriptions issued by Respondent were outside the usual course of professional practice and beneath the standard of care due to Respondent's failure to maintain complete and accurate records for M.P. Finally, in accordance with Dr. Kennedy's testimony, I find that M.P. exhibited evidence of drug abuse or chemical dependency that was not adequately addressed by Respondent until after she overdosed in his office.]

Material Falsification

In its GSPHS, the Government alleged that, on November 6, 2019, the Respondent made a material misrepresentation in his renewal application for his Tennessee-based DEA COR, W18070589C. Specifically, in response to liability question three, the Respondent answered "no," which he knew or should have known to be a false response. GX 26. Liability question three queries whether the applicant has ever surrendered for cause, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or have any such action pending. An affirmative answer to question 3 would trigger an investigation by a diversion investigator whether to issue the registration or to deny it. The Respondent answered "No" to question 3.

In support, the Government cites to the State of Tennessee Department of Health, Notice of Charges and Memorandum for Assessment of Civil Penalties, dated May 2018. GX 29. [In this document, the state requested that "Respondent's certificate to operate a Pain Management Clinic . . . be suspended, revoked, or otherwise disciplined." GX 29, at 25.] A year later

in May 2019, the Chancery Court for the State of Tennessee, 20th Judicial District, Davidson County, Part 3, issued an order Reversing Denial of Stay, but Accompanying Stay with Conditions. GX 27. The stay was conditioned upon the Respondent “not writing any prescriptions during the pendency of the stay; . . . and/or not providing direct patient care including but not limited to diagnosing, treating, operating on or prescribing for any person.” GX 27, at 2. Therefore, as of May 2019, the Conditions preclude the Respondent from writing prescriptions or providing direct patient care during the pendency of the stay and were reportable restrictions. When asked on his November 6, 2019 application whether Respondent had ever had a state professional license or controlled substance registration revoked, suspended, or restricted or had any such action pending, he was required to, but did not, disclose these events.*X⁴⁷ Therefore, I find clear, unequivocal, and convincing evidence that Respondent submitted a registration application containing a false answer to the third Liability question.

[My finding about Respondent’s submission of a false answer involves restrictions on Respondent’s state license to dispense controlled substances. *Id.* 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). Accordingly, it is clear that having authorization to dispense controlled substances is a prerequisite to my ability to grant an applicant’s application. Respondent’s false response to the third Liability question directly implicated my statutorily-mandated analysis and my decision by depriving me of legally relevant facts when I evaluated Respondent’s registration renewal application. *See Frank Joseph Stirlacci, M.D.*, 85 FR 45,229, 45,235 (2020). Accordingly, I find, based on the CSA and the analysis underlying multiple Supreme Court decisions explaining “materiality,” that the falsity

*X Omitted text. The Government also alleged that Respondent’s surrender of his pain clinic’s license also warranted an affirmative response to question 3 on Respondent’s personal application. I find that I do not need to reach a decision on this evidence as the Government has already presented ample evidence that Respondent materially falsified his application when he failed to report that his authority to dispense controlled substances was restricted.

⁴⁷ [Omitted the original text containing this footnote.]

Respondent submitted was material. *Frank Joseph Stirlacci, M.D.*, 85 FR at 45,235.] *Y *Z

Government’s Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). At the outset, I find that the Government has demonstrated and met its burden of proof in support of its allegations relating to the prescribing of controlled substances to patients UC, M.P., M.W., C.F., B.C., and M.H. The Government has also sustained their burden as to the material misrepresentation allegation.

Public Interest Determination: The Standard

[Under Section 304 of the CSA, “[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 by such section.” 21 U.S.C. 824(a)(4).]⁴⁸ Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with the “the public interest.”

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

(2) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant’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.

21 U.S.C. 823(f). “These factors are . . . considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003).

Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it

*Y This language replaces the ALJ’s original analysis for clarity.

