

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Sometime before 1968, three cultural items were removed from Tennessee. In 1968, these items were given to the Bixby Memorial Free Library by Ernst Bilhuber, a Euro-American collector of Native American objects and resident of the Vergennes area. The three items are one bowl portion of a Bird Effigy Pipe (inventory number 1968.1.20), one Fish Effigy Bowl (inventory number 1968.1.134), and one Chickasaw Red Bird Effigy Footed Water Jug (inventory number 1968.1.140).

The Bird Effigy Pipe is made of brown sandstone. The pipe is carved to resemble the head of a bird, and the bowl is carved into the top of the head. A stem for smoking would have been attached to the bird's neck. The Fish Effigy Bowl is made of Mississippian grayware. The object is round with a fish head protruding from one end and fish tail protruding from the opposite side. There are also several "fins" protruding from the sides of the bowl.

The Chickasaw people have a link to the southeastern United States, including Tennessee, as documented in the Treaty of 1816. During consultation with representatives of The Chickasaw Nation, the three objects listed in this notice were recognized by the Chickasaw team as funerary in nature, and similar to previously repatriated associated funerary objects that had been removed from ancestral burials in their homelands, which encompass the Tennessee area. Consequently, the Bixby Memorial Free Library has determined that a relationship of shared group identity can reasonably be traced between The Chickasaw Nation and the Muskogean linguistic cultures connected with the items listed in this notice.

Determinations Made by the Bixby Memorial Free Library

Officials of the Bixby Memorial Free Library have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the three cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and

are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.

- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Chickasaw Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Patricia Reid, Bixby Memorial Free Library, 258 Main Street, Vergennes, VT 05491, telephone (802) 877-2211, email patricia.reid@bixbylibrary.org, by May 12, 2021. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Chickasaw Nation may proceed.

The Bixby Memorial Free Library is responsible for notifying The Chickasaw Nation that this notice has been published.

Dated: March 26, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-07407 Filed 4-9-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17-31]

Jennifer L. St. Croix, M.D.; Decision and Order

I. Introduction

On April 12, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Jennifer L. St. Croix, M.D. (hereinafter, Respondent), of Covington, Tennessee. OSC, at 1. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. FS2669868 and the denial of "any pending application to modify or renew such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that . . . [her] continued registration is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f)." *Id.*

The substantive grounds for the proceeding, as alleged in the OSC, are that Respondent "committed such acts

as would render . . . [her] registration . . . inconsistent with the public interest.' See 21 U.S.C. 824(a)(4)." *Id.* at 3. Specifically, the OSC alleged that Respondent violated the commitments she made to DEA when she executed a three-year Memorandum of Agreement (hereinafter, MOA) effective June 25, 2011. *Id.* at 2. According to the OSC, Respondent's MOA commitments, to "abide by all Federal, State, and local laws and regulations pertaining to controlled substances" and to "maintain a log of all controlled substances prescribed, administered or dispensed to patients at . . . [her] registered premises or elsewhere, including call-in prescriptions, for review by DEA personnel at any time," were what permitted her to maintain an unrestricted registration. *Id.*

First, according to the OSC, Respondent continued to issue "prescriptions to individuals who are intimate or close acquaintances, and provided prescription drug logs to DEA that were noncompliant with the terms of the June 2011 MOA" due to the falsities included in ten of them.¹ *Id.* The OSC also alleged that Respondent failed to maintain medical records pertaining to her prescribing of controlled substances, and that she prescribed controlled substances to an individual with whom she had a "romantic interaction." *Id.* The authorities that the OSC listed for these allegations are 21 U.S.C. 843(a)(4)(A), 21 CFR 1306.04(a), Tenn. Code Ann. § 63-6-214(b)(1), Tenn. Code Ann. § 63-6-214(b)(12), Tenn. Comp. R. & Regs. R. 0880-2-.14(6)(a)(4) and (e), and Tenn. Comp. R. & Regs. R. 0880-2-.14(8)(a) (adopting opinion 8.14 of the American Medical Association Code of Ethics). *Id.* at 2-3.

Second, the OSC alleged that Respondent failed to submit MOA-required prescription drug logs to DEA for six months even though "DEA's subsequent review of prescription data revealed that . . . [she] issued controlled substance prescriptions during" those months.² *Id.* at 3. The OSC cited 21 U.S.C. 823(f)(5) as the statutory basis for this allegation. *Id.*

Third, according to the OSC, Respondent "stored controlled substances in an exterior storage shed at

¹ The charged falsities were alleged to be in Respondent's drug log submissions dated August, October, and November of 2012, February, May, June, July, October, and November of 2013, and January 2014. OSC, at 2.

² The six months during which Respondent allegedly issued controlled substance prescriptions without submitting prescription drug logs to DEA were February, March, and April 2012 and January, March, and April 2013. OSC, at 3.

. . . [her] private residence . . . for dispensing from . . . [her] private residence . . . sometime between March 7, 2013 and November 6, 2013.” *Id.* The OSC cited 21 CFR 1301.12(a) as the basis for the allegation that Respondent stored controlled substances at an unregistered location. *Id.*

Fourth, the OSC charged Respondent with violating 21 CFR 1301.71(a), failure to provide effective controls or procedures to guard against the theft or diversion of controlled substances, due to her admission that “the door to . . . shed did not close securely.” *Id.*

Fifth, connected to the charge that Respondent purchased controlled substances “for dispensing from . . . [her] private residence,” the OSC alleged that Respondent “did not conduct an initial inventory of controlled substances received on March 7, 2013, nor did . . . [she] maintain records of . . . [her] dispensing these drugs as required by 21 CFR 1304.03(a) and (b), 1304.04(g), 1304.11(b) and (e), and 1304.21(a).” *Id.*

In sum, the OSC alleged that Respondent’s actions, when judged under 21 U.S.C. 823(f)(2), (f)(4) and (f)(5), “render[] . . . [her] continued registration with the DEA to handle controlled substances inconsistent with the public interest.” *Id.* at 3–4.

The OSC notified Respondent of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 4 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to file a corrective action plan. OSC, at 4–5 (citing 21 U.S.C. 824(c)(2)(C)).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge (hereinafter, ALJ) John J. Mulrooney, II. The parties submitted ten stipulations.³ Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD), at 3–4. In addition, the Chief ALJ took official notice of two documents concerning Respondent issued by the Tennessee Board of Medical Examiners (hereinafter, TBME) after giving the parties notice of his intent to do so and receiving no objection. Official Notice Order dated March 1, 2018, attaching Notice of

³ The tenth stipulation states that “Respondent did not treat patients referred to in the record as Patient JJ or Patient NJ at Methodist Fayette Hospital, Baptist Memorial Hospital, and/or McNairy Regional Hospital. RD, at 4; *see also infra* section II.D.

Charges and Memorandum of Assessment of Civil Penalty and Costs dated June 3, 2016 (hereinafter, Notice of Charges) and Final Order dated May 24, 2017 (hereinafter, TBME Final Order).

The hearing in this matter took place in Nashville, Tennessee on March 13 and 14, 2018. The Chief ALJ filed the RD on May 10, 2018.⁴ RD, at 1. Noting that Respondent had already been “afforded the administrative grace” of a MOA, the Chief ALJ recommended that Respondent’s registration be revoked and that any pending applications for its renewal be denied. *Id.* at 68, 70. Respondent filed exceptions to the RD on May 30, 2018. Letter of the Chief ALJ to the Acting Administrator dated June 7, 2018, at 1. The Government neither filed exceptions nor responded to Respondent’s Exceptions. *Id.* After the Chief ALJ certified the record and transmitted it to me, Respondent, on July 12, 2018, submitted a Motion to Consider Amended Corrective Action Plan (hereinafter, MCACAP).

Having examined and considered the record in its entirety, I agree with the conclusion of the Chief ALJ that Respondent’s registration should be revoked and that all pending applications for its renewal or modification should be denied.⁵ I make the following findings.

II. Findings of Fact

A. Respondent’s Controlled Substance Registration

The parties stipulated that Respondent is “currently registered . . . as a practitioner in Schedules II–V under DEA registration number FS 2669868” in Covington, Tennessee.⁶ Prehearing Ruling dated June 12, 2017 (hereinafter, Prehearing Ruling), at 1; RD, at 3. The parties and the Chief ALJ further agreed that Respondent’s registration “remains current based upon Respondent’s submission of an application for renewal of registration on January 31, 2017.”⁷ RD, at 3; *see also* Order Denying the Government’s

⁴ The Chief ALJ’s Corrected Page Order was filed on May 11, 2018.

⁵ I reviewed, and agree with, the ultimate rulings and conclusions of all of the Chief ALJ’s procedural decisions.

⁶ The parties agreed to nine additional stipulations. Prehearing Ruling, at 1–2; RD, at 3–4. Eight of these nine concern the scheduling history of oxycodone, Percocet, Tussionex, Lortab, Xanax, Soma, Ambien, and phentermine. *Id.*

⁷ The parties also agreed that Respondent submitted a request to modify the registered address of her registration from Tennessee to the Virgin Islands on January 31, 2017. Prehearing Ruling, at 1–2; RD, at 3.

Motion for Termination of Proceedings dated July 25, 2017, at 6.

B. The Investigation of Respondent

In March of 2011, Respondent applied for a registration. GX 3 (MOA), at 1. The ensuing investigation of the application resulted in four allegations “which if proven in an administrative hearing, could constitute grounds to deny . . . [Respondent’s] application for registration.” *Id.* at 1; *see also id.* at 1–2. According to the four allegations, Respondent was arrested in Colorado and Nebraska for felony drug possession and in Wisconsin for aggravated battery/intent to cause great harm, and Respondent “admitted to prescribing controlled substances to friends and family members including her mother in law as well as some neighbors and friends of her former husband,” “admitted to working for a Telemedicine Organization in which the legitimacy of many of the prescriptions could be called into question,” and admitted that her relationship with her ex-husband “resulted in often questionable behavior in regards to prescribing . . . [and] her being around illegal drugs at times.” *Id.* at 1–2.

According to the MOA, DEA agreed to grant Respondent’s application for a registration in Schedules II through V and Respondent agreed to five specific courses of conduct. *Id.* at 2–3.⁸ First, Respondent agreed “to abide by all Federal, State and local laws and regulations pertaining to controlled substances” as well as the “additional obligations imposed upon . . . [her] pursuant to” the MOA. *Id.* at 2. Second, Respondent agreed that “she will not prescribe, administer or dispense any controlled substances to family members” and that, if she does, she agreed “to immediately execute a DEA Form 104, Voluntary Surrender of Controlled Substances Privileges, thereby relinquishing all authority to prescribe, administer or dispense controlled substances.” *Id.*

Third, Respondent agreed to “maintain a log of all controlled substances prescribed, administered or dispensed to patients at her registered premises or elsewhere, including call-in prescriptions, for review by DEA personnel at any time.” *Id.* The MOA specified the elements to be captured in the log—patient, date, and the name, strength, and quantity of the prescribed controlled substance—and how

⁸ Respondent also agreed to multiple specific matters such as having advice of Counsel and “knowledge of the events described herein,” comprehending all of the MOA, and entering the MOA voluntarily. GX 3, at 2; *see id.* 2–4.

Respondent was to maintain and transmit the log to DEA. *Id.*

Fourth, Respondent agreed that “DEA personnel may enter her office and/or registered location at any time during regular business hours without prior notice to verify compliance with” the MOA. *Id.* Respondent specifically agreed “to permit entry of DEA personnel without an Administrative Inspection Warrant or other written notices or other means of entry.” *Id.* Fifth, Respondent agreed “to immediately notify the DEA prior to any change of business address and/or change in status of her State medical license and/or state controlled substance authority” and “to promptly notify the DEA of any change of address or requests for modification of registration.” *Id.* at 3. Respondent agreed to make these notifications in writing and to transmit them to the specific Diversion Group Supervisor “by certified mail with return receipt requested.” *Id.*

The MOA’s terms included that it was the “full and complete agreement” of Respondent and DEA, that “[n]o other promises or agreements will be binding unless placed in writing and signed by both parties,” and that the “terms and provisions . . . [were] executed in good faith.” *Id.*

In March of 2014, according to the testimony of the Diversion Investigator assigned to the matter (hereinafter, DI), a Tennessee Department of Health employee (hereinafter, TDHI) investigating a complaint against Respondent contacted DEA. Tr. 38–39. TDHI’s investigative work was related to allegations that Respondent reported controlled substances as stolen and was providing medical care to her boyfriend, J.J., and his brother, N.J. *Id.* at 40. The DEA investigation that led to the issuance of this OSC ensued.

C. The Government’s Case

The Government’s case includes fifteen exhibits, one of which has twelve parts, and two witnesses, DI and Stephen Loyd, M.D. All but one of the Government’s exhibits—GX 10—were admitted into the record. When the Government initially moved the admission of GX 10, purporting it to be J.J.’s medical record, the Chief ALJ sustained Respondent’s objections, citing foundation and relevance. *Id.* at 132–33 (Chief ALJ ruling that “I’ll sustain the objection . . . I have every confidence that it is the document that . . . [DI] received from . . . [TDHI]. But I just don’t know what . . . [TDHI] sent him or what the purpose of it was or where she got it. And that being the case, then I wouldn’t know how to use

the document. . . . [F]or the time being, . . . [GX 10] I’m going to exclude based on the objections without prejudice for . . . [Government Counsel] to make, as I said, another run at it.”); *see also id.* at 127–131. The Government did not end up being successful at introducing GX 10.

