Dated: July 23, 2020.

Melody Braswell,

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

[FR Doc. 2020–16351 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0076]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Restoration of Explosives Privileges—ATF Form 5400.29

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

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until August 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

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

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

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

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

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *The Title of the Form/Collection:* Application for Restoration of Explosives Privileges.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5400.29.

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

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

Primary: Individuals or households.

Other: Business or other for-profit.

Abstract: Persons who wish to ship, transport, receive, or possess explosive materials, but are prohibited from doing so, must complete the Application for Restoration of Explosives Privileges—ATF Form 5400.29. The completed form must be submitted to ATF, to determine if the applicant is likely to act in a manner that endangers public safety, and that granting relief is not contrary to the public interest.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 300 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes to complete the form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 150 hours, which is equal to 300 (# of respondents) * 1 (# of responses per respondents) * .5 (30 minutes or the total time to complete each response).

(7) *An Explanation of the Change in Estimates:* The adjustment to this IC include an increase in the public burden cost to $9,765, which is due to inclusion of the cost to conduct ATF in-person interviews with both the respondent's supervisor and a coworker, as well as mailing costs.

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

Dated: July 23, 2020.

Melody Braswell,

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

[FR Doc. 2020–16350 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Salvatore Cavaliere, D.O.; Decision and Order

On April 2, 2018, the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Salvatore Cavaliere, D.O. (hereinafter, Respondent). OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. FC2341876 pursuant to 21 U.S.C. 824(a)(4) ''because [he had] committed acts which render [his] registration inconsistent with the public interest . . . .'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

I. Procedural History

Specifically, the OSC alleged that Respondent sold to an acquaintance, approximately 32,000 dosage units of Lortab [1] and approximately 16,000 dosage units of Norco [2] outside of the usual course of professional practice in violation of 21 CFR 1306.04(a). *Id.* at 2–3. The OSC also alleged that Respondent failed to maintain records required by both federal and state law. *Id.* at 3–4. Specifically, it alleged that Respondent failed to maintain and provide a dispensing log in violation of 21 CFR 1304.03(b) and 1304.21(a), Mich. Comp. Laws Ann. §§ 333.7303a and 333.17745 (West 2020),[3] and Mich. Admin. Code r.

[1] Lortab is hydrocodone bitartrate/acetaminophen 7.5/500mg—which at the time was a Schedule III controlled substance. *Id.* at 2.

[2] Norco is hydrocodone bitartrate/acetaminophen 7.5/325mg—a Schedule III controlled substance until October 2014, and a Schedule II controlled substance since October 2014. *Id.* at 2. Hereinafter, ''hydrocodone bitartrate/acetaminophen'' will be used to refer to Lortab and Norco collectively.

[3] Throughout this Decision, I have cited to the Michigan Compiled Laws Annotated current through P.A. 2020, No. 129, of the 2020 Regular Session, 100th Legislature. Although I have cited to a contemporary compilation, the substantive portions of the Michigan Compiled Laws that I cite in this Decision were in effect at all times relevant to this case. *See* Mich. Comp. Laws Ann. (West, current through P.A. 2010, No. 383 (End) of the

Continued

338.3153 (2020),[4] or copies of his inventories of controlled substances in violation of 21 CFR 1304.11(c) and Mich. Admin. Code r. §§ 338.3151 and 338.3152.[5] *Id.* Finally, the OSC alleged that Respondent issued prescriptions outside of the usual course of professional practice and beneath the standard of care for the State of Michigan in violation of 21 CFR 1306.04(a), and he failed to document adequate patient files for eight individual patients in violation of Mich. Comp. Laws Ann. §§ 333.7303 and 333.16213. *Id.* at 4–5.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 6 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 6 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated May 1, 2018, Respondent timely submitted a designation of representative, which stated, ''My client desires to waive any hearing in this cause.'' [6] Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) B, at 1. Simultaneously, Respondent submitted a proposed Corrective Action Plan.[7] *Id.* at 3–8. On May 15, 2018, a former Assistant Administrator of the Diversion Control Division rejected Respondent's proposed Corrective Action Plan and ''den[ied] the request to discontinue or defer administrative proceedings.'' RFAAX C.

On March 22, 2019, the Government forwarded its RFAA, along with the evidentiary record in this matter, to my office. Attached to the RFAA were 383 pages of exhibits including, but not limited to, declarations from a DEA Diversion Investigator and a DEA Special Agent, 62 pages of prescriptions issued by Respondent, 33 pages of patient records, and 216 pages of text messages from Respondent's cell phone. RFAAX A–G. The RFAA asserted that ''Respondent has waived his right to a hearing in this matter and did not file a written statement of position in lieu of a hearing request.'' RFAA, at 1. Despite Respondent's waiver the Government certified that the RFAA and all of the exhibits thereto were served on Respondent's representative. RFAA, at 33.

Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Respondent committed acts rendering his continued registration inconsistent with the public interest. I further find that revocation is the appropriate sanction. Based on the representations of the Government in its RFAA, I make the following findings of fact.

II. Findings of Fact

A. Respondent's DEA Registration

Respondent is registered with DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. FC2341876, at 525 East Big Beaver Road, Suite #100, Troy, MI 48083. RFAAX D (Controlled Substance Registration Certificate). This registration expired on August 31, 2019.[8] *Id.*

B. Overview of the Government's Evidence Supporting the Allegations

As discussed above, the Government alleged three factual bases for the revocation of Respondent's registration pursuant to 21 U.S.C. 824(a)(4) and 823(f). OSC, at 1. First, the Government alleged that Respondent dispensed and sold controlled substances (specifically hydrocodone bitartrate/acetaminophen) to an acquaintance outside of the ordinary course of professional practice. *Id.* at 2–3. As evidence in support of this allegation, the Government presented DEA records from the Automation of Reports and Consolidated Orders System (hereinafter, ARCOS) and records received from McKesson Corporation pursuant to a subpoena showing Respondent's purchases of hydrocodone bitartrate/acetaminophen. RFAAX E–1 (Respondent's Purchase History from ARCOS), and E (Declaration of DI), at 1–2. The Government presented records of prescriptions for controlled substances that Respondent issued to individual B.S., which were received pursuant to a subpoena on CVS Pharmacy. RFAAX E–3 (Copies of Prescriptions Issued by Respondent to B.S.), and E, at 2–3. The Government presented copies of text messages between individual B.S. and Respondent that were received from Respondent's cell phone pursuant to a search warrant on July 13, 2016. RFAAX E–4 (Text Messages Between respondent and B.S.), and E, at 3. And finally, the Government presented the affidavit of a DEA Diversion Investigator (hereinafter, DI), which summarized her investigation, including the statements made by B.S. during an interview. RFAAX E.

Second, the Government alleged that Respondent was unable to provide to DEA various records that Respondent was required by law to maintain. *Id.* at 3–4. As evidence in support of this allegation, the Government presented the affidavit of DI regarding the results of a search warrant executed at Respondent's registered address on July 13, 2016. RFAAX E, at 3.

And third, the Government alleged that Respondent issued prescriptions outside of the usual course of professional practice and beneath the standard of care in the State of Michigan, and that he failed to maintain complete patient files for seven [9] individual patients. *Id.* at 4–5. As evidence in support of this allegation, the Government presented patient records received from Respondent pursuant to an administrative subpoena issued by a DEA Special Agent (hereinafter, SA) that was served on October 30, 2017, and answered on November 16, 2017. RFAAX F (Declaration of SA), including Exhibits F–1 through F–7 (Patient Files), and F–9 (Letter from Respondent's Representative dated November 15, 2017). The Government presented pharmacy records received by the SA (pursuant to administrative subpoenas) during the course of her investigation. RFAAX F–8 (Copies of Prescriptions Issued by Respondent), and F, at 2. And finally, the Government presented evidence from its expert witness, R. Andrew Chambers, M.D., regarding the applicable standard of care. RFAAX G (Declaration of R. Andrew Chambers,

2010 Regular Session of the Michigan Legislature, 95th Legislature).

[4] Throughout this Decision, I have cited to the Michigan Administrative Code current through June 15, 2020. Although I have cited to the contemporary version, the substantive portions of the Michigan Administrative Code that I cite in this Decision were in effect at all times relevant to this case. *See* Mich. Admin Code r. §§ 338.3151–3153 (2002).

[5] The OSC contained a third record keeping allegation, but the Government appears to have abandoned the third allegation and did not include any evidence in support of the allegation or otherwise brief the issue in the RFAA; therefore, I am not including it herein. *Compare* OSC, at 3–4, *with,* RFAA, at 9, 30–31.

[6] As the Respondent filed a designation of representative and submitted a Corrective Action Plan as permitted by the OSC, I find that the Government's service of the OSC was adequate.

[7] Respondent's proposed Corrective Action Plan would, among other things, have Respondent follow the various laws he was alleged to have violated, meet quarterly with a ''physician monitor,'' complete eight hours total of continuing medical education in recordkeeping and substance abuse addition, and surrender his DEA Certificate of Registration for six months. RFAAX B.

[8] The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019).

[9] In the RFAA, the Government abandoned the allegations as to one patient, C.C. *Compare,* OSC, at 4, *with* RFAA, at 10–14.