*Z Omitted ALJ’s discussion of the pain clinic’s license. *See supra* n. *X. I have also consolidated the ALJ’s original section entitled “Conditions of Stay” with the preceding paragraph for brevity.

⁴⁸ [This text replaces the ALJ’s original text and omits his original footnote for clarity.]

deems appropriate in determining whether a registrant’s registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); *see also Morall v. DEA* at 173–74; *Henry J. Schwarz, Jr., M.D.*, 54 FR 16422, 16424 (1989). Moreover, the Agency is “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d at 482; *see also Morall*, 412 F.3d at 173. [Omitted for brevity.] The balancing of the public interest factors “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” *Krishna-Iyer, M.D.*, 74 FR at 462.

The Government’s case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of the Respondent’s COR based primarily on conduct most aptly considered under Public Interest Factor’s [Two and] Four.⁴⁹

[Factors Two and Four: The Respondent’s Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances] *AA

According to the Controlled Substances Act’s (hereinafter, CSA) implementing regulations, a lawful controlled substance order or prescription is one that 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). The Supreme Court has stated, in the context of the CSA’s requirement that schedule II controlled substances may be dispensed only by written prescription,

⁴⁹ [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.*, 76 FR 19,434, 19,444 (2011) (“The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent’s DEA certification is consistent with the public interest.”) Here, to the extent that Tennessee’s decision not to revoke or suspend Respondent’s individual authority to handle controlled substances could weigh in his favor, I find that any such weight would be significantly reduced by the circumstances of the loss of his practice’s license, and the pending nature of the state action on his individual license.] Likewise, the record contains no evidence that the Respondent has been convicted of a crime related to controlled substances (Factor Three).

*AA The ALJ only evaluated the evidence under Factor 4. However, Respondent’s dispensing experience is clearly relevant to my determination as to whether or not Respondent’s continued registration is consistent with the public interest, and I have made changes throughout this section accordingly.

that “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

I found above that the Government’s expert credibly testified as supported by Tennessee law, that the standard of care requires a practitioner, before prescribing controlled substances, to take an adequate medical history including an assessment of the patient’s pain history and potential for substance abuse; perform and document an adequate physical examination; and create a legitimate written treatment plan for the patient’s individual needs and to discuss the risks and benefits of the use of controlled substances with the patient. Additionally, I found that practitioners are required to maintain complete and accurate records for their patients. I also found above that Respondent issued approximately ninety-five controlled substance prescriptions outside the usual course of professional practice and beneath the standard of care. This is because for each of the relevant prescriptions, I found that the Respondent failed to take an adequate medical history including an assessment of each patient’s pain history and potential for substance abuse; perform and document an adequate physical examination; and/or create a legitimate written treatment plan for each patient’s individual needs and/or discuss the risks and benefits of using controlled substances with the patient. I also found that each of the relevant prescriptions were issued outside the usual course of professional practice and beneath the standard of care due to Respondent’s failure to maintain complete and accurate records.

Respondent repeatedly issued prescriptions without complying with the applicable standard of care and state law thus demonstrating that his conduct was not an isolated occurrence, but occurred with multiple patients. See *Kaniz Khan Jaffery*, 85 FR 45,667, 45,685 (2020). For example, Respondent’s medical records for each of the individuals at issue had verbatim language repeated throughout the relevant time frame stating, “Patient has a long standing h/o insomnia and anxiety for several years. Anxiety symptoms include sob, palpitations, sweating, dizziness, shaking, insomnia, irritability, pacing, moodiness and feeling faint. Right now no headache, no dizziness, no nausea, no vomiting, no abdominal pain, no diarrhoea [sic.], no

constipation, no sob, no chest pain, no palpitations.” GX 9, at 85; GX 11, at 39; Tr. 286–87. This verbatim language was included in each patient’s record and in UC’s records to which UC testified credibly that he did not report having any of the anxiety symptoms identified in the chart.