DI followed up on the telephone call he received from TDHI by gathering information. He obtained a copy of the MOA. DI served an administrative subpoena on the Tennessee Department of Health Controlled Substance Monitoring Database (hereinafter, CSMD) to obtain a list of controlled substance prescriptions that Respondent issued. *Infra.* He secured a copy of the DEA Form 106 that Respondent submitted about the theft or loss of controlled substances, GX 5 (hereinafter, DEA theft report). *Id.* at 45–49. The DEA theft report shows that Respondent reported the theft or loss of Testosterone Cyp, Zolpidem Tartrate, Phentermine, and Alprazolam. GX 5, at 1–2.

I agree with the Chief ALJ’s assessment of DI’s credibility, that DI “presented as an objective, experienced regulator with no apparent agenda, who provided answers that, even in some difficult areas . . . rang true.” RD, at 14. I also agree with the Chief ALJ that DI “resisted the temptation to embellish the statements purportedly made by the Respondent, . . . [J.J., and N.J.] although it was arguably clear that doing so would have strengthened the case for a sanction.” *Id.* Accordingly, I agree with the Chief ALJ and find that DI’s “testimony was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in these proceedings,” and I make corresponding findings of fact as a result. *Id.*

DI investigated how it came to be that Respondent possessed the controlled substances that she reported as stolen on the DEA theft report. Tr. 50–73. Over Respondent’s objections, the Government successfully moved the admission of the entire twelve-page packet of McKesson Medical-Surgical Inc. (hereinafter, McKesson), parent of Moore Medical Inc. (hereinafter, Moore Medical purchase packet), “records of all purchases made” by Respondent.⁹

⁹ Respondent objected to the admission of page 6 of GX 6 on the grounds of scope (Respondent is “not charged with a crime in using the hospital’s credit card, as stated here”) and prejudice, arguing that the page “should not be considered by the Court in assessing penalties against” Respondent. Tr. 56, 66; *see also id.* at 56–59, 66–69. In admitting the entirety of GX 6, the Chief ALJ stated that “[i]t seems to me to eliminate that part of it [page 6] would leave an analytical hole in the documents that were provided. . . . I don’t know how the evidence is going to turn out, but if the evidence turns out that this unauthorized use of a credit card

GX 6. The first two pages of the Moore Medical purchase packet are the Declaration of a McKesson employee whose job responsibilities include “obtaining [McKesson] documentation and information in response to subpoenas and other requests.” *Id.* at 1–2; Tr. 51–53. According to the Declaration, the rest of GX 6 had originally been produced in response to a Grand Jury Subpoena served in March 2017. Tr. 50–69.

The third page of the Moore Medical purchase packet is the “Controlled Substance Report” showing the controlled substances shipped to Respondent in March 2013. GX 6, at 3; Tr. 53–54. According to the Controlled Substance Report, Zolpidem, Testosterone Cyp, Phentermine, Carisoprodol, and Alprazolam were shipped to Respondent at “969 Tennessee Avenue South, Parsons TN 38361.”¹⁰ GX 6, at 3. DI testified that he compared the content of the DEA theft report, GX 5, with the content of this “Controlled Substance Report” and concluded that the quantity of the controlled substances reported on the DEA theft report is identical to the quantity of controlled substances received from Respondent’s purchase from Moore Medical. Tr. 49–50. (“I looked at the number where they listed the quantity lost and compared that to a[n] invoice that I obtained under subpoena from Moore Medical, and the numbers of the amounts that were taken or reported as taken in this agreed with what was the number of containers that were taken or delivered to . . . [Respondent].”).

The fourth page of the Moore Medical purchase packet includes much of the same information as appears on the third page plus the date Respondent ordered the controlled substances, February 26, 2013, and the method of payment, “credit card.” GX 6, at 4; Tr. 54. The fifth page of the Moore Medical purchase packet shows, among other things, that Respondent’s “Company Name” in the McKesson records is “St. Croix LLC.” GX 6, at 5; *see also* Tr. 55–56. The fifth page also shows the shipping address as “969 Tennessee Ave South, Decatur [sic] Gch.” GX 6, at 5; *see also* Tr. 55–56.

The sixth page of the Moore Medical purchase packet summarizes a

is relevant because she wasn’t supposed to be getting those drugs, and it was all part of a plan to keep them in an unauthorized way, and that reflects on her, I probably would consider that. But the fact that she violated some rule about a credit card, that’s not charged, and I don’t think it impacts much beyond arguably credibility.” *Id.* at 68. I agree with the Chief ALJ.

¹⁰ This was Respondent’s registered address at the time.

telephone call from an individual at Decatur County General Hospital on March 5, 2013. GX 6, at 6; Tr. 59–60. According to that “Account Note,” the individual “wanted to advise us” of his belief that Respondent, a “contractor at the Hospital,” placed an Order and “has left with the product.” GX 6, at 6; *see also* Tr. 56, 59–60. It states that the individual is “going to contact their Local Police to file charges.” GX 6, at 6; *see also* Tr. 59–60. Page 6 of the Moore Medical purchase packet also suggests that “Decatur Cgh” means “Decatur County General Hospital.” GX 6, at 6; Tr. 59–60.

The seventh page of the Moore Medical purchase packet includes two views of Respondent’s registration, FS2669868, showing the expiration date of February 28, 2014. GX 6, at 7; Tr. 60. The address on the registration captured on this page is “969 Tennessee Avenue South, Parsons, TN 38361–0000.” GX 6, at 7; *see also* GX 2, at 1 (DEA Certification of Respondent’s Registration History stating that “969 Tennessee Avenue” was Respondent’s registered address as of June 13, 2011, and that Respondent’s registered address changed on January 3, 2014).

The eighth page of the Moore Medical purchase packet is titled “Declaration of Controlled Substances Purchases,” is signed by Respondent, and is dated February 12, 2013. GX 6, at 8; Tr. 60–61. The Declaration includes information appearing on previous pages of GX 6: “Jennifer St. Croix, M.D./ St. Croix LLC” (for “customer name”), “969 Tennessee Ave S, Parsons TN 38361” (for “address, city and state”), and “FS2669868” (for “DEA registration #”). GX 6, at 8. Respondent “declare[d] and attest[ed]” that she “fully complies with all federal and state laws and regulations on the dispensing of controlled substances including but not limited to dispensing to patients only pursuant to a legitimate prescription issued in the course of an established doctor-patient relationship . . . and only for a legitimate medical purpose.” *Id.* Regarding her purchase of so-called “Lifestyle Drugs,” such as Phentermine and Alprazolam, Respondent stated that her “requirements for [their] purchase] . . . are necessary for [the] [a]ddition of Age Management Medicine, weight loss & wellness to private practice.” *Id.*; *see also* Tr. 60–61 (DI’s testimony that this record is used to “verify a reasoning behind the purchase from a practitioner to verify that what they’re ordering is for a legitimate purpose or get the reasoning behind ordering the controlled substances.”). Respondent “certifie[d]” that she “made sufficient inquiry to be able to make this declaration truthfully,

accurately, and without material omissions.” GX 6, at 8. She also “affirm[ed] by signing this declaration that the above is true and correct to the best of . . . [her] knowledge and belief.” *Id.*

The ninth through twelfth pages of the Moore Medical purchase packet contain the label “invoice.” *Id.* at 9–12. In two places on the ninth page, the record shows Respondent’s home address. *Id.* at 9; Tr. 62, 65. The ninth page also shows the “ship to” registered address for the order, the same address as Respondent’s registered address, which is also the address of Decatur County General Hospital. GX 6, at 9; Tr. 62, 65. The data points addressed in the invoice are item number, item description, order quantity, ship quantity, “B/O Qty,” dollar unit price, “U/M,” “\$ Extended,” sales tax, and “ship from.” GX 6, at 9, 11–12. The items described on the invoice are both controlled substances and medicines that are not controlled. *Id.* The invoice does not list the controlled substances separately from the medicines that are not controlled. *Id.*

DI testified that his investigation included attempting to contact the individual with Decatur County General Hospital whose call was memorialized as an “Account Note” on the sixth page of the Moore Medical purchase packet. Tr. 70–72. According to DI, he ended up speaking with the Decatur County General Hospital Chief Executive Officer who succeeded that individual (hereinafter, DCGH CEO). *Id.* at 71–72. A result of that telephone conversation with DCGH was DI’s receipt of an “incident report” indicating to him “that there was possibly the diversion of controlled substances.”¹¹ *Id.* at 73. DI testified that his follow-up included an unannounced interview of Respondent at her residence on May 19, 2014.¹² *Id.* at 73–74.

DI testified that during the interview, Respondent admitted that she had ordered a “small amount” of controlled substances, telling DI she did so because “she was thinking about starting her own private practice,” although she added that she never did. *Id.* at 76. DI testified that Respondent told him that “she received the controlled substances at Decatur County General [Hospital], she brought them to her residence and secured them in an outside storage shed that was behind her residence.” *Id.* at 77. DI testified that if Respondent were

“going to administer or if she’s going to dispense controlled substances or she’s going to hold controlled substances for dispensing, she would have to have a registration there” but, to his knowledge, Respondent’s residence was never a DEA registered location. *Id.* at 76, 78; *see also* GX 2, 1–2. DI recounted that Respondent said “she didn’t look in the storage shed again until she went there to conduct an inventory that was requested by the Tennessee Department of Health Office of Investigations.” Tr. 77–78. At that time, she learned that the controlled substances were missing from the shed. GX 4 (Memphis Police Department Incident Report dated November 6, 2013) (hereinafter, Memphis Police Incident Report), at 1, 3; *see also* Tr. 121–22. According to the Memphis Police Incident Report, Respondent told the police that the controlled substances went missing “anytime between March and . . . [November 6, 2013] as she never goes into the shed.” GX 4, at 3. The Memphis Police Incident Report also stated that “There was no scene to process. There was no damage to the shed, as the door was unlocked.” *Id.*

According to DI, Respondent asked if he would like to see the shed where she had stored the controlled substances and took the two Diversion Investigators “behind her residence outside” to the shed that was “built onto the back of her townhouse” and was “about the size of a closet . . . [p]robably about four feet across, maybe four feet deep[,] and maybe eight feet tall.” Tr. 79–81; *see also id.* at 154 (shed was attached to Respondent’s residence). The shed did not have a window, DI stated. *Id.* at 84. DI testified that the shed “was probably about 30 yards or so” from the street and that “[t]here was no fence or anything at the rear of her house. It was just open all the way back, and there were other townhouses that were adjacent to hers that opened up to this area.” *Id.* at 79; *see also id.* at 82–83. DI described the shed’s door as a “hollow-core door” with “just a regular doorknob that would be operated with a key,” but stated that Respondent “just turned it and opened it right up.” *Id.* at 81–82. DI testified that the door “was rather beat up, and the frame of the door was kind of damaged some, and also where the lock was, . . . [Respondent] stated that it didn’t shut very well.” *Id.* at 82; *see also id.* at 83–84 (DI adding that the shed door “looked like it would be fairly easy to open up” and that he could not “positively say” that he saw any signs of break-in).

DI testified that his interview of Respondent also addressed controlled substance recordkeeping requirements.

¹¹ The Government did not offer the “incident report” into evidence and, therefore, I am not considering it.

¹² DI testified that another Diversion Investigator assisted him with the interview of Respondent. Tr. 74–75.

Id. at 84–85. He testified that he asked Respondent if she had created an initial inventory and that her response was “she had never created a regulatory or an initial inventory.” *Id.* at 85–87.

DI testified that Respondent told him she is not treating any family members. *Id.* at 88. He stated that she admitted treating J.J. and N.J., telling DI she treated them “on the side,” and referred to J.J. as her boyfriend with whom she had a romantic relationship “for a brief time.” *Id.* at 89; *see also id.* at 182–85, 189, 199–200; *contra* GX 6, at 8 (Respondent’s declaration and attestation that she “dispens[es] controlled substances] to patients only pursuant to a legitimate prescription issued in the course of an established doctor-patient relationship”). DI testified that J.J. also stated that he had a romantic relationship with Respondent “for a brief period of time.” *Id.* at 196–97. DI stated that N.J. said “he saw . . . [Respondent] either at his brother’s [J.J.’s] house—on one occasion he saw her at a pharmacy . . . in a parking lot.” *Id.* at 198–99. Both J.J. and N.J., during DI’s interviews of them, told DI that “the drugs [Respondent prescribed for them] were based on a complaint of injuries that they had.” *Id.* at 201–02. DI testified that Respondent told him she did not maintain medical records for either J.J. or N.J. *Id.* at 89; *see also id.* at 188–90.

When DI followed up on Respondent’s statement that she did not maintain medical records, he learned from an attorney in the Office of General Counsel of the Tennessee Department of Health that the attorney had received a medical record purportedly for J.J. from Respondent’s previous Counsel. *Id.* at 127–28. DI testified that the attorney emailed him what she had received from Respondent’s previous Counsel. *Id.* at 128–30; GX 10. DI stated that the purported chart “didn’t have a name on it.” Tr. 129. He testified that, since Respondent “had told me that she had not kept patient charts for N.J. or J.J. when I interviewed her at her residence . . . [.] I was doubtful about where these charts—the alleged—the charts may have come from . . . [o]r if they had been created after the fact.” *Id.* at 133.

Respondent’s Counsel objected to the admission of GX 10 because, she stated, it was “represented as a complete medical chart” for J.J. *Id.* at 131. The Chief ALJ sustained her objection based on foundation and relevance. *Id.* at 132–33. His ruling, he advised, was without prejudice for Government’s Counsel to “make . . . another run at it.” *Id.* at 132. Government’s Counsel subsequently presented arguments to the Chief ALJ for the admission of GX 10. *Id.* at 136–

37. His argument included that Respondent had noticed she would be relying on “virtually the same exhibit” as a medical record for J.J. consisting of five more pages than GX 10. *Id.* at 138–39. The Chief ALJ did not change his ruling; GX 10 was never admitted. *Id.* at 139–42. I agree with this and the other evidentiary rulings of the Chief ALJ during the hearing.