M.D.), and G–1 (Curriculum Vitae of R. Andrew Chambers, M.D.).

C. Applicable Standard of Care in the State of Michigan

The Government retained Dr. Chambers to review medical files obtained during the investigation for seven patients, and to evaluate the medical files for compliance with the standard of care and usual course of the professional practice in Michigan. Dr. Chambers is a practicing, board-certified addiction psychiatrist. RFAAX G, at 1; and G–1, at 1–2. He is also an Associate Professor of Psychiatry at the Indiana University School of Medicine, Department of Psychiatry, IU Neuroscience Center and the head of the Addiction Psychiatry Training Program ''where [h]e train[s] psychiatrists and physicians on the diagnosis and treatment of mental illness and drug addiction.'' RFAAX G, at 1. Although Dr. Chambers is licensed in Indiana, he has ''reviewed various materials to familiarize [him]self with the standard of care for the prescribing of controlled substances in Michigan.'' *Id.* at 3. Moreover, DEA previously found that ''Dr. Chambers [was] qualified to provide an expert opinion on the standards of professional practice for prescribing controlled substances under the Michigan Board's Guidelines and Michigan law,'' among other things. *Bernard Wilberforce Shelton, M.D.,* 83 FR 14,028, 14,036 (2018). I find that Dr. Chambers is an expert in the standards of professional practice for prescribing controlled substances in Michigan and I credit his uncontroverted report.

Dr. Chambers credibly declared that, in Michigan, ''any controlled substance must be prescribed for a legitimate or professionally recognized therapeutic purpose.'' RFAAX G, at 4. To properly determine whether a prescription has a legitimate or professionally recognized therapeutic purpose, ''a practitioner must take a complete medical history of the patient and conduct an adequate examination to determine if there is a legitimate medical basis for so prescribing.'' *Id.* Pursuant to § 333.7303a of the Michigan Compiled Laws, before prescribing or dispensing a controlled substance to a patient, a licensed provider must ''ask the patient about other controlled substances the patient may be using. The prescriber shall record the patient's response in the patient's medical or clinical record.'' Mich. Comp. Laws Ann. § 333.7303a (West 2020); *see also* RFAAX G, at 4.

Dr. Chambers stated that when evaluating the use of controlled substance for pain control specifically, ''a complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of pain on physical and psychological function, and history of substance abuse.'' RFAAX G, at 4. Dr. Chambers attested based on his knowledge and experience ''that taking a complete medical history and documenting the patient's complaint, medical history, and history of substance abuse is required to meet the standard of care for the prescribing of any controlled substance, not just those prescriptions which relate to pain control.'' RFAAX G, at 5.

Regarding recordkeeping, under Michigan law, a physician ''shall keep and maintain a record for each patient for whom he or she has provided medical services, including a full and complete record of tests and examinations performed, observations made, and treatments provided.'' Mich. Comp. Laws Ann. § 333.16213(1) (West 2020); *see also* RFAAX G, at 5. This record must be maintained ''for a minimum of 7 years from the date of service to which the record pertains.'' *Id.* Similarly, ''[a] dispensing prescriber shall include in a patient's chart of clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber.'' *Id.* (citing, Mich. Comp. Laws Ann. § 333.17745(3) (West 2020)). Dr. Chambers attested based on his knowledge and experience, ''that keeping accurate and complete patient records is required to meet the standard of care for the prescribing of any controlled substance.'' RFAAX G, at 5.

Having read and analyzed all of the record evidence and law, I find that Dr. Chambers' declaration concerning a Michigan physician's standard of care when prescribing controlled substances is supported by substantial evidence—in particular that it is consistent with the explicit text of Michigan law and Michigan Guidelines. As such, I apply the standard of care for the State of Michigan as described by Dr. Chambers and Michigan law.

D. Allegation That Respondent Unlawfully Dispensed/Sold Controlled Substances to B.S.

Having read and analyzed all of the record evidence, I find that the Government has demonstrated by substantial evidence that Respondent unlawfully sold and dispensed controlled substances, namely hydrocodone bitartrate/acetaminophen,[10] to B.S. without a legitimate medical purpose.

DI ''began an investigation into Respondent after receiving information that Respondent was providing an individual with the initials B.S. with entire bottles of hydrocodone bitartrate/acetaminophen products in exchange for cash.'' RFAAX E, at 1. On September 28, 2016, DI participated in an interview of B.S.[11] *Id.* at 4. During that interview, ''B.S. explained that she had received controlled substances and prescription[s] for controlled substances from Respondent without a legitimate medical purpose between approximately late 2001 until August 2015.'' *Id.*

More specifically, B.S. explained that at some point after she met Respondent, she went to dinner with him and ''told Respondent that she took 'Vicodin' and asked whether he knew anyone that would sell her pain medication.'' *Id.* According to B.S., Respondent said that ''he would help [B.S] obtain Vicodin by calling prescriptions into pharmacies for her . . . [and] that he could provide her with whole bottles of controlled substances.'' *Id.* There is no indication in the record that B.S. was a patient of Respondent's, that B.S. visited Respondent at his medical practice, or that Respondent conducted any examination of B.S.[12] *See,* RFAAX E, and E–1—E–4.