Agency decisions highlight the Agency’s interpretation that “[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician’s prescribing practices are ‘within the usual course of professional practice.’” *Cynthia M. Cadet, M.D.*, 76 FR 19,450, 19,464 (2011). DEA’s ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that he prescribed a controlled substance—adequate documentation is critical to that assessment. See *Kaniz-Khan Jaffery*, 85 FR at 45,686. Further, as Dr. Kennedy testified, “maintaining a patient on scheduled medications . . . sometimes at high dosages, without having honest, accurate, complete medical records is dangerous.” Tr. 352–53. This is because, according to Dr. Kennedy, “those medical records will instruct other people who look at them as to what the motivation was for the treatment . . . [a]nd if what is documented in the medical record simply doesn’t make sense or is something that is in conflict . . . [t]hat can . . . present a dangerous situation.” Tr. 353. Therefore, recordkeeping is not only important for compliance, but also for the safety of the patients.

DEA decisions have found that “just 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 . . .” *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.*, 80 FR 28,643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998). “Diversion occurs whenever controlled substances leave ‘the closed system of distribution established by the CSA’” *Id.* (citing *Roy S. Schwartz*, 79 FR 34,360, 34,363 (2014)). In this case, I have found that Respondent issued controlled substance prescriptions without complying with his obligations under the CSA and Tennessee law. See *George Mathew, M.D.*, 75 FR 66,138, 66,148 (2010).

With regard to Tennessee law, I find that in issuing controlled substances prescriptions that were outside the usual course of professional practice and beneath the standard of care, Respondent issued prescriptions that were “not in the course of professional practice” in violation of TENN. CODE ANN. § 63–6–214(b)(12). The Tennessee guidelines require that a physician: (1) Take a documented medical history; (2) conduct a physical examination; and (3) perform an adequate “assessment and consideration of the [patient’s] pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance.” TENN. COMP. R. & REGS. 0880–02–.14(6)(e)(3)(i). I found above that respondent failed to conduct an adequate assessment and consideration of the pain and potential for substance abuse and failed to conduct a physical examination for each of the individuals at issue including UC. Additionally, Rule 0880–02–.14 (6)(e) requires physicians to create a “written treatment plan tailored for the individual needs of the patient” that considers the patient’s “pertinent medical history and physical examination as well as the need for further testing, consultation, referrals, or use of other treatment modalities.” I found above that respondent failed to prepare a tailored written treatment plan for each of the individuals at issue including UC. Tennessee guidelines also requires the physician to “discuss the risks and benefits of the use of controlled substances,” which I found above that Respondent failed to do for UC, C.F., B.C., M.H., and M.P., and “keep [c]omplete and accurate records of the care,” which Respondent failed to do for each of the individuals at issue including UC. *Id.* at 0880–02–.14(6)(e)(3)(ii)–(v).

Additionally, TENN. CODE ANN. § 63–6–214(b)(13) prohibits a physician from prescribing controlled substances to a person “addicted to the habit of using controlled substances” without “making a bona fide effort to cure the [patient’s] habit.” Crediting Dr. Kennedy’s testimony, I found above that Respondent acted outside the bounds of this law with regard to patients M.W., C.F., M.H., and M.P.]

The evidence is clear the Respondent violated the Tennessee regulations alleged, and the Tennessee professional standards. The Tennessee regulations are related to controlled substances. [Overall, I find that in issuing ninety-five prescriptions beneath the

applicable standard of care and outside the usual course of professional practice in Tennessee, Respondent violated 21 CFR 1306.04(a) in addition to Tennessee law, and these violations of law weigh against Respondent's continued registration under Public Interest Factors 2 and 4.]⁵⁰

Sanctions^{*BB}

[Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made minimal effort to establish that he can be entrusted with a registration.

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. 871(b). This authority specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." *Gonzales v. Oregon*, 546 U.S. 243, 259 (2006). A clear purpose of this authority is to "bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking." *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not he has presented "sufficient mitigating evidence to assure the Administrator that he can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 FR 21,931, 21,932 (1988)). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam*

Krishna-Iyer, 74 FR 459, 463 (2009) (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); see also *Jackson*, 72 FR at 23,853; *John H. Kennedy, M.D.*, 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62,884, 62,887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. See *Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016).]