As already discussed, DI stated that he served a subpoena on the CSMD seeking a “listing of all the prescriptions that . . . [Respondent] had listed in the CSMD for the period of June 2011 through March or April 2014.” *Id.* at 91. He testified that he found “several prescriptions that were attributed to” J.J. and N.J. *Id.* at 92. Then, DI testified, he obtained the original prescriptions issued to J.J. and N.J. from the pharmacies where they were filled. *Id.* at 93. He stated that he issued subpoenas to the three hospitals on whose paper the prescriptions were purportedly written seeking medical records for J.J. and N.J.¹³ *Id.* at 94. The three “no-record” responses that DI received from the hospitals were admitted into evidence. GX 8.

DI also subpoenaed the prescriptions that Respondent issued to J.J. and N.J. Tr. 99–101. DI identified GX 9 as consisting of copies of eighteen original controlled substance prescriptions, front and back, that Respondent issued for J.J. *Id.* at 99–100. The eighteen controlled substance prescriptions were issued for Percocet, Zolpidem, Alprazolam, and Tussionex. GX 9. The prescriptions in GX 9 were issued on either “Methodist Healthcare Discharge Prescription Orders,” “McNairy Regional Hospital Elite Emergency Services,” or “Baptist Memorial Hospital—Tipton” paper. *Id.*

DI also testified that GX 11 consists of copies of original controlled substance prescriptions that Respondent issued for N.J. Tr. 101. According to GX 11, Respondent issued controlled substance prescriptions to N.J. for Tussionex and Lortab. GX 11. The prescriptions in GX 11 were issued on either “Methodist Healthcare Discharge Prescription Orders” or “Baptist Memorial Hospital Tipton Discharge Medications” paperwork. *Id.*

DI testified that GX 12a through GX 12l contain “copies of some of the prescription logs that were submitted to the [DEA] Nashville District Office.” Tr. 104–05. He clarified that the contents of GX 12a through GX 12l “list N.J. and J.J., I believe.” *Id.* at 106.

During his testimony, DI pointed out that Respondent’s April 2014 MOA-

required drug log does not include a controlled substance prescription that Respondent issued to N.J. for Tussionex on April 30, 2014.¹⁴ *Compare* GX 11, at 5 and GX 12l, at 10; Tr. 116–17.

Regarding the OSC charge that Respondent failed to provide six MOA-required drug logs, DI described during his testimony the steps he took to ascertain whether DEA received those logs. Tr. 106–14; *see also id.* at 148–52. He also testified that, given his belief that Respondent sent the drug logs to DEA by certified or registered mail, he asked her about certified return receipt cards when he interviewed Respondent at her residence. *Id.* at 147; *see also id.* at 148 (DI’s testimony that Respondent told him that “she sent everything in certified mail.”). “[S]he went to a back portion of her house and came back with about four or five cards,” he reported. *Id.* at 147. When DI asked her if she had any more cards, she answered in the negative. *Id.*

After DI’s testimony, the Government called Stephen Loyd, M.D., its second and final witness. *Id.* at 203–83. Dr. Loyd is a practitioner whose medical license in Tennessee and DEA registration were in good standing and were never subject to discipline. *Id.* 206. His professional experience includes being a hospital “residency program director for internal medicine,” practicing hospital medicine, and working in a hospital emergency department. *Id.* at 231. Dr. Loyd testified that “the course that’s required for every physician in the State of Tennessee on controlled substances, I teach.” *Id.* at 249–50. Having read and analyzed all of the record evidence, I agree with the Chief ALJ’s determination to recognize Dr. Loyd as an expert in internal medicine with an emphasis on the proper prescribing of controlled substances in Tennessee.¹⁵ *Id.* at 214.

Dr. Loyd testified that the 1995 Policy Statement of the Tennessee Board of Medical Examiners, entitled “Management of Prescribing with Emphasis on Addictive or Dependence-Producing Drugs,” GX 15 (hereinafter, Tennessee Controlled Substance Prescribing Policy Statement), applies to Respondent’s allegedly unlawful controlled substance prescribing as Tennessee’s chronic pain guidelines did not go into effect until after the time period alleged in the OSC. *Id.* at 211–12; *see also id.* at 281–82. I agree with

¹⁴ Government Counsel “withdrew” his statement to the Chief ALJ that “[w]e’ll go through” the other pages of GX 11 and GX 12l to identify any other discrepancies between GX 11 and GX 12l. Tr. 119–20.

¹⁵ Respondent’s Counsel did not object to this determination. Tr. 214.

¹³ The six subpoenas were admitted into evidence. GX 7.

Dr. Loyd's assessment and the application of the Tennessee Controlled Substance Prescribing Policy Statement to this proceeding.

Dr. Loyd correctly characterized the Tennessee Controlled Substance Prescribing Policy Statement as setting out the nine "steps that were accepted practice for the proper prescribing of when . . . [controlled substance] medications were indicated" for acute or chronic pain. *Id.* at 215–16. He explained the first step, having a "workup sufficient to support a diagnosis," as the "establishment of a proper diagnosis that would indicate a need for a controlled substance for pain." *Id.* at 216; GX 15, at 1. Dr. Loyd testified that the workup sufficient to support a diagnosis begins with the patient's chief complaint, "[a]ll of the things surrounding that chief complaint, the who, what, where, when, why, how, around that chief complaint," and "then the history of present illness." Tr. 224. He noted that pain is a symptom, not a disease, and "so the first part . . . is establishing a diagnosis as to the root of the pain, so you can address that, rather than the symptom." *Id.* at 218.

For pain patients in general, including chronic pain patients, Dr. Loyd testified that "it's vitally important that you have some kind of subjective statements from the patient as to the limitations the pain is causing and their activities of daily living." *Id.* at 224. Knowing the patient's limitations caused by the pain is important, he explained, because the purpose of a practitioner's intervention is "to try to improve that patient's functioning with whatever condition that they have." *Id.* at 225. If the patient's limitations are "very little," he suggested that the associated risks would render a controlled substance intervention inappropriate. *Id.* He also suggested that the efficacy of the intervention is judged by the intervention's impact or lack of impact on the patient's limitations caused by the pain. *Id.*

In a similar vein, Dr. Loyd summarized the second and third steps as concerning "the use of non-controlled substance modalities to try to address the pain issues first, before moving onto a controlled substance." *Id.* at 216.

Regarding the fourth step, Dr. Loyd pointed out that "the reality here is that these [controlled substance] medications are very effective, but they also have abuse potential." *Id.* at 217. As such, he testified, "you have to weigh the risk versus benefits, and so . . . there are some things that you need to do to try to ascertain your patients' risk for abusing one of these prescribed

controlled substances." *Id.* "One of the big risk factors for misusing prescribed controlled substances," he explained, "is someone that has a history or a family history of substance use disorder," including alcohol and prescription pills. *Id.* at 226. Urine drug screens, he testified, are "sometimes the truth serum for that history" and assist with the practitioner's determination of whether an "underlying substance use disorder . . . [is] really the problem, instead of the problem that they're presenting." *Id.* at 227–28; *see also id.* at 230. Dr. Loyd reported that, initially, he will "usually do a 10 or 12 panel [urine drug screen] that has a mixture of prescribed drugs, as well as illicit drugs, and the common illicit drugs are on there, methamphetamine, cocaine, marijuana." *Id.* at 228–29. Subsequently, if he prescribed a controlled substance for treatment, the urine drug screen he orders will test "to make sure those drugs are in their system" and, if not, he "want[s] to know where they're going. And most of the time that's diversion." *Id.* at 229; *see also id.* at 230 (Someone would "pretty much live under a rock not to know what's going on in our state in Tennessee right now with regards to prescription drug abuse. So we have a lot of pills that are diverted.").

Along these lines, Dr. Loyd described the fifth step, obtaining informed consent "as to the risk of developing a dependence and addiction on the prescribed medication, even if it's for [a] legitimate medical need." *Id.* at 218. Dr. Loyd explained that "the approach has been to start with the least invasive, least dangerous things first, so as in the treatment of any disease, you want to be as least invasive as possible." ¹⁶ *Id.*

Regarding the standard of care for the general practice of medicine, Dr. Loyd described the initial patient visit as when the practitioner "establish[es] the framework and the groundwork of where you're starting, and subsequent medical visits will be . . . based on the intervention that you make in the first medical visit and what kind of improvements or not improvements that you have at subsequent visits." *Id.* at 223. Further, he characterized patient safety as the practitioner's "first consideration," citing to the Hippocratic Oath as "First, do no harm" and then "Second, then try to help." *Id.* at 224.

Dr. Loyd also testified about the importance of obtaining medical records from previous treating practitioners. *Id.*

¹⁶ "Somebody has chest pain, you don't move straight to open-heart surgery," Dr. Loyd analogized. Tr. 218. "There are things that you do prior to that and open-heart may be where you wind up, but definitely not where you start." *Id.*

at 225. A practitioner uses the information in other practitioners' treatment records to inform what treatment to prescribe and what treatments not to prescribe. *Id.* at 225–26.

Dr. Loyd testified that he worked with physician contractors in a hospital setting. *Id.* at 231. He testified that, in his experience, hospital physician contractors work in a group and report to the contractor head of the group. *Id.* at 232. The contractor group head, in turn, is "accountable to the hospital for the services they contract for," Dr. Loyd continued. *Id.* He specifically testified that contractor physicians are "subject to the record-keeping that's required by the accrediting bodies, Joint Commission, as well as Medicare, Medicaid, all the insurance companies and most commonly, the hospital that you're working for, and you're also subject to peer review within that same hospital." *Id.* at 232–33. Regarding record-keeping, Dr. Loyd testified that "there's a lot of risk with . . . not maintaining a patient record and safety would be the biggest one." *Id.* at 235–36. He continued that "it will violate . . . standards from accrediting bodies, such as Joint Commission." *Id.* at 236. Concluding, Dr. Loyd added that "you also get into the fact that if you don't have a medical record and you billed for that service to an insurance company, you don't have the documentation to support a level of care for that reimbursement, so that gets into what's considered to be fraud." *Id.*

Dr. Loyd continued to testify in increasing detail about the importance of maintaining medical records, or patient charts, during his testimony about GX 9 (prescriptions Respondent issued to J.J.), GX 11 (prescriptions Respondent issued to N.J.), and GX 14 (Dr. Loyd's report on Respondent's controlled substance prescribing for N.J. dated October 1, 2016). Medical records are the "crux," he stated, the "foundation of what we're trying to do here." Tr. 240. He explained that they are "going to establish . . . history, present illness, past medical history, surgical history, social history, physical examination, assessment and plan, . . . [and they are] going to validate how a diagnosis was arrived at and the subsequent treatment plan for that diagnosis . . . [and] for a lot of other things, other than that." *Id.* Dr. Loyd testified that he would expect Respondent to take a history, including a personal drug history, conduct a physical examination, make a diagnosis, start any intervention with a treatment that has the highest potential for benefit and the lowest amount of risk, and

establish and document informed consent before prescribing a controlled substance. *Id.* at 241–44.

As memorialized in his report regarding N.J., GX 14, Dr. Loyd explained that he received copies of three controlled substance prescriptions Respondent issued to N.J., but no medical record by Respondent about N.J. “so I couldn’t comment as to the thoroughness of the history, the appropriateness of the diagnosis.” *Id.* at 246; *see also id.* at 241 (discussing the controlled substances that Respondent prescribed for N.J.) As such, Dr. Loyd’s report summarizing his “findings for the material that . . . [he] reviewed that day” was five sentences, including the statement that “[t]here were no medical records to support the history, physical examination and thought process that led to the prescribing of these medications.” *Id.* at 246; GX 14, at 1. Dr. Loyd’s report concluded that “[e]ssentially, the controlled substances were prescribed with nothing to support their use” and, thus, that the “controlled substances prescribed for . . . [N.J.] were prescribed outside the scope of accepted medical practice and were not for a legitimate medical purpose.” GX 14, at 1.

Respondent’s Counsel, among other things, asked Dr. Loyd whether he had been “advised since the preparation of . . . [his] report that there are, in fact, medical records that exist for N.J.” and whether he had “seen those records.”¹⁷ Tr. 259. Dr. Loyd responded affirmatively to both questions. *Id.* at 259–60. He testified that he did not supplement his initial report after seeing those records. *Id.* at 260. Dr. Loyd also indicated that he was provided “nothing [on which] to base” an opinion about whether N.J. “exhibited any signs of drug dependency, . . . drug abuse . . . [or] drug-seeking behavior . . . [or] whether N.J. was] diverting these drugs to anyone else . . . [or] suffered any harm because of these prescriptions.” *Id.* at 260–61.

Thereafter, Government’s Counsel asked Dr. Loyd whether the “proposed” N.J. medical records included “any personal history of substance abuse with regard to any of the prescriptions that were issued.” *Id.* at 261, 271. Dr. Loyd answered that “[t]here was a block on the ED chart that asked about substance use and . . . [N.J.] denied alcohol or . . . [illicit] drugs. So she did do it, yes.” *Id.* at 271. He continued his

answer by stating that he would have expected to see documentation of follow-up to verify this information due to the “potential health risk for sure in combining substances that work in the central nervous system” with alcohol use since it would increase the “risk of a bad outcome.” *Id.* at 273. He testified, though, that he did not see any documentation of Respondent’s having addressed with N.J. the potential risks of mixing the controlled substances she prescribed for him with alcohol and of dependence and/or addiction with prolonged use. *Id.* at 273–74.