[10] Hydrocodone bitartrate/acetaminophen is often marketed under the brand name ''Vicodin,'' but other brand names include ''Norco'' and ''Lortab.'' RFAA, at 3 (citing National Drug Code Directory, *https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm*). Prior to October, 2014, hydrocodone was a Schedule III controlled substance, but since October 6, 2014, it has been a Schedule II controlled substance. RFAA, at 3 (citing 79 FR 49,661 (2014)).

[11] The only evidence in the record reflecting B.S.'s statements comes from DI's affidavit memorializing the September 28, 2016 interview of B.S. (DI participated in the interview). RFAAX E, at 4–5. Even assuming B.S.'s statements are hearsay, I will consider them. ''Provided it is relevant and material, hearsay is admissible in [an] administrative proceeding,'' and may ''under certain circumstances . . . constitute substantial evidence.'' *Mireille Lalanne, M.D.,* 78 FR 47,750, 47,752 (2013) (citing *Bobo* v. *U.S. Dept. of Agric.,* 52 F.3d 1406, 1414 (6th Cir. 1995) (internal citations omitted)). Here, the record reflects that declarant died in April 2017 (RFAAX E, at 5) and is therefore unavailable to provide direct affidavit or testimony; there is no indication B.S.'s statements are biased and are likely against B.S.'s own interest; B.S.'s statements are not contradicted by any of the evidence in the record—in fact B.S.'s statements are strongly corroborated by the relevant evidence in the record. As such, I find that B.S.'s statements as captured by DI's affidavit have demonstrated reliability and credibility as discussed throughout this section and I afford them full weight.

[12] Instead, the record reflects that B.S. would often leave money for Respondent in her mailbox

Continued

DI learned that B.S. and Respondent would communicate by text message. RFAAX E, at 4. ''In the text message[s], B.S. would refer to the Vicodin as 'books' and Valium as 'magazines.' '' *Id.* In the beginning, Respondent would order and deliver two, 500-count bottles of hydrocodone bitartrate/acetaminophen to B.S. at her house for $2,000.[13] RFAAX E, at 4. Later, beginning in either 2013 or 2014, Respondent began to deliver ten, 100-count bottles of hydrocodone bitartrate/acetaminophen for $2,000.[14] *Id.* ''B.S. indicated that she took all of the pills that Respondent sold her—as many as 30 a day . . . .'' *Id.* at 5.

DEA, pursuant to a search warrant and with Respondent's consent, had a forensic technician image Respondent's cell phone. *Id.* at 3. As a result of that process, DI was able to obtain and review the text messages between Respondent and B.S. *Id.* ''[DI] read B.S. various examples of the text messages that were recovered from Respondent's cell phone . . . and B.S. confirmed that they referred to the purchase of controlled substances by B.S. from Respondent.'' *Id.* at 5. I find that the text messages between Respondent and B.S. corroborate the information provided by B.S. during her interview.

Further, the evidence demonstrates that Respondent and B.S. exchanged text messages regarding the purchase of 'books' in close temporal proximity to Respondent placing orders for controlled substances. *See* RFAAX E–4. The below example is illustrative:

Example 1:

- 6/13/2013, 1:35 p.m., from Respondent to B.S.: ''Barb I need to put in the order for books. Do you want me to get you some magazines?'' RFAAX E–4, at 140.
- 6/13/2013, 7:23 p.m., from B.S. to Respondent: ''Hi Sal that would b great. Thank u[.]'' *Id.* at 139.
- 6/19/2013, transaction date for two bottles, for a total of 1,000 dosage units of Hydrocodone Bit.7.5MG/Acetamin tablets is reported by McKesson Corporation for Respondent. RFAAX E–1, at 2.
- 6/22/2013, 6:27 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can u let me know when the books come in? Thank you[.]'' RFAAX E–4, at 135.
- 6/22/2013, 6:30 p.m., from Respondent to B.S.: ''They're in. At funeral home call later[.]'' *Id.* at 134.
- 6/24/2013, 7:16 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can we meet up tomarrow [sic.] because I'm going out of town Wed. morning? Thank you[.]'' *Id.* at 133.
- 6/24/2013, 10:21 p.m., from Respondent to B.S.: ''Ok. How's 9. I have a meeting til [sic.] 8:30 downtown Detroit[.]'' *Id.* at 132.
- 6/24/2013, 10:23 p.m., from B.S. to Respondent: ''That would b great!'' *Id.*
- 6/25/2013, 8:04 a.m., from Respondent to B.S.: ''C u then[.]'' *Id.*