While the Respondent has conceded that his medical charts contained several errors he never accepted responsibility for [the violations I have found]. His testimony defending the identical indications among his patients in support of his anxiety and insomnia diagnoses was not at all credible. The lack of a credible explanation for the inclusion of results in UC's chart of tests and examinations which did not take place weighs heavily against a finding of acceptance of responsibility. Furthermore, although he testified, he did not address the material falsification allegation. I therefore find that any acceptance of responsibility has neither been unequivocal nor complete.

[In all, Respondent failed to explain why, in spite of his misconduct, he can be entrusted with a registration. "The degree of acceptance of responsibility that is required does not hinge on the respondent uttering "magic words" of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator." *Jeffrey Stein, M.D.*, 84 FR 46,968, 49,973 (2019). Here, having considered Respondent's case and statements, I am left with no confidence in Respondent's future compliance with the CSA.]

Egregiousness and Deterrence

[The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.*, 83 FR at 18,910 (collecting cases).] I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. [Respondent issued approximately 95 prescriptions for controlled substances outside the usual

course of professional practice and beneath the standard of care.] The proven misconduct involved fabricated medical charts, failure to meaningfully address serious and ongoing indications of drug abuse and diversion by several of his patients, as well as other red flags. The proven misconduct also involved the material falsification of his application for his CSA registration renewal in Tennessee.*^{CC}

[In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. See *Joseph Gaudio, M.D.*, 74 FR 10,083, 10,095 (2009); *Singh*, 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case.] Allowing the Respondent to retain his COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite ignoring obvious signs of abuse, diversion and other serious red flags, the wholesale failure to maintain adequate, complete and accurate medical charts, and after making a material falsification on a renewal application. Revoking the Respondent's COR communicates to registrants that the DEA takes all of these failings under the CSA seriously and that severe violations will result in severe sanctions.

[Omitted.]^{*DD}

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough*, 73 FR at 387. The Respondent's material misrepresentation compounds the Respondent's instant burden. Although the Respondent offered some evidence of mitigation, even if considered, it has not overcome the loss of trust resulting from the allegations found herein.

*^{CC} Remaining analysis of egregiousness omitted for relevance.

*^{DD} I agree with the ALJ that Respondent's testimony lacked credibility and I have given it little-to-no weight in reaching my decision. However, in light of Respondent's failure to unequivocally accept responsibility, it is not necessary for me to assess whether Respondent's testimony also lacked candor and I have therefore omitted the ALJ's discussion of this topic.

⁵⁰ An expert's opinion that a doctor's treatment of patients fell below the standard of care is probative of whether the doctor violated 21 CFR 1306.04(a). *Bienvenido Tan, M.D.*, 76 FR 17,673, 17,681 (2011).

*^{BB} I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

[There is simply no evidence that Respondent's behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.]

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. In evaluating Factors [Two and] Four of 21 U.S.C. 823(f), I find that the Respondent's COR is inconsistent with the public interest. Furthermore, I find that the Respondent has failed to overcome the

Government's *prima facie* case by unequivocally accepting responsibility and establishing that he can be trusted with a registration.

Therefore, I recommend that the Respondent's DEA COR Control No. BO4959889 should be *revoked*, and that any pending applications for modification or renewal of the existing registration, including the pending application for a new DEA COR Control No. W18070589C, and any applications for additional registrations, be *denied*.

Mark M. Dowd,
U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby

revoke DEA Certificate of Registration No. BO4959889 issued to Samson K. Orusa, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any other pending applications for renewal or modification of this registration, the pending application for new DEA COR Control No. W18070589C, as well as any other pending application of Samson K. Orusa, M.D., for registration in Tennessee. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

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