Government’s Counsel asked Dr. Loyd whether the “proposed” N.J. medical records indicated “any settings where . . . [N.J.] was purportedly treated.” *Id.* at 267; *see also id.* at 274. Dr. Loyd opined the “emergency department as well as I can tell.” *Id.* at 267–68. He also testified that he would expect a medical record’s statement about the setting at which medical treatment was provided to be accurate. *Id.* at 275. Dr. Loyd also testified that he “was surprised that once that initial [emergency department] visit happened, that from then on . . . [N.J.’s] respiratory and pain issues were] not taken care of in a primary care setting . . . or his primary care physician or a pain medicine specialist setting.”¹⁸ *Id.* at 269. He indicated that he “absolutely” would have expected to see coordination of treatment between an emergency department physician and a primary care physician given N.J.’s extended period of treatment in an emergency room setting, but found no evidence of it in the “proposed” N.J. medical records. *Id.* He also noted that, “whenever we’re talking about a case like this, . . . [seeking treatment at the emergency department] would have been a red flag that somebody is coming in here explicitly for narcotics.” *Id.* at 278. He elaborated by asking “why are they not presenting to their other doctor, to their primary care physician, who knows them much better than we do.” *Id.*

Government’s Counsel asked Dr. Loyd whether he saw any evidence of urine drug screening in the “proposed” N.J. medical records. *Id.* at 269–70. Dr. Loyd testified that he would have expected to see urine drug screening “[g]iven that a controlled substance was prescribed on multiple occasions,” but he did not. *Id.* Dr. Loyd stated that he would have expected N.J. to give informed consent “prior to the prescribing [of] controlled

substances,” but that he “did not see informed consent in the [proposed N.J.] medical record.” *Id.* at 270. He elaborated by testifying that N.J.’s family history of alcoholism, alcohol abuse, or alcohol misuse put N.J. “by definition at increased risk to misuse prescribed controlled substances” such that he would want to give N.J. “informed consent of the risk and benefits of using . . . [controlled] medication including his risk for possible misuse and development of subsequent dependence and/or addiction.” *Id.* at 270–71.

Further, Government’s Counsel asked Dr. Loyd whether he saw any evidence in the “proposed” N.J. medical records that Respondent had “explore[d] limitations on N.J.’s activities as a result of pain.” *Id.* at 276. Dr. Loyd responded that he thought, although he “could have misread this,” that “there was concern of whether or not . . . [N.J.] would be able to maneuver himself with regards to his weapon.”¹⁹ *Id.*; *see also id.* at 268 (Dr. Loyd’s testimony about N.J.’s “proposed” medical records that “there was some concern that he was having problems with maneuvering in his job with regards to . . . the pain that he was having.”). Dr. Loyd testified that he saw nothing in N.J.’s “proposed” medical records that Respondent explored any treatment modality for N.J. other than a controlled substance. *Id.* at 276. Dr. Loyd also testified that Respondent did not document, in the “proposed” N.J. medical records, that she followed up with N.J. during any subsequent visit about whether the controlled substance prescription she issued for him was effective by, for example, asking him whether he was able to maneuver as he needed to do his job after starting the controlled substance therapy. *Id.* at 276–77.

Dr. Loyd summarized the “fundamental issues” he had with the “proposed” N.J. medical records “as far as the proper prescribing [of] controlled substance[s],” stating that the “root of the issue is really in the establishment of the diagnosis being such that it would have required a controlled substance before trying any other non-controlled substance modality for treatment.” *Id.* at 274. He testified that, after reviewing the “proposed” medical records for N.J., he did not change his opinion that Respondent prescribed controlled substances for N.J. for no legitimate purpose. *Id.* at 277.

I agree with the Chief ALJ that Dr. Loyd “presented as knowledgeable, objective, and thoughtful in his answers,

¹⁷ The Government did not mention a medical record for N.J. in its Exhibit List or in either of its Pre-Hearing Statements. Presumably, Respondent provided her Counsel with the medical records for N.J. about which Respondent’s Counsel asked Dr. Loyd. Tr. 259.

¹⁸ Dr. Loyd stated that he has seen patients use emergency departments for medical treatment due to “economic reasons,” such as no health insurance. Tr. 277–78.

¹⁹ The testimonies of both DI and Dr. Loyd indicate that N.J. worked for the Sheriff, possibly as a Deputy Sheriff. Tr. 200, 268.

without any indication of an agenda.” RD, at 17. In this Decision/Order, I give controlling weight to Dr. Loyd’s testimony as did the Chief ALJ because Dr. Loyd “has extensive experience practicing, writing, and lecturing on the subject matter of his testimony.” *Id.* Further, I note that Respondent did not put on a case or proffer a witness, let alone an expert, to rebut Dr. Loyd’s testimony. As such, in addition to the independent persuasiveness of Dr. Loyd’s testimony, his testimony is unrebutted in the record before me.

D. Respondent’s Case

Immediately after the Government rested, Respondent’s Counsel moved for summary disposition on the ground that the Government had not established a *prima facie* case. Tr. 285–86. Among other things, the motion was based on the theory that the Government introduced no evidence that the drug logs Respondent submitted to DEA were “falsified,” as opposed to simply “not correct,” because the incorrect material was not a mandated data point in the MOA. *Id.* at 286–87. The motion argued that the MOA does not prohibit Respondent from issuing controlled substance prescriptions to J.J. because it only prohibits prescribing to “family members,” and boyfriends, friends, and “intimate acquaintances” are not “family members.” *Id.* at 287.

The summary disposition motion argued that the Government failed to establish a violation based on Respondent’s medical care of J.J. “in that those records are not before the Court . . . “[s]o there’s really nothing to consider.” *Id.* at 287–88. The summary disposition motion explicitly acknowledged the existence of the charge that Respondent created no medical records for N.J. while claiming that “any criticisms were not . . . presented to [Respondent] as far as the quality of the care, the need for those prescriptions and so she, therefore, was not prepared to respond to those.”²⁰ *Id.* at 288.

Regarding the allegation that Respondent did not store controlled substances securely, the summary disposition motion argued that “according to the [G]overnment’s own witness, if . . . [Respondent] kept . . . [controlled substances] in a locked, secure cabinet within the shed, that

would have been in compliance with the . . . plain language of the regulations.” *Id.* at 289. According to the motion, “[t]here is no evidence that . . . [Respondent] dispensed any medications from this residence, that she operated any business or that she intended to operate a business” and, therefore, “many of the regulations that were cited . . . [in the OSC] are not applicable.”²¹ *Id.*

The summary disposition motion counted initial inventory requirements among the “many” inapplicable regulations cited in the OSC. *Id.* at 291. Referring to the legal argument that the invoice Respondent received in connection with the Moore Medical purchase satisfied the “initial inventory” requirement, the motion admitted that the invoice “failed to specify” whether the “inventory” was taken at the beginning or the end of the day. *Id.* The motion minimized this deficiency, arguing that “this was not an ongoing concern,” that Respondent “was the only one who had control of these drugs,” and that “[i]f this case is about the fact she didn’t say whether it was the beginning or the end of the day, I mean that’s not why we’re here.” *Id.* at 291–92. According to the motion, Respondent “had not yet commenced a business.” *Id.* at 294. “I think they’re reading way too much into” the declaration in the Moore Medical purchase packet, the motion argued, and “[t]here’s no evidence that she had any kind of any ongoing—that she had a medical clinic that she was operating, that she . . . dispense[d] any of these drugs . . . [– s]he didn’t charge for seeing patients, which is—that’s conducting a business.” *Id.* The motion argued that “[t]hese regulations are designed for people who are seeing patients and dispensing these drugs and documenting the distribution thereof” and “[i]t’s imposing far too many requirements on somebody who is just anticipating doing so in the future.” *Id.*; see also *id.* at 295.

The Chief ALJ provided input during the presentation of Respondent’s summary disposition motion. Tr. 290–310. The Chief ALJ pointed out the weaknesses and deficiencies of the motion’s arguments while agreeing with their strengths. *Id.* For example, the Chief ALJ agreed that the burden is on the Government to present a *prima facie* case, and stated clearly that the “question is, in viewing the evidence in

the light most favorable to the [G]overnment, have they put some evidence on everything they would need to make out a *prima facie* case.” *Id.* at 295; see also *id.* at 299 (Chief ALJ’s statements pointing to record evidence countering the argument that the Government had not met its burden for the allegation that Respondent did not submit all of the MOA-required drug logs); *id.* at 300–01 (Chief ALJ’s assessment of whether the Government presented sufficient evidence to establish its case, and views on the appropriateness of a sanction); *id.* at 301–03 (discussion involving Respondent’s Counsel and Chief ALJ about the record evidence to date about MOA compliance); *id.* at 303–05 (conversation between Respondent’s Counsel and the Chief ALJ about unlawful prescribing allegations); *id.* at 305–07 (focused analysis of the existing record evidence and stipulation concerning the documentation of Respondent’s controlled substance prescribing); *id.* at 307–09 (targeted discussion of “nonsense” and “anomalies” in Respondent’s controlled substance prescribing documentation).

In addition to hearing the back-and-forth between her Counsel and the Chief ALJ, Respondent also had the benefit of hearing the position of Government’s Counsel on several issues, substantive and procedural. *Id.* at 310–15. For example, Government’s Counsel repeatedly argued that Respondent’s Counsel had presented argument about her “theory of the case,” as opposed to “sworn testimony.” *Id.* at 310–11. He explicitly addressed the Government’s position that, “as the record stands now, there are no patient charts in the record [for either J.J. or N.J.], one of the charges . . . in the charging documents.” *Id.* at 313.

The analyses and discussions that took place in Respondent’s presence also included the Chief ALJ’s ruling on Respondent’s motion for summary disposition. *Id.* at 311–12, 314–15, 322–29. In denying Respondent’s summary disposition motion, the Chief ALJ provided input on specific matters at issue in the proceeding. First, he specifically stated that the Government had “put forth some evidence that some information on the dispensing logs, including the location where patients N.J. and J.J. were treated may be inaccurate.” *Id.* at 324. The Chief ALJ added that, for the Government to prevail on this allegation, “there is no requirement that purported falsehoods be restricted to information that was specifically required by the terms of the MOA.” *Id.*

²⁰ The summary disposition motion stated that DI “did not determine that the drugs were being diverted or there was nothing indicating it was for anything other than a legitimate medical purpose from his perspective as a non-physician.” Tr. 288. She added that N.J., himself, “offer[ed]” that there was a legitimate medical purpose for the controlled substance prescriptions. *Id.*

²¹ According to Respondent’s summary disposition argument, her residence “was not a principal place of business or professional practice. She did not manufacture, distribute, import, export, or dispense drugs at that location. That is undisputed under the record.” Tr. 289.

Second, the Chief ALJ stated that he was reserving Respondent's motion as to whether Respondent violated the MOA by prescribing controlled substances to J.J., assuming that Respondent and J.J. were romantically involved. *Id.* at 324–25. The Chief ALJ noted that the Government cited to “authority under Tennessee law that prescribing to a patient . . . [with] whom the physician has a romantic involvement falls below the applicable standard of care in prescribing, and thus this aspect of the motion is denied.” *Id.* at 325. He also noted that “a precise timeline of the romantic involvement [between Respondent and J.J.] was not established.” *Id.* Third, the Chief ALJ also stated that the Government presented “at least some evidence that controlled substance prescribing to patient J.J. in the face of a potential romantic relationship and in the absence of medical documentation . . . could place the prescribing as outside the course of a professional practice and without a legitimate medical purpose[,], and in violation of Tennessee state law.” *Id.* at 325–26.

Fourth, on the allegation of unlawful controlled substance prescribing to N.J., the Chief ALJ similarly denied Respondent's motion, stating that the Government presented “at least some evidence that the prescribing was done without medical documentation, and even if medical documentation that had been previously presented by the Respondent, albeit presented late were presumed valid, that it was inadequate to establish that the prescribing was done for [a] legitimate medical purpose and within the course of a professional practice.” *Id.* at 326.

Fifth, the Chief ALJ denied Respondent's motion for summary disposition on the allegation that Respondent failed to provide DEA with all of the drug logs required by the MOA. *Id.* at 326–27. He stated that DI testified about how the relevant DEA office processes mail and about the search DI conducted for Respondent's drug logs. *Id.* at 327.

Sixth, the Chief ALJ stated that the Government presented “some evidence that the Respondent did maintain controlled substances in this residential outside shed” and reserved the “legal issue as to whether their registration was required.” *Id.* Seventh, also regarding the allegation that Respondent stored controlled substances in a shed with inadequate security, the Chief ALJ denied Respondent's summary disposition motion because the Government presented “some evidence that the Respondent stored controlled substances in a shed with a modest lock

under conditions that arguably did not satisfy the security requirements set forth in the regulations actually or substantially.” *Id.* at 328.

Eighth, the Chief ALJ denied Respondent's motion concerning the initial controlled substance inventory requirement because the Government presented “some evidence that the Respondent admitted to DI . . . that she never prepared or maintained an initial inventory as well as evidence in a declarations signed by the Respondent that she was expanding an already existing practice.” *Id.* at 328–29. He added that “an invoice prepared by the vendor would not satisfy her inventory obligation under the regulations.”²² *Id.* at 329.

After the Chief ALJ ruled on her motion for summary disposition, Respondent stipulated that she did not treat J.J. or N.J. at a hospital. *Id.* at 330–31; *see also supra* n.3. She also obtained the Chief ALJ's approval to receive into evidence her corrective action plan as Administrative Law Judge Exhibit 29. Tr. 334–35 (Chief ALJ's statement that the “corrective action plan is not something that the administrative law judge deals with,” “[i]t's not part of what I have to recommend,” “I can include it in the record or not,” and “[i]t needs to go to the Office of Diversion Control.”).