During her interview, B.S. explained, ''On occasion, B.S. would run out of Vicodin between shipments and Respondent would write her a prescription to 'help her out.' '' RFAAX E, at 5. I find that the text messages between Respondent and B.S. and the record as a whole corroborates this statement. For example:

Example 2:

- 12/30/2013, 11:22 a.m., from Respondent to B.S.: ''Barb. I'll be putting in an order for the books Thursday[.] I'll hold off on the magazines and order those next month. I'm trying to stay on top of things in case there are back orders or delays[.]'' RFAAX E–4, at 105.
- 12/30/2013, 7:23 p.m., from B.S. to Respondent: ''Sounds great . . . thank u[.]'' *Id.* at 104.
- 1/9/2014, 8:01 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can u let me know when the books come in? Thank u[.]'' *Id.* at 103.
- 1/13/2014, 3:02 p.m., from Respondent to B.S.: ''Orders have been changed. The books come in bottles of 100 and not 500 as before. So an order will be placed on Friday [1/17/14] for 10 bottles of 100 same cost. I knew there was going to be a glitch. So they should be in next week. Ok?'' *Id.* at 102.
- 1/13/2014, 10:15 p.m., from B.S. to Respondent: ''Hi I just got ur message. I only have a couple left and I'm really starting to worry. Thank u for trying.'' *Id.* at 101.
- 1/18/2014, 12:19 a.m. (in three parts), from B.S. to Respondent: ''Hi Sal sorry to text u so late. I don't have any books left and I feel sooo terrible. I don't know what to do and I'm sorry to bother u with this but can . . . u PLEASE call in a script I am just really getting sick? If u can the number is [redacted] b-day [redacted] CVS. I am so sorry but I don't want to check [into] a treatment center. I'm sorry to bother u.'' *Id.* at 100.
- 1/18/2014, 12:13 p.m., from Respondent to B.S.: ''Done. Ready in 1 hour.'' *Id.*
- 1/18/2014, 1:15 p.m., from B.S. to Respondent: ''Thank u[.]'' *Id.* at 99.
- 1/18/2014, Prescription issued from Respondent to B.S. for Hydrocodone Bitartrate—Acetaminophen, 300 MG–7.5 MG, quantity 50. RFAAX, E–2 (MAPS Report Showing Prescriptions Issued to B.S.). *See also* E–3, at 3.
- 1/23/2014, 11:51 p.m., from B.S. to Respondent: ''Hi Sal please call me when the books come in. Thank you[.]'' RFAAX E–4, at 98.
- 1/24/2014, 5:39 a.m., from Respondent to B.S.: ''I called them yesterday. They didn't call me back. I'm so irate. I told them its been three weeks. I'm calling again today[.]'' *Id.* at 97.
- 1/27/2014, 7:20 p.m., from B.S. to Respondent: ''Hi Sal do u know when the books r coming in?'' *Id.* at 96.
- 1/28/2014, transaction date for ten bottles for a total of 1,000 dosage units of Hydrocodone Bitartrate/Aceta 7 tablets is reported by McKesson Corporation for Respondent. RFAAX E–1, at 2.
- 1/28/2014, 9:00 p.m., from B.S. to Respondent: ''Hi Sal do u think they will b in tommarrow [sic.]?'' RFAAX E–4, at 95.
- 1/28/2014, 10:32 p.m., from Respondent to B.S.: ''I'll call. . . . As I said. I can give you some thurs to hold you by til they come in[.]'' *Id.*
- 1/28/2014, 10:36 p.m., from B.S. to Respondent: ''O.k. Thank u. I have been getting really sick I've been in bed sick so please do that. I can buy them if u want I just REALLY need them.[T]hank u[.]'' *Id.*
- 1/30/2014, 8:38 p.m., from B.S. to Respondent: ''Hi Sal my brother came over because I have the flu. Can u PLEASE put them in the mailbox so he does not see. Please text me. Thank u[.]'' *Id.* at 94.

In addition to being supported by the text messages, B.S.'s statements to DI are supported by other evidence in the record. Specifically, DEA's ARCOS records show ''that Respondent had purchased approximately 48,000 dosage units of hydrocodone/acetaminophen from McKesson Corporation between 2011 and 2015.'' RFAAX E, at 1–2. Additional records show that, ''between September 2012 and June 2014, Respondent purchased 22 100-count bottles of Diazepam [also called Valium] 10mg from McKesson Corporation.'' *Id.* at 2. Respondent's final purchase from

and Respondent would leave the controlled substances on her porch or at her back door. *See* RFAAX E–4, at 61 (''Hi Sal . . . I left $ in the mailbox. Can u leave on porch I'l[l] bring in latee [sic.].''). *See also id.* at 3, 83, 84, 94, 110, 116, 119, 127, 147, 150, 188, 196, and 198.

[13] I find that the text messages in the record corroborate B.S.'s statement as to the price charged by Respondent. For example:

- ''You just owe 1000 since the other one never came in.'' RFAAX E–4, at 198.
- ''Sorry mags are 100 each[.]'' *Id.* at 173.
- ''I do have an order for 4 books and 6 magazines. Total $4600[.]'' *Id.* at 130.
- ''They sent me 20. So it's two months. $4k[.]'' *Id.* at 84.

[14] Respondent would also order and deliver to B.S. upon request, 100-count bottles of Valium for $100. *Id.* However, the Government did not pursue any action related to Respondent's sale of Valium, so I am not including the Valium in my findings.

McKesson Corporation was on August 12, 2015, which aligns with B.S.'s statement that she ''decided to quit illegally taking controlled substances in August 2015[,] and that she stopped buying controlled substances from Respondent at that point.'' RFAAX E at 5; and E–1, at 3.

In short, I credit B.S.'s statements as reflected in DI's affidavit—B.S.'s statements are not only uncontradicted, but they are fully supported and corroborated by the relevant evidence in the record. Additionally, based on the entire body of evidence before me, I find that between March 2011 and August 2015, Respondent sold and dispensed controlled substances (hydrocodone bitartrate/acetaminophen) to B.S. approximately 45 times (a total of approximately 48,000 dosage units) without any evidence of a valid doctor-patient relationship.[15]

E. Allegation That Respondent Failed To Maintain Controlled Substances Records

Having read and analyzed all of the record evidence, I find that the Government has proven by substantial evidence that Respondent was unable to provide DEA with a dispensing log or inventory. RFAA, at 9. On July 13, 2016, DEA executed a federal search warrant at Respondent's registered address. RFAAX E, at 3. ''During the execution of the search warrant, [DI] requested that Respondent provide [DI] with dispensing records for the controlled substances he had purchased from McKesson Corporation.'' *Id.* Respondent informed DI ''that no dispensing log had ever been kept. . . .'' *Id.* Finally, DI requested that Respondent ''provide [her] with copies of any inventories of controlled substances[, but Respondent] did not provide them.'' *Id.* I find that Respondent did not provide a dispensing log or an inventory to DI.

F. Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice and in Violation of Michigan Law

The Government submitted a declaration from SA attesting that, ''[o]n October 30, 2017, [SA] served an administrative subpoena . . . on Respondent requesting patients records for . . . individuals who had been prescribed testosterone by Respondent during 2017.'' RFAAX F, at 1. On November 16, 2017, SA received copies of the requested patient records from Respondent along with a letter ''explain[ing] that the provided materials represented 'all the records [Respondent] ha[d] in reference to the patients delineated in attach[ment] to the Subpoena. . . .'' *Id.* at 1 (citing F–9). The issuance of prescriptions to and maintenance of records for seven patients, D.K., F.C., M.A., M.D., S.C., S.D., and S.H., are at issue in this matter. RFAA, at 9–14. Dr. Chambers reviewed the patient files maintained by Respondent for these seven patients and reviewed copies of certain prescriptions for controlled substances issued by Respondent to these patients. RFAAX G, at 6.

1. Patient D.K.

According to the subpoenaed pharmacy records, Respondent issued a prescription to D.K. for ''testosterone cypionate'' [16] on November 6, 2014, with one refill.[17] RFAAX F–8, at 6. The prescription was filled on November 7, 2014, and refilled on January 29, 2015. *Id.* at 7–9. The earliest dated patient record received from Respondent regarding D.K. was dated February 26, 2015.[18] *See* RFAAX F–1. On February 26, 2015, D.K. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, ''Reason for today's visit:'' was left blank; none of the yes or no questions, such as ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' were completed; and the ''CURRENT MEDICATIONS/VITAMINS:'' section was also left blank. *Id.* at 2. Respondent's records for D.K. also included ''Progress Notes,'' which begin on February 26, 2015, by documenting the administration of testosterone to D.K. *Id.* at 4, and RFAAX G, at 6.