Thereafter, Respondent's Counsel advised the Chief ALJ that Respondent was not going to present a case, stating that her client “would like to accept responsibility for her errors in this case” and “[w]e would just request leniency in your recommendations.” Tr. 335. The Chief ALJ appropriately pointed out that, for a respondent to prevail, prior Agency decisions require a respondent's unequivocal acceptance of responsibility and the submission of appropriate remedial measures. *Id.* at 336–37 (Chief ALJ's statements, including “I want to make you aware of it. . . . I just wanted to raise that with you before you've rested.”). Respondent reaffirmed her decision to rest after consulting again with her Counsel during a break that the Chief ALJ took specifically for that purpose. *Id.* at 337–39.

Accordingly, I find that Respondent's decision not to present a case was communicated to the Chief ALJ after she had been present at the hearing, after she had the opportunity to observe and hear the Government's evidence in support of the OSC's allegations, and

²² When Respondent's Counsel asked for the Chief ALJ's ruling on the allegation that Respondent did not complete dispensing logs, he indicated that his ruling was subsumed in the rulings he issued. Tr. 329.

after she had the opportunity to hear the Chief ALJ's ruling denying her motion for summary disposition. I find that Respondent's decision not to present a case was communicated after the Chief ALJ received her corrective action plan into evidence and after she stipulated that she never treated J.J. or N.J. in a hospital. I further find that after Respondent's decision not to present a case was first communicated to the Chief ALJ, the Chief ALJ offered his interpretation of past Agency decisions' statements about the unequivocal acceptance of responsibility and his practical reflection that her not presenting a case “cuts off any other evidence coming in.” *Id.* at 338. I also find that, after the Chief ALJ offered his interpretation and practical reflection, Respondent's Counsel asked for and received “a few minutes to confer with my client in response to Your Honor's comments.” *Id.* at 337. Finally, I find that Respondent consulted with her Counsel before the initial communication of her decision not to present a case, and had the additional opportunity to consult with her Counsel after the Chief ALJ offered his interpretation and practical reflection. *Id.* at 338 (Respondent's Counsel, responding to the Chief ALJ's question about how much time “will be enough” to confer with her client about whether to present a case, stating that “I mean, we've discussed it, so there's not much additional we need to discuss, but just in light of the point Your Honor has raised, I want to just make sure that I have an opportunity for her to talk about this before making any final decisions.”).

Respondent's decision not to present a case means that there are no factual disagreements between witnesses' testimonies that I need to resolve.

E. Allegation That Respondent Continued To Issue Controlled Substance Prescriptions to Individuals Who Are Intimate or Close Acquaintances, and to an Individual With Whom She had a “Romantic Interaction” in Violation of Tenn. Comp. R. & Regs. R. 0880-2-.14(8)(a) and Tenn. Code Ann. § 63-6-214(b)(1)

The OSC charged Respondent with “issuing prescriptions to individuals who are intimate or close acquaintances.” OSC, at 2. DI testified that both Respondent and J.J. told him that they were in a romantic relationship for a brief period time.²³ I credit DI's testimony. I find, however,

²³ When DI interviewed him, N.J. also stated that Respondent and J.J. were girlfriend-boyfriend. Tr. 199.

that this evidence of a boyfriend-girlfriend relationship, a romantic relationship, or any other record evidence detail neither the parameters of the romantic involvement of Respondent and J.J. nor the period of time of that romantic involvement.

F. Allegations That Respondent Provided Controlled Substance Prescription Drug Logs to DEA With Falsified Entries “Noncompliant With Terms of the June 2011 MOA” in Violation of 21 U.S.C. 843(a)(4)(A), and “Provid[ed] Misleading Information to Investigating Agents” Implicating 21 U.S.C. 823(f)(5)

The OSC alleged that Respondent’s drug log submissions to DEA for August, October, and November of 2012, February, May, June, July, October, and November of 2013, and January 2014 contained false entries “noncompliant with the terms of the June 2011 MOA” because they “represented that . . . [she] issued controlled substance prescriptions to J.J. and his brother N.J. . . . while treating these individuals at Methodist Fayette Hospital in Somerville, Tennessee; Baptist Memorial Hospital in Covington, Tennessee; and/or McNairy Regional Hospital in Selmer, Tennessee.” OSC, at 2. It also alleged that Respondent “provid[ed] misleading information to investigating agents, 21 U.S.C. 823(f)(5).” *Id.* at 3.

I find that the record evidence includes twelve instances when Respondent submitted drug logs to DEA with entries concerning J.J. and/or N.J. whose cover transmittal letters and specific J.J. and N.J. entries falsely, according to one of the parties’ stipulations, indicate that “[a]ll prescriptions were written while on duty as the ER physician at the named hospital for registered patients.” GX 12a, at 1, 4, and 5 (October 2012, two for J.J. and two for N.J.); GX 12b, at 1 and 4 (November 2012, two for J.J.); GX 12c, at 1, 6, and 7 (February 2013, two for J.J. and one for N.J.); GX 12d, at 1, 9, and 16 (April–May 2013, two for J.J. and one for N.J.); GX 12e, at 1, 7, and 18 (May–June 2013, two for J.J. and one for N.J.); GX 12f, at 1 and 9 (July 2013, one for N.J.); GX 12g, at 1, 6, and 17 (August 2013, two for J.J. and one for N.J.); GX 12h, at 1 and 3 (October 2013, two for J.J.); GX 12i, at 1, 4, and 7 (November 2013, two for J.J.); GX 12j, at 1 and 2 (January 2014, one for J.J.); GX 12k, at 1 and 5 (February 2014, one for J.J.); GX 12l, at 1 and 3 (April 2014, one for J.J.); *see also supra*, section II.C. and section II.D. (discussing the stipulation reached during the hearing). Likewise, I find that the stipulation Respondent

agreed to during the hearing that she did not treat J.J. or N.J. at a hospital is Respondent’s implicit admission that those twelve cover transmittal letters she sent DEA with the MOA-required drug logs contained in GX 12a through GX 12l and the individual entries for J.J. and N.J. in those drug logs are not fully accurate. *Supra*, section II.D. (discussing the stipulation reached during the hearing).

Accordingly, I find substantial un rebutted record evidence that Respondent provided controlled substance prescription drug logs to DEA with falsified entries, thereby providing misleading information to DEA investigators.

G. Allegation That Respondent Issued Controlled Substance Prescriptions to J.J. and N.J. for No Legitimate Medical Purpose and Outside the Usual Course of Professional Practice in Violation of 21 CFR 1306.04(a), Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(a)(4) and (e), and Tenn. Code Ann. § 63–6–214(b)(12)

The OSC alleged that Respondent “issued controlled substances . . . [to J.J. and N.J.] for no legitimate medical purpose and outside the usual course of professional practice,” citing provisions of federal and state law. OSC, at 2. I find that DI’s un rebutted testimony, in conjunction with GX 7, GX 8, and GX 9, establish that Respondent issued controlled substance prescriptions to J.J. on paperwork from a hospital at which Respondent did not treat J.J. GX 7, GX 8, GX 9, Tr. 99–103; *see also supra*, section II.D. (discussing the stipulation reached during the hearing). I further find that these prescriptions were written over the course of eighteen months and were for Percocet (eleven prescriptions for this Schedule II controlled substance), Tussionex (two prescriptions for this Schedule II controlled substance), Zolpidem (one prescription for this Schedule IV controlled substance), and Alprazolam (four prescriptions for this Schedule IV controlled substance).

I also find that DI’s un rebutted testimony, in conjunction with GX 7, GX 8, and GX 11, establish that Respondent issued controlled substance prescriptions to N.J. on paperwork from a hospital at which Respondent did not treat N.J. GX 7, GX 8, GX 11, Tr. 100–03; *see also supra*, section II.D. (discussing the stipulation reached during the hearing).

As already discussed, the Exhibits entered into the record do not include medical records purporting to be either for J.J. or for N.J. I note that this matter is due, in part, to Respondent’s successful objection to the admission of

a proposed Government exhibit purporting to be Respondent’s medical record for J.J. and to her decision during the administrative hearing not to present a case.²⁴ *Supra* section II.D. Accordingly, I find that substantial record evidence shows that Respondent did not adequately document in a medical record her controlled substance prescribing for either J.J. or N.J.²⁵

H. Allegation That Respondent Failed To Maintain Medical Records Pertaining to Her Prescribing of Controlled Substances to N.J. in Violation of Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(e)(3)(i) and Tenn. Code Ann. § 63–6–214(b)(12)

Similarly, the OSC alleged that Respondent “fail[ed] to maintain treatment records pertaining to . . . [her] prescribing of controlled substances to N.J.” OSC, at 2. The record certified to me contains no admitted exhibit constituting a medical record that Respondent created for N.J. The un rebutted record evidence shows that DI subpoenaed the medical records of the three hospitals at which Respondent served as a contract emergency medicine physician and that all three of the hospitals provided a “no record” response for N.J. medical records. GX 7, GX 8. This OSC charge puts the Government in a position of proving a negative. Despite this hurdle, I find substantial record evidence that Respondent did not maintain medical records adequately documenting her controlled substance prescribing for N.J. There are six reasons for my finding.

First, as already discussed, I find that the relevant three hospitals sent “no record” responses after receiving DI’s subpoenas for N.J. medical records. Second, I find that, if medical records existed concerning her controlled substance prescribing for N.J., Respondent certainly would know about them and be able to raise their existence in furtherance of her defense against the

²⁴ The record also shows the awareness of Respondent’s Counsel of a “proposed” medical record for N.J. and her decision not to take steps to have it introduced into the record. *Supra* section II.C; *infra* section II.H.

²⁵ In addition, this Agency has applied, and I apply here, the “adverse inference rule.” As the D.C. Circuit explained, “Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.” *Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW) v. Nat’l Labor Relations Bd.*, 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance v. District of Columbia*, 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent’s decision not to provide evidence within her control gives rise to an inference that the evidence is unfavorable to Respondent.

OSC. She chose not to do so and she did not do so. Instead, after raising the matter herself by questioning Dr. Loyd about whether he was “advised since the preparation of . . . [his expert] report that there are, in fact, medical records that exist for N.J.” and asking him whether he has “seen those records,” Respondent chose not to delve into the content of “those records” or Dr. Loyd’s opinion of them. Tr. 259–61. Instead, she asked him about whether he updated his expert report, (he answered in the negative), she questioned him further about the content of his expert report, and she inquired about matters not addressed in his expert report before ending her cross-examination. *Id.* at 260–61. After the Government’s second question on re-direct, she objected about not having received Dr. Loyd’s “new opinions” because he had not supplemented his expert report and claimed to be “blind-sided” and “sandbagged.” *Id.* at 261–67. After the Chief ALJ announced his finding that she had “opened the door” and denied her objections, decisions with which I agree, Respondent heard the Government’s extensive re-direct of Dr. Loyd.

Third, I find that that Government re-direct of Dr. Loyd focused largely on the insufficiency of the “proposed” medical records for N.J. as documentation for the prescribing of controlled substances. *Id.* at 267–77. The re-direct explored what the “proposed” N.J. medical record indicated about N.J.’s multiple visits to Respondent, a physician practicing emergency medicine, as opposed to visits to a primary care physician, and the lack of evidence of coordination of treatment between Respondent and N.J.’s primary care physician. *Id.* at 267–69. It addressed the lack of urine drug screening despite the multiple controlled substance prescriptions and the lack of documented informed consent. *Id.* at 269–70. The re-direct also explored the lack of evidence that Respondent addressed with N.J. his increased risk of misusing controlled substances given his family history of substance use disorder, the lack of evidence that Respondent followed up on N.J.’s report of “occasional alcohol use,” and the lack of evidence that Respondent warned N.J. about the potential risk of mixing alcohol and controlled substances. *Id.* at 270–74. It concerned the lack of evidence that Respondent explored with N.J. treatment modalities other than controlled substances and the lack of evidence that Respondent asked N.J. about the impact of the controlled substance therapy on his mobility. *Id.* at

276–77. Finally, it concluded with Dr. Loyd’s testimony that his review of the “proposed” N.J. patient chart did not change his opinion that Respondent prescribed controlled substances to N.J. without a legitimate medical purpose. *Id.* at 277. Despite her hearing the damaging testimony the Government elicited from Dr. Loyd on re-direct, Respondent declined the opportunity for re-cross, allowing this damaging testimony to stand, un rebutted. *Id.* at 279.

Fourth, I apply the “adverse inference rule,” as the Agency has done in the past, to the fact that Respondent did not offer into evidence any medical records she created in conjunction with her controlled substance prescribing for N.J. As the D.C. Circuit explained, “Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.” *Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW) v. Nat’l Labor Relations Bd.*, 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance v. District of Columbia*, 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent’s decision not to provide evidence within her control gives rise to an inference that any such evidence is unfavorable to her.

Fifth, I find that Respondent, after hearing Dr. Loyd’s damaging expert testimony, agreed to a joint stipulation admitting that she did not treat N.J. (or J.J.) at any of the three hospitals at which Respondent practiced as a contract emergency physician at the time and to which DI had issued subpoenas for J.J. and N.J. medical records. Tr. 330–31. In this context, the stipulation is damaging to Respondent’s OSC defense because the record evidence was that Respondent wrote the controlled substance prescriptions she issued to N.J. (and J.J.) on the paper of one of these three hospitals. GX 9 and GX 11. The stipulation thus highlights an irregularity in Respondent’s controlled substance prescribing for N.J. (and J.J.).

Sixth, for all of these reasons, I find that Respondent was aware of the existence of the “proposed” N.J. medical records and did not seek their admission because she did not consider them to be records that adequately documented her controlled substance prescribing for N.J.

I. Allegation That Respondent Violated the Terms of the MOA by Failing To Provide Drug Logs to DEA for Periods During Which She Issued Controlled Substance Prescriptions, Implicating 21 U.S.C. 823(f)(5)

The OSC alleged that Respondent “failed to provide drug logs to DEA in February, March, and April 2012; and January, March and April 2013” although she “issued controlled substance prescriptions during the above periods.” OSC, at 3. The record includes documentary evidence that Respondent issued a controlled substance prescription, for Tussionex, to N.J. on April 30, 2014. GX 11, at 5. The drug log that Respondent submitted to DEA for April 2014, however, does not include this Tussionex prescription issued to N.J. on April 30, 2014. GX 12l. Accordingly, I find that Respondent submitted to DEA a drug log for April 2014 that did not comply with the MOA because it did not include the April 30, 2014 controlled substance prescription she issued to N.J. for Tussionex.

At the hearing, the Government suggested, but subsequently “withdrew” its suggestion, that Respondent issued other controlled substance prescriptions that she did not document in a drug log submitted to DEA. Tr. 117, 119–20. I compared the prescriptions Respondent issued for J.J. and N.J. according to GX 9 and GX 11 with Respondent’s drug logs in the record, GX 12a through GX 12l. The only discrepancy that I found, based on the prescriptions in the record for which there is a drug log in the record, is the same prescription about which DI testified: To N.J. for Tussionex, dated April 30, 2014.

Further, I found two prescriptions, one each in GX 9 (J.J.) and GX 11 (N.J.) for which there is no Respondent drug log in the record: To J.J. for Alprazolam dated January 16, 2013, and to N.J. for Tussionex dated September 13, 2012. Both September 2012 and January 2013 are months covered by the MOA’s drug log requirement. The issue, therefore, is whether Respondent provided DEA with a drug log for the months of September 2012 and January 2013 or whether, as Respondent suggests, she provided DEA a drug log for those months but DEA misfiled them.

DI’s unrefuted testimony is that Respondent admitted to him that she used certified mail to send her drug logs to DEA, and that Respondent did not provide DI with certified mail proof of having sent the missing MOA-required drug logs to DEA. *Supra* section II.C. As already discussed, the Agency has applied, and I am applying here, the “adverse inference rule.” *Supra* section

II.G. and section II.H. According to that rule, Respondent's failure to provide relevant evidence within her control, in this case certified mail proof of having sent the September 2012 and January 2013 MOA-required drug logs to DEA, gives rise to an inference that the evidence is unfavorable to her. My application of the "adverse inference rule" is particularly appropriate in this case because the MOA requires Respondent to maintain her controlled substance prescribing, administering, and dispensing records "in a separate file or log, in chronological order," a copy of which shall be sent to DEA monthly. GX 3, at 2. In other words, the MOA requirement to which Respondent agreed calls for her to maintain the controlled substance records and to send a copy of them to DEA monthly. *Id.* As such, Respondent should have had a complete set of the MOA-required records to provide the DI on his demand, not merely incomplete proof that she sent DEA the MOA-required logs every month by certified mail.

Accordingly, I find that the record includes substantial evidence that Respondent did not provide drug logs to DEA for the months of September 2012 and January 2013 even though she issued a controlled substance prescription in each of those two months. The OSC noticed the lack of a drug log for January 2013, so I sustain that specific OSC charge. OSC, at 3. The OSC did not notice the lack of a drug log for September 2012, so I do not consider my finding that Respondent did not provide a drug log to DEA for that month in this Decision and Order. I do not sustain the other charges in paragraph 4 of the OSC due to the lack of substantial record evidence to support them. *Id.*

J. Allegation That Respondent Stored Controlled Substances at an Unregistered Location in Violation of 21 CFR 1301.12(a)

The OSC alleged that Respondent stored controlled substances in an exterior storage shed at her residence, an unregistered location. OSC, at 3. Respondent admitted that she stored controlled substances in the exterior storage shed attached to her residence. *See, e.g.,* GX 4, at 3; *see also supra* section II.C. The record includes no evidence that the address of Respondent's residence and attached shed appears on a certificate of registration issued to her. GX 1 (Facsimile of Respondent's DEA Certificate of Registration), at 1; GX 2 (Certification of Respondent's Registration History), at 1–2; GX 4, at 1

(address of Respondent's residence and attached shed).

Further, Respondent represented to a controlled substance supplier that she required the controlled substances she was purchasing for her "private practice" of medicine, and gave that controlled substance supplier "St Croix LLC" as her company's name. GX 6, at 8, 5. After having those controlled substances shipped to the address on her registration, the address of one of the hospitals at which she worked as a contract physician, she moved the controlled substances to a shed attached to her residence. GX 6, at 6, 8; GX 2, at 1; TBME Final Order, at 2. She admitted "writing prescriptions for controlled substances for . . . J.J. who she treated at her home." TBME Final Order, at 3. She subsequently reported that the controlled substances had been stolen from the shed attached to her residence. GX 4, at 1, 3.

Accordingly, I find that the record includes substantial evidence that Respondent stored controlled substances at the shed attached to her residence, an unregistered location.

K. Allegation That Respondent Failed To Provide Effective Controls or Procedures To Guard Against the Theft or Diversion of Controlled Substances as Required by 21 CFR 1301.71(a)

The OSC alleged that Respondent "failed to provide effective controls or procedures to guard against the theft or diversion of controlled substances as required by 21 CFR 1301.71(a). OSC, at 3. The undisputed record evidence is that Respondent reported to the Memphis Police Department the "theft" of controlled substances from the "shed attached to . . . [her] residence." GX 4, at 1–3. According to the Memphis Police Department Incident Report, "[t]here was no damage to the shed, as the door was unlocked." *Id.* at 3. DI also testified that the shed had a "regular doorknob that would be operated with a key," among other things. Tr. 81; *see also supra* section II.C. Accordingly, I find that the record includes substantial evidence that Respondent stored controlled substances in an inadequately-secured shed, that she reported the theft of the controlled substances from that shed, and that controlled substances she stored in the shed attached to her residence were stolen from that shed.

L. Allegations That Respondent Did Not Conduct an Initial Inventory of Controlled Substances Received on March 7, 2013, and That Respondent Did Not Maintain Records of the Controlled Substances She Dispensed as Required by 21 CFR 1304.03(a) and (b), 1304.04(g), 1304.11(b) and (e), and 1304.21(a)

The OSC alleged that Respondent "did not conduct an initial inventory of controlled substances received on March 7, 2013." OSC, at 3. The record evidence does not include an initial inventory, or any inventory, of the controlled substances Respondent purchased and received that meets regulatory requirements. Further, according to DI's uncontroverted testimony, Respondent admitted to him that "she had never created a regulatory or an initial inventory." *Id.* at 86–87. Accordingly, I find both that Respondent did not conduct an initial inventory of the controlled substances she received on March 7, 2013, and that she admitted she did not conduct such an initial inventory.

The OSC also alleged that Respondent did not "maintain records of . . . [her] dispensing" of the controlled substances she received on March 7, 2013. OSC, at 3. The record does not include substantial evidence that Respondent dispensed any of the controlled substances she received on March 7, 2013. *Supra* section II.C. Accordingly, I find that this allegation is not supported by substantial record evidence.

III. Discussion

Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Under Section 304 of the Controlled Substances Act (hereinafter, CSA), "[a] registration . . . to . . . distribute[] or 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). In the case of a "practitioner," which is defined in 21 U.S.C. 802(21) to include a "physician," Congress directed the Attorney General to consider the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the . . .

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 15,227, 15,230 (2003).

According to Agency decisions, I “may rely on any one or a combination of factors and may give each factor the weight [I] deem [] appropriate in determining whether” to revoke a registration. *Id.*; see also *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U.S. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); see also *Akhtar-Zaidi*, 841 F.3d at 711; *Hoxie*, 419 F.3d at 482. “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as appellate courts have recognized, findings under a single factor are sufficient to support the revocation of a registration. *MacKay*, 664 F.3d at 821.

Under DEA’s regulation, “[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government’s evidence in support of its *prima facie* case is confined to Factors One, Two, Four, and Five.²⁶ I find that the

²⁶ As to Factor Three, there is no evidence in the record that Respondent has a “conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(f)(3). However, as Agency decisions have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010), *pet. for rev. denied, MacKay*

Government’s evidence satisfies its *prima facie* burden of showing that Respondent’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f). I further find that Respondent chose not to put on a case to rebut the Government’s *prima facie* case.

A. Factor One—Recommendation of the Appropriate State Licensing Board

Factor One calls for consideration of the “recommendation of the appropriate state licensing board or professional disciplinary authority” in the public interest determination. 21 U.S.C. 823(f)(1). The record evidence does not include a direct recommendation to the Agency from the TBME about Respondent’s continued registration.

As already discussed, the Chief ALJ, without objection from either party, took official notice of the TBME Final Order concerning Respondent. *Supra* section I. The TBME Final Order concerns some of the matters addressed in the OSC and in this proceeding: The MOA, Respondent’s purchase of controlled substances and the Declaration of Controlled Substances Purchases in the Moore Medical purchase packet, the Memphis Police Incident Report, and Respondent’s controlled substance prescribing for J.J. TBME Final Order, at 2–3. The TBME found facts sufficient to establish that Respondent engaged in unprofessional, dishonorable or unethical conduct in violation of Tenn. Code Ann. § 63–6–214(b)(1), failed to create and maintain medical records in violation of Tenn. Comp. Rules & Regs. 0880–02–.15(4)(a), and violated Tenn. Comp. Rules & Regs. 0880–02–.15(4)(d) by failing to include, in all medical records produced in the course of the practice of medicine for all patients, all information and documentation listed in Tenn. Code Ann. § 63–2 101(c)(4) and such additional information necessary to ensure that a subsequent reviewing or treating physician can both ascertain the basis for the diagnoses, treatment plan and outcomes, and provide continuity of care.

The TBME ordered the reprimand of Respondent’s Tennessee medical license, ordered her to complete successfully multiple specific medical courses, ordered her to “maintain good and lawful conduct,” and ordered her to pay assessed civil penalties and costs. *Id.* at 5–6.

v. Drug Enf’t Admin., 664 F.3d 808 (10th Cir. 2011). Agency decisions have therefore held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.*

While the TBME Final Order is not a “direct recommendation” for purposes of Factor One, it does indicate a recommendation on a subset of the allegations and evidence before me. *John O. Dimowo, M.D.*, 85 FR 15,800, 15,810 (2020).²⁷ I apply the same analysis and reach the same conclusion here given the differences between the allegations and evidence set out in the TBME Final Order and the allegations and evidence before me. In sum, while the terms of the TBME Final Order are not dispositive of the public interest inquiry in this case and are minimized due to the differences in the evidence in the TBME Final Order and the uncontroverted record evidence before me, I consider the TBME Final Order’s reprimand of Respondent’s Tennessee medical license and give it minimal weight in Respondent’s favor since the TBME charges could have resulted in the suspension or revocation of her medical license.²⁸ Notice of Charges, at 1.

Factors Two and/or Four—The Respondent’s Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

1. Allegation That Respondent Continued To Issue Controlled Substance Prescriptions to Individuals Who Are Intimate or Close Acquaintances, and to an Individual With Whom She Had a “Romantic Interaction” in Violation of Tenn. Comp. R. & Regs. R. 0880–2–.14(8)(a) and Tenn. Code Ann. § 63–6–214(b)(1)

The first Tennessee authority the OSC cited for this allegation adopts Opinion 8.14 of the American Medical Association Code of Ethics. This Opinion concerns observing professional boundaries and meeting professional responsibilities. <https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-observing-professional-boundaries-and-meeting-professional/2015-05>.²⁹

²⁷ The *John O. Dimowo, M.D.* Agency decision stands for the proposition that “[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state ‘recommendation’ referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state.” 85 FR at 15,810.

²⁸ Respondent’s Exceptions to Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated May 30, 2018 (hereinafter, *Resp Exceptions*), at 14.

²⁹ American Medical Association Code of Ethics Opinion 8.14 was updated in March of 1992 and then again in June of 2016. The text of Opinion 8.14 on the website that is dated 2015, therefore, was in effect at the time relevant to the allegations underlying this proceeding.

According to the Opinion, “sexual contact that occurs concurrent with the patient-physician relationship constitutes sexual misconduct.” AMA Code of Ethics Opinion 8.14 (2015).

As already discussed, the Government did not present substantial evidence that Respondent issued controlled substance prescriptions to J.J. concurrent with a period during which they engaged in sexual contact. *Supra* section II.E. Accordingly, I find that the Government did not present sufficient evidence to support this allegation and, therefore, I find that there is no factual basis in the record to support this allegation.

2. Allegation That Respondent Issued Controlled Substance Prescriptions to J.J. and N.J. for No Legitimate Medical Purpose and Outside the Usual Course of Professional Practice in Violation of 21 CFR 1306.04(a), Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(a)(4) and (e), and Tenn. Code Ann. § 63–6–214(b)(12), and
3. Allegation That Respondent Failed To Maintain Medical Records Pertaining to Her Prescribing of Controlled Substances to N.J. in Violation of Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(e)(3)(i) and Tenn. Code Ann. § 63–6–214(b)(12).

According to the CSA, “Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[] or dispense, a controlled substance.” 21 U.S.C. 841(a)(1). The CSA’s implementing regulations state, among other things, that 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).