Dr. Chambers pointed out that the earliest dated document in D.K.'s patient file was dated ''more than three months after Respondent issued Patient D.K. a prescription for a controlled substance.'' *Id.* at 7. Additionally, ''Respondent failed to document the prescription that was issued in November 2014 and failed to maintain any records relating to that prescription or relating to any medical examinations performed or observations made prior to the issuance of that prescription.'' *Id.*

Dr. Chambers, based on his review of the patient file for D.K., opined, and I agree, that Respondent ''failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances, and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 6. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient D.K. dated November 6, 2014, was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

2. Patient F.C.

According to the subpoenaed pharmacy records, Respondent issued a prescription to F.C. for ''Cheratussin AC Syrup'' [19] on August 28, 2011, with one refill.[20] RFAAX F–8, at 38. The earliest dated patient record received from Respondent for F.C. was a ''Progress Note,'' dated November 1, 2011, regarding testosterone and progesterone. *See* RFAAX F–2, at 3; RFAAX G at 7. In addition to the ''Progress Notes,'' Respondent's patient file for F.C. contained an undated contact sheet for F.C. and an undated ''Comprehensive History Evaluation'' that was not fully completed. RFAAX F–2, at 1–2. For example, ''Reason for today's visit:'' was left blank; the yes or no question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed; and the ''PAST MEDICAL HISTORY'' and ''FAMILY HISTORY'' sections were left blank. *Id.* at 2.

There is no mention of the Cheratussin AC prescription in the November 1, 2011, ''Progress Note''—in fact, there is no mention of Cheratussin AC anywhere in the patient file, and Respondent issued additional prescriptions to F.C. for Cheratussin dated May 2, 2013, October 3, 2014, and May 24, 2015. RFAAX F–2, at 3; F–8, at 31–37; G at 8.

Dr. Chambers pointed out that ''Respondent failed to document the Cheratussin AC prescriptions that were issued to Patient F.C. between August 2011 and May 2015, and failed to maintain any records relating to those prescription[s] or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.* He went on to observe that ''Patient F.C.'s patient

[15] This finding is further supported by my finding below that Respondent maintained no records as to the purchases from McKesson Corporation.

[16] Dr. Chambers stated that ''testosterone cypionate'' is a Schedule III controlled substance. RFAAX G, at 6.

[17] There are no records related to the prescription dated November 6, 2014, in the patient file. RFAAX F–1 (Patient File for Patient D.K.).

[18] Respondent's records contained an undated record with D.K.'s general information, such as date of birth and contact information. RFAAX F–1, at 1.

[19] Dr. Chambers stated that ''Cheratussin AC'' is a Schedule V controlled substance. RFAAX G, at 7–8.

[20] There are no records related to the prescription dated August 28, 2011, in the patient file. RFAAX F–2 (Patient File for Patient F.C.).

file does not include any records of any examinations or visits related to the [Cheratussin AC] prescriptions nor does it provide any basis to assess the reason for the issuance of a Cheratussin AC prescription to Patient F.C.'' *Id.* Per Dr. Chambers, ''[w]hile the patient 'progress notes' reference various hormone prescriptions, the Cheratussin AC prescriptions are not documented in the patient file.'' *Id.*

Dr. Chambers, based on his review of the patient file for F.C., opined, and I agree, that ''Respondent failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 8. Dr. Chambers further concluded, and I agree, that ''four prescriptions issued by respondent to Patient F.C. dated August 28, 2011; May 2, 2013; October 3, 2014; and May 24, 2015, were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

3. Patient M.A.

According to the subpoenaed pharmacy records, Respondent issued a prescription for ''Vicodin'' [21] to M.A., dated June 6, 2011.[22] RFAAX F–8, at 24–25. The earliest patient record received from Respondent regarding M.A. was a contact sheet, dated December 10, 2014. *See* RFAAX F–3, at 1. The only other records in the patient file are a document titled ''Informed Consent to Perform A Hair Transplant . . .'' signed and dated December 11, 2014, and, according to Dr. Chambers, ''an untitled sheet of paper potentially indicating the administration of testosterone to Patient M.A. on three occasions'' between April 2015 and June 2017. RFAAX F–3, at 2–3, and G, at 9.

Dr. Chambers opined that, ''Respondent's patient file for Patient M.A. does not include *any* medical history; does not include *any* documentation regarding any examinations or tests performed; does not include *any* assessment or diagnosis of Patient M.A.'' *Id.* Dr. Chambers also stated that it is significant that ''the information sheet is dated . . . years after the prescription for controlled substances was issued.'' *Id.*

Dr. Chambers, based on his review of the patient file for M.A., opined, and I agree, that ''Respondent failed to conduct or document an adequate physical exam; failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 9. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient M.A. dated June 6, 2011[,] was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 10.