Respondent’s registration is for her medical practice in Tennessee. As such, I also evaluate the record evidence according to the applicable laws and standard of care in Tennessee.³⁰ The Government alleged that Respondent violated the standard of care in Tennessee, citing Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(a)(4) and (e), Tenn. Code Ann. § 63–6–214(b)(12), and Tennessee Controlled Substance Prescribing Policy Statement, GX 15.³¹

According to these Tennessee authorities, a physician may be

disciplined for prescribing a controlled substance “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.” Tenn. Code Ann. § 63–6–214(b)(12). These Tennessee authorities state that the prescribing of a controlled substance will be presumed to be legitimate if, among other things, it takes place “[a]fter a documented medical history . . . and physical examination . . . including an assessment and consideration of the pain, physical and psychological function, any history, any potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a . . . controlled substance.” Tenn. Comp. R. & Regs. R. 0880–2–.14(6)(e)(3)(i); *see also supra* section II.C. (standard of care testimony of Dr. Loyd); GX 15, at 1–2 (Tennessee Controlled Substance Prescribing Policy Statement that “It is not what you prescribe, but how well you manage the patient’s care, and document that care in legible form, that is important,” “What the Board *does* have is the expectation that physicians will create a record that shows: –Proper indication for the use of drug or other therapy; –Monitoring of the patient where necessary; –The patient’s response to therapy based on follow-up visits; and –All rationale for continuing or modifying the therapy.” “Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that *non-addictive modalities are not appropriate or they do not work*,” and “To reiterate, one of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is *inadequate records*.”); GX 14 (“There were no medical records to support the history, physical examination and thought process that led to the prescribing of these medications. Essentially, the controlled substances were prescribed with nothing to support their use. The controlled substances prescribed for N.J. were prescribed outside the scope of accepted medical practice and were not for a legitimate medical purpose.”); Tr. 277 (the “proposed” medical records for N.J. did not change Dr. Loyd’s opinion that Respondent prescribed controlled substances for N.J. for no legitimate purpose); *id.* at 240 (Dr. Loyd’s testimony that the medical record is the “crux.” It is the foundation that

establishes history, present illness, past medical history, surgical history, social history, physical examination, assessment and plan, and that is going to validate how a diagnosis was arrived at and the subsequent treatment plan for that diagnosis.).

I already found that the substantial record evidence is that Respondent did not document in a medical record her controlled substance prescribing for either J.J. or N.J., and that there is substantial record evidence that Respondent did not maintain records adequately documenting her controlled substance prescribing for N.J. *Supra* sections II.C., II.G., and II.H. Based alone on a subset of the Tennessee legal requirements for legitimate controlled substance prescribing, the uncontroverted record evidence is that Respondent’s prescribing of controlled substances for J.J. and N.J. was not legitimate. For example, it did not take place after Respondent documented a medical history for, and physical exam of, either J.J. or N.J. *Supra* sections II.C. and II.G. In fact, as the record evidence does not even include a medical record for J.J. or N.J., Respondent’s controlled substance prescribing does not, by definition, satisfy applicable Tennessee legal authorities.³² Accordingly, I sustain both of these OSC charges, finding that Respondent’s controlled substance prescribing for J.J. and N.J. was not for a legitimate medical purpose and was outside the usual course of professional practice in Tennessee.

4. Allegation That Respondent Stored Controlled Substances at an Unregistered Location in Violation of 21 CFR 1301.12(a)

The regulations implementing the CSA require that a “separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are . . . dispensed by a person.” 21 CFR 1301.12(a). The CSA defines “dispense” to “include[e] the prescribing . . . of a controlled substance”—a fact that Respondent’s arguments and exceptions downplay. 21 U.S.C. 802(10); *see also* OSC, at 3; Resp Exceptions, at 1–4. Respondent asks me to find that her storage of controlled substances in the shed attached to her residence was lawful because her residence was not a principal place of business or professional practice and she did not “dispense” controlled substances from

³⁰ *See Gonzales v. Oregon*, 546 U.S. 243, 269–71 (2006).

³¹ Respondent did not offer any exhibit purporting to address or memorialize the Tennessee standard of care. She did not object when the Chief ALJ proposed to take official notice of GX 15. Tr. 332–33.

³² For all of these reasons, I reject Respondent’s claim that it is a “legal fiction” that Respondent had “no medical records” for J.J. and N.J. Resp Exceptions, at 12.

there. *Id.* According to her Exceptions, Respondent only had the “intention of eventually opening a private practice” and “[t]here is simply no evidence in the record that Respondent issued a single prescription for a controlled substance from her residence.” *Id.* at 1, 4. I decline to do so.

First, Respondent submitted no record evidence, let alone substantial record evidence, providing a factual basis for her argument. Indeed, the substantial record evidence includes Respondent’s representation that she was engaged in private practice, called St. Croix LLC, and that her justification for purchasing controlled substances was to support the “addition” of age management medicine, weight loss, and wellness to her private practice. GX 6, at 8; *see also* TBME Final Order, at 3 (Respondent’s admission that she wrote controlled substance prescriptions for J.J. whom “she treated at her home”). Second, her argument conflicts with a core principle of the CSA, the establishment of a closed regulatory system devised to “prevent the diversion of drugs from legitimate to illicit channels.” *Gonzales v. Raich*, 545 U.S. 1, 13–14, 27 (2005). Respondent’s proposal would be a danger to public health and safety as it would allow the storage of controlled substances anywhere, as long as no dispensing took place at the location. Respondent offers no convincing argument that the CSA gives me authority to adopt her proposal. Further, there is none and I decline to establish such a dangerous policy.

I already found that the record includes substantial, uncontroverted evidence, including Respondent’s admission, that Respondent stored controlled substances at an unregistered location. *Supra* section II.J. I found substantial, uncontroverted evidence that Respondent represented to her controlled substance supplier that the controlled substances she ordered were required for her “private practice.” *Id.* I also found substantial, uncontroverted evidence that Respondent admitted writing controlled substance prescriptions for J.J. whom she admitted she treated at her home. *Id.* Accordingly, I sustain the OSC charge that Respondent stored controlled substances at an unregistered location.

5. Allegation That Respondent Failed To Provide Effective Controls or Procedures To Guard Against the Theft or Diversion of Controlled Substances as Required by 21 CFR 1301.71(a)

According to 21 CFR 1301.71(a), “[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of

controlled substances.” As already discussed, I found substantial record evidence that Respondent stored controlled substances in an inadequately secured shed and that she reported the theft of the controlled substances from that shed. *Supra* section II.K. By itself, the fact that controlled substances were stolen from the shed in which Respondent stored them is substantial record evidence that she did not provide “effective” controls or procedures to guard against theft or diversion of controlled substances. If more evidence were required, the uncontroverted record evidence also details the out-in-the-open location of the shed in which Respondent chose to put the controlled substances she had purchased and the minimally protective door, knob, and lock Respondent put between the outside world and the controlled substances. *Supra* section II.C. and section II.K. For all of these reasons, I reject Respondent’s claims that the shed was “securely locked . . . [and] substantially constructed.” Resp Exceptions, at 8–11.

Accordingly, I find that Respondent failed to provide effective controls or procedures against the theft or diversion of controlled substances in violation of 21 CFR 1301.71(a).

6. Allegations That Respondent Did Not Conduct an Initial Inventory of Controlled Substances Received on March 7, 2013 and That Respondent Did Not Maintain Records of the Controlled Substances She Dispensed as Required by 21 CFR 1304.03(a) and (b), 1304.04(g), 1304.11(b) and (e), and 1304.21(a)

The OSC alleges that Respondent did not conduct an initial inventory of the controlled substances she received on March 7, 2013. I already found both that Respondent did not conduct an initial inventory of the controlled substances she received on March 7, 2013, and that she admitted she did not conduct such an initial inventory. *Supra* section II.L.

Among her arguments concerning this allegation, Respondent posited that it is acceptable to use the Moore Medical purchase invoice for the controlled substances as an initial inventory. *See, e.g.*, Tr. 292–93; Resp Exceptions, at 7–8. I reject Respondent’s arguments and her positions that minimize the inventory requirement in general. I also reject Respondent’s dismissal of the deficiency, the failure to specify whether the inventory was taken at the beginning or the end of the day, that renders the Moore Medical purchase invoice an insufficient substitute for an initial inventory. *See, e.g.*, Tr. 291–95.

I note, however, that Respondent accurately pointed out that the portion of the regulation stating that inventories “may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory” was not alleged in the OSC. Tr. 292; 21 CFR 1304.11(a). I agree that the OSC did not notice section 1304.11(a) and that Respondent did not consent to litigate it. Accordingly, although I found substantial evidence that Respondent violated this inventory requirement, I find that the OSC did not give Respondent adequate notice of 21 CFR 1304.11(a) and, as a result, I do not sustain the OSC allegation that Respondent did not conduct an initial inventory of the controlled substances she received on March 7, 2013.³³

The OSC also alleges that Respondent did not maintain records of the controlled substances she dispensed. 21 CFR 1304.03(b). The Government, however, did not present substantial evidence that Respondent dispensed controlled substances. *Supra* section II.L. I find that a predicate to finding substantial evidence that Respondent did not maintain records of the controlled substances she dispensed is substantial evidence that Respondent actually dispensed controlled substances. Accordingly, the record does not include substantial evidence that Respondent dispensed controlled substances and, therefore, there is no factual basis on which the allegation that Respondent failed to maintain dispensing records may stand.

Factor Five—Respondent’s “Conduct Which May Threaten the Public Health and Safety.”

1. Allegations That Respondent Provided Prescription Drug Logs to DEA With Falsified Entries “Noncompliant With Terms of the June 2011 MOA” in Violation of 21 U.S.C. 843(a)(4)(A), and “Provid[ed] Misleading Information to Investigating Agents” Implicating 21 U.S.C. 823(f)(5)

The OSC cites 21 U.S.C. 843(a)(4)(A) as the basis for the allegation that Respondent provided non-MOA compliant falsified controlled substance prescription drug logs to DEA. OSC, at 2. The Government has not, however, established the existence of each of the

³³ Citing 21 CFR 1304.11(b), Respondent argues in her exceptions that she was not under a duty to conduct an initial inventory for the controlled substances she received on March 7, 2013. Resp Exceptions, at 4–7. I disagree with Respondent’s arguments for the reasons already discussed and reiterate that I am not sustaining the OSC’s initial inventory allegation solely because it was not noticed adequately.

elements of 21 U.S.C. 843(a)(4)(A). For example, according to the provision, the furnished or omitted “false or fraudulent material information” must pertain to “any application, report, record, or other document required to be made, kept, or filed.” 21 U.S.C. 843(a)(4)(A). The Government did not establish that Respondent’s controlled substance drug logs constitute a document “required to be made, kept, or filed” under any provision from 21 U.S.C. 801 through 21 U.S.C. 971. In sum, the Government has not established all of the elements of 21 U.S.C. 843(a)(4)(A) and, therefore, the Government has not proven that this provision applies to the facts of this case. Accordingly, I do not sustain the OSC allegation based on 21 U.S.C. 843(a)(4)(A).³⁴

I already found that there is substantial record evidence that Respondent provided misleading information to investigating DEA agents. *Supra* section II.F. This misleading information “may threaten the public health and safety” by, for example, impeding DEA’s investigative efforts. Accordingly, I shall consider Respondent’s provision of misleading information to DEA under Factor Five. 21 U.S.C. 823(f)(5).

2. Allegation That Respondent Violated the Terms of the MOA by Failing To Provide Drug Logs to DEA for Periods During Which She Issued Controlled Substance Prescriptions, Implicating 21 U.S.C. 823(f)(5)

The MOA that Respondent signed calls for her to “maintain a log of all controlled substances prescribed, administered or dispensed to patients at her registered premises or elsewhere,” for her to “maintain” the controlled substance prescribing, administering, and dispensing information “in a separate file or log, in chronological order,” and for her to send a copy of the log to DEA every month. GX 3, at 2. The uncontroverted record evidence is that Respondent did not comply fully with this requirement. *Supra* section II.I. (my findings that Respondent submitted to DEA an incomplete controlled substance prescription drug log for April 2014 and that Respondent did not provide a drug log to DEA for the month of January 2013, even though the record contains substantial evidence that she issued a controlled substance prescription in that month).

³⁴ Given my decision not to sustain the 21 U.S.C. 843(a)(4)(A) allegation, I need not address Respondent’s exception to the Chief ALJ’s conclusion that Respondent “intentionally or knowingly submitted false information” to DEA. Resp Exceptions, at 11–12.

Respondent’s argument that she sent DEA the MOA-required logs rings hollow because the MOA also requires that she maintain the required information herself. Had she done so, she would have been able to provide DI with complete evidence of her full compliance with the MOA controlled substance prescription drug log requirement. As she apparently did not, or at least chose not to submit evidence that she did, I find that Respondent failed to provide fully-compliant controlled substance prescription drug logs to DEA for periods during which she issued controlled substance prescriptions. Accordingly, I shall consider Respondent’s failure to comply fully with the MOA controlled substance prescription drug log requirement under Factor Five. 21 U.S.C. 823(f)(5).

Summary of Factors One, Two, Four, and Five

As found above concerning Factor One, while the TBME Final Order is not a “direct recommendation” for purposes of Factor One, it indicates a recommendation on a subset of the allegations and evidence before me. As such, while the terms of the TBME Final Order are not dispositive of the public interest inquiry in this case and are minimized due to the differences in the evidence laid out in the TBME Final Order and the uncontroverted record evidence before me, I consider the TBME Final Order’s reprimand of Respondent’s Tennessee medical license minimally in her favor because the TBME charges could have resulted in the suspension or revocation of her medical license.

Regarding Factors Two and Four, the Government did not establish with substantial evidence that Respondent engaged in “sexual misconduct” by issuing controlled substance prescriptions to J.J. “concurrent” with having “sexual contact” with him. The Government also did not establish with substantial evidence that Respondent failed to maintain records of the controlled substances she dispensed. Although there is substantial record evidence that Respondent did not conduct an initial inventory of the controlled substances she received on March 7, 2013, I am not weighing this charge against her due to OSC notice insufficiencies.

Also regarding Factors Two and Four, there is substantial evidence in the record before me that Respondent issued controlled substance prescriptions over the course of eighteen months, including fifteen Schedule II controlled substances, for no legitimate

medical purpose and outside the usual course of professional practice, that Respondent failed to maintain medical records pertaining to her prescribing of controlled substances, that Respondent stored controlled substances at an unregistered location, and that Respondent failed to provide effective controls or procedures to guard against the theft or diversion of controlled substances.

Regarding Factor Five, although the Government did not establish all of the elements of a violation of 21 U.S.C. 843(a)(4)(A), the Government did put substantial evidence into the record that Respondent submitted a drug log to DEA that did not include every controlled substance prescription she issued during the period covered by the drug log. The Government also put substantial evidence into the record that Respondent did not comply with the MOA by failing to provide a drug log to DEA for a month during which she issued a controlled substance prescription. The Government also put substantial evidence into the record that Respondent included misleading information in the drug logs she submitted to DEA about the locations at which she issued controlled substance prescriptions. OSC, at 3.

Accordingly, I conclude that it would be “inconsistent with the public interest” for Respondent to have a registration due to the substantial evidence of her violations of the CSA and its implementing regulations. 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f); *see Wesley Pope*, 82 FR 14,944, 14,985 (2017).

Sanction

Where, as here, the Government presented a *prima facie* case that it would be “inconsistent with the public interest” for Respondent to retain a registration, and Respondent did not rebut the Government’s *prima facie* case, the “burden of proof shifts” to Respondent “to show why . . . [she] can be trusted with a registration.” *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018), quoting *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *see also MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005)). Further, past performance is the best predictor of future performance and, when a registrant has “failed to comply with . . . [her] responsibilities in the past, it makes sense for the agency to consider whether . . . [she]

will change . . . [her] behavior in the future.” *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, 789 F. App’x, 724, 733 (citing *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d at 831 (citing *MacKay v. Drug Enf’t Admin.*, 664 F.3d at 820 (“[T]hat consideration is vital to whether continued registration is in the public interest.”) and *Alra Labs., Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995) (“An agency rationally may conclude that past performance is the best predictor of future performance.”))).

Circuit courts have also approved the Agency’s acceptance of responsibility requirement. *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, 789 F. App’x, at 732; *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d at 830 (citing *MacKay v. Drug Enf’t Admin.*, 664 F.3d at 820 (“The DEA may properly consider whether a physician admits fault in determining if the physician’s registration should be revoked.”); see also *Jeffrey Stein, M.D.*, 84 FR 46,968, 46,972–73 (2019) (unequivocal acceptance of responsibility); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009) (collecting cases). The Agency has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases); *Samuel Mintlow, M.D.*, 80 FR at 3652 (“Obviously, the egregiousness and extent of a registrant’s misconduct are significant factors in determining the appropriate sanction.”). The Agency has also considered the need to deter similar acts in the future by Respondent and by the community of registrants. *Id.*

In terms of egregiousness, the violations that the record evidence shows Respondent committed go to the heart of the CSA—not complying with the closed regulatory system devised to “prevent the diversion of drugs from legitimate to illicit channels” and not prescribing controlled substances in compliance with the applicable standard of care and in the usual course of professional practice. *Gonzales v. Raich*, 545 U.S. at 13–14, 27.

Respondent did not testify. As already noted, after the Chief ALJ issued his Recommended Decision, in which he concluded that Respondent’s acceptance of responsibility through her Counsel was “ineffectual” and did not “point[] to anything that she was acknowledg[ing] that she did wrong,” Respondent submitted her MCACAP. *Supra* section I; RD, at 66. In the MCACAP, Respondent submitted a signed and notarized Affidavit dated

July 11, 2018. In the Affidavit, Respondent stated that she:

accept[ed] responsibility for the mistakes and inadvertent errors in judgment I made that are the subject of this matter, including, but not necessarily limited to: a. Failing to appreciate the importance of accurate record-keeping as it relates to the logs required by my 2011 Memorandum of Agreement with the DEA; b. Failing to keep better treatment records for J.J. and N.J.; c. Failing to keep better prescription records for J.J. and N.J.; d. Failing to have more thorough and detailed treatment plans for J.J. and N.J.; [and] e. Listing J.J. and N.J. as patients of any hospital in my DEA logs.

MCACAP Affidavit, at 2. While Respondent’s Affidavit-based acceptance of responsibility points to areas in which she admits to making “mistakes and inadvertent errors of judgment,” she admits that her Affidavit does not go to the trouble of naming all of her “mistakes and inadvertent errors of judgment.” *Id.* Further, the Affidavit describes the areas for which she takes responsibility in general terms only, and the areas do not include all of the violations the Government proved with substantial evidence. For example, while Respondent’s Affidavit states that she failed to “keep better treatment records,” “keep better prescription records,” and “have more thorough and detailed treatment plans,” the record certified to me contains no “treatment records,” no “prescription records,” and no “treatment plans” whatsoever. *Supra* section II.G. and II.H.

DEA agreed to grant Respondent’s last application for a registration upon her execution of the MOA. MOA, at 2 (“Upon execution by all parties to this agreement, DEA agrees to grant . . . [Respondent’s] application for DEA registration in Schedules II through V.”). A term of the MOA is that Respondent “agrees to abide by all Federal, State and local laws and regulations pertaining to controlled substances.” *Id.* As already discussed, I found that Respondent failed to abide by “all Federal, State and local laws and regulations pertaining to controlled substances.” *Supra* sections III.B.2., III.B.3., III.B.4., III.B.5., III.C.1., and III.C.2. Yet, while the MCACAP indicates that Respondent subsequently attended and passed the courses required by the TBME Final Order plus others, nothing in the MCACAP and certified record convinces me that Respondent learned from those courses and will apply consistently going forward what those courses taught about the CSA’s recordkeeping requirements and prescribing controlled substances in compliance with the applicable standard of care and in the usual course

of professional practice. For example, Respondent’s Affidavit states that she acknowledges “failing to seek legal and compliance counsel, as well as educating . . . [herself] on the pertinent rules and regulations of controlled substance, prior to taking any actions related to my desire to open a private practice.” *Id.* Instead of being reassuring, this portion of Respondent’s acknowledgement is very concerning because it exhibits her view that her need to become educated on the “pertinent rules and regulations of controlled substances” is tied to her opening a private practice, not to her being entrusted with a registration.

Further, Respondent’s Affidavit does not address her ordering controlled substances for delivery at her registered address and her removal of those controlled substances from her registered address to the shed attached to her home. Even after reading the MCACAP and Respondent’s Affidavit, I see nothing in them or in the record certified to me suggesting that Respondent appreciates that Congress passed, and the President of the United States signed into law, a statute that requires registrants to take specific actions to keep controlled substances in a closed regulatory system created to “prevent the diversion of drugs from legitimate to illicit channels.” There is little in the record before me showing that Respondent appreciates the difference between ordering controlled substances and ordering groceries.³⁵ In sum, given Respondent’s failure to comply with the MOA’s provisions and her failure to demonstrate her ability to apply the information conveyed in the courses Respondent attended and passed, it is not reasonable for me, at this time, to believe that Respondent’s future handling and prescribing of controlled substances will comply with legal requirements.³⁶ *Alra Labs., Inc. v.*

³⁵ Respondent’s eighth Exception asserts that the “record as a whole establishes that the continued registration of Respondent . . . would be consistent with the public interest.” Resp Exceptions, at 13. The Exception does not elaborate on this assertion, and the fact that Respondent did not present a case contributes substantially to the assertion’s incredibility. The Exception’s statements that J.J. and N.J. “affirmed that the prescriptions issued by Respondent were to treat them for injuries they had” and that the “Government produced no competent evidence that the prescriptions were not for legitimate medical needs” are not helpful. The legitimacy of controlled substance prescriptions is assessed by applicable federal and state legal standards and standards of care, not by the opinions of those to whom the prescriptions were issued. *Supra* section II.G., II.H., III.B.2., and III.B.3; see also Resp Exceptions, at 13–14.

³⁶ I do not consider remedial measures when a Respondent does not unequivocally accept responsibility. Respondent’s MCACAP presentation

Drug Enf't Admin., 54 F.3d at 452 (“An agency rationally may conclude that past performance is the best predictor of future performance.”). Accordingly, I shall order that Respondent’s registration be revoked and that all pending applications to renew or modify Respondent’s registration, and any application for a new registration in Tennessee, be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FS2669868 issued to Jennifer L. St. Croix, M.D. I further hereby deny any pending application of Jennifer L. St. Croix, M.D., to renew or modify this registration, as well as any other pending application of Jennifer L. St. Croix, M.D. for registration in Tennessee. This Order is effective May 12, 2021.

D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021–07410 Filed 4–9–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Publication of Model Notices for Health Care Continuation Coverage Provided Pursuant to the Consolidated Omnibus Budget Reconciliation Act (COBRA) and Other Health Care Continuation Coverage, as Required by the American Rescue Plan Act of 2021, Notice

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice of the availability of the model health care continuation coverage notices required by the American Rescue Plan Act of 2021.

SUMMARY: On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 (ARP). Section 9501(a)(5)(D) and (6)(D) of ARP directs the Department of Labor (Department) to develop model notices for use by group health plans and other entities that, pursuant to the ARP, must provide notices of the availability of premium reductions and additional election periods for health care continuation coverage. This document announces the availability of the model notices.

DATES: April 12, 2021.

of remedial efforts was limited, unpersuasive, and not reassuring.

FOR FURTHER INFORMATION CONTACT: David Sydlik, Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, (202) 693–8335. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) created the health care continuation coverage provisions of title I of the Employee Retirement Income Security Act of 1974 (ERISA), the Internal Revenue Code (Code), and title XXII of the Public Health Service Act (PHS Act). These provisions are commonly referred to as the COBRA continuation provisions, and the continuation coverage that they mandate is commonly referred to as COBRA continuation coverage. Under the ARP, premium assistance is available to certain individuals who are eligible for COBRA continuation coverage due to a qualifying event that is a reduction in hours or an involuntary termination. If an individual qualifies for the premium assistance, the individual need not pay any of the COBRA premium otherwise due to the plan. This premium assistance is available for COBRA continuation coverage for periods of coverage from April 1, 2021 through September 30, 2021. Group health plans subject to the COBRA continuation provisions are subject to the ARP’s premium assistance provisions, notice requirements, and an additional election period. Federal COBRA continuation coverage provisions do not apply to group health plans sponsored by employers with fewer than 20 employees. However, participants and beneficiaries of group health plans sponsored by employers with fewer than 20 employees may be eligible for the premium assistance under state laws that provide comparable coverage, often referred to as “mini-Cobra,” with an alternative notice required under the ARP for these plans not subject to federal COBRA laws.¹

¹ Under COBRA, group health plans must provide covered employees and their families with certain notices explaining their COBRA rights. A group health plan must provide covered employees and qualified beneficiaries with a notice which describes their right to COBRA continuation coverage and how to make an election (election notice). The ARP provides that COBRA election notices already provided for qualifying events occurring during this time period but which did not include information on the availability of the premium assistance are not complete. As such, the end of the 60-day period for electing COBRA continuation coverage is measured from when a complete notice is provided. Moreover, although under COBRA a timely election generally requires a plan to make coverage available retroactively to

The ARP requires group health plans to provide four notices: (1) A “General Notice,” (2) an “Alternative Notice,” (3) a “Notice in Connection with Extended Election Periods,” and (4) a “Notice of Expiration of Period of Premium Assistance.” Under ARP section 9501(a)(5)(B), the General Notice, the Alternative Notice, and the Notice in Connection with Extended Election Periods must include:

- A prominent description of the availability of the premium assistance, including any conditions on the entitlement;
- a form to request treatment as an “Assistance Eligible Individual”²;
- the name, address, and telephone number of the plan administrator (and any other person with relevant information about the premium assistance);
- a description of the obligation of individuals paying reduced premiums who become eligible for other coverage to notify the plan and the penalty for failing to meet this obligation; and
- (if applicable) a description of the opportunity to switch coverage options.

The Notice in Connection with Extended Election Periods must also include a description of the extended election period. The ARP also requires group health plans to provide a Notice of Expiration of Period of Premium Assistance to individuals whose premium assistance is coming to an end (whether due to the expiration of their COBRA continuation coverage or the expiration of the period of premium assistance), which must explain that the premium assistance for such individual will expire soon; include a prominent identification of the date of such expiration; and explain that such individual may be eligible for coverage without any premium assistance through—(I) COBRA continuation coverage; or (II) coverage under a group health plan. This notice must be provided within the period that is 45 days before the date of such expiration and ending on the day that is 15 days before the date of such expiration. The Departments of Labor and the Treasury share jurisdiction for enforcement of the COBRA continuation provisions. The Department of Labor is committed to

the date of the loss of coverage, the ARP allows an individual to elect COBRA continuation coverage with premium assistance for a period beginning on or after April 1, 2021.

² In general, an “Assistance Eligible Individual” is, with respect to coverage beginning April 1, 2021 and ending September 30, 2021, an individual who is eligible for COBRA continuation coverage as a result of a reduction in hours or an involuntary termination of employment; and who elects COBRA coverage (when first offered or during the additional election period).