4. Patient M.D.

According to the subpoenaed pharmacy records, Respondent issued a prescription for ''Valium'' [23] (a controlled substance) to M.D., dated May 24, 2013.[24] RFAAX F–8, at 18–19. The earliest patient record received from Respondent regarding M.D. was dated April 11, 2014. *See* RFAAX F–4. On April 11, 2014, M.D. completed a contact sheet, signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 1–3. For example, ''Reason for today's visit:'' was left blank and the yes or no question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed. *Id.* at 2. Respondent's records for M.D. also included ''Progress Notes,'' and an untitled document, which show that ''Respondent prescribed testosterone products for 'hair loss' on four occasions between April 11, 2014[,] and September 19, 2017.'' *Id.* at 4–5, and RFAAX G, at 10.

Dr. Chambers pointed out that the first patient record was dated ''almost a year after Respondent issued Patient M.D. a prescription for a controlled substance.'' *Id.* Moreover, Dr. Chambers observed that ''Respondent failed to document the prescription that was issued in May 2013 and failed to maintain any records relating to that prescription or relating to any medical examinations performed or observations made prior to the issuance of that prescription.'' *Id.* at 10–11.

Dr. Chambers, based on his review of the patient file for M.D., opined, and I agree, that with regard to the Vicodin prescription, ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 10. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient M.D. dated May 24, 2013[,] was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 11.

5. Patient S.C.

According to the subpoenaed pharmacy records, Respondent issued prescriptions for ''Vicodin'' [25] to S.C., dated October 12, 2013, and April 2, 2014.[26] RFAAX F–8, at 27. The earliest dated [27] patient record received from Respondent regarding S.C. was dated December 26, 2016. *See* RFAAX F–5. On December 26, 2016, S.C. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, ''Reason for today's visit:'' was left blank and the yes or no questions, ''SOCIAL HISTORY: . . . Alcohol: YES/NO,'' and ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' were not completed. *Id.* at 2. Respondent's records for S.C. also included ''Progress Notes,'' showing ''administration of testosterone to Patient S.C. on [ ] two occasions: December 16, 2016 and October 30, 2017.'' *Id.* at 4; RFAAX G, at 11.

Dr. Chambers pointed out that ''Respondent's patient file for Patient S.C. [does] not include *any* documentation regarding any examinations or tests performed; does not include *any* assessment or diagnosis of Patient S.C.[;] [n]or does the patient file document the issuance of the prescriptions for controlled substances [(Vicodin)] referenced above.'' *Id.* Finally, Dr. Chambers stated that ''the documents in the patient file are dated . . . years after the prescriptions for controlled substances were issued.'' *Id.*

Dr. Chambers, based on his review of the patient file for S.C., opined, and I agree, that with regard to the Vicodin prescriptions, ''Respondent failed to conduct or document an adequate physical exam; failed to document the patient's complaint; failed to document the patient's use of other controlled

[21] Dr. Chambers stated that, at the time, ''Vicodin'' was a Schedule III controlled substance. RFAAX G, at 9.

[22] There are no records related to the prescription dated June 6, 2011, in the patient file. RFAAX F–3 (Patient File for Patient M.A.).

[23] Dr. Chambers stated that ''Valium'' is a Schedule IV controlled substance. RFAAX G, at 10.

[24] There are no records related to the prescription dated May 24, 2013, in the patient file. RFAAX F–4 (Patient File for Patient M.D.).

[25] Dr. Chambers stated that, at the time, ''Vicodin'' was a Schedule III controlled substance. RFAAX G, at 11.

[26] There are no records related to the prescriptions dated October 12, 2013, and April 2, 2014, in the patient file. RFAAX F–5 (Patient File for Patient S.C.).

[27] The records contained an undated record with S.C.'s general information, such as date of birth and contact information. RFAAX F–5, at 1.

substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 12. Dr. Chambers further concluded, and I agree, that ''the two prescriptions issued by Respondent to Patient S.C. dated October 12, 2013[,] and April 2, 2014[,] were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

6. Patient S.D.

Respondent maintained patient records for S.D. dating back to December 5, 2011. *See* RFAAX F–6 (Patient File for Patient S.D.). On December 5, 2011, S.D. documented his contact information, completed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 1–3. For example, the ''CURRENT MEDICATIONS/VITAMINS'' section was blank and the question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed. *Id.* at 2. The patient file for S.D. also contained "'Progress Notes' demonstrating prescriptions for various hormones[28] issued to Patient S.D. on numerous occasions between December 5, 2011, and October 27, 2017.'' RFAAX G, at 13; F–6, at 4–9.

According to the subpoenaed pharmacy records, Respondent issued prescriptions for ''Valium'' [29] to S.C. dated March 24, 2012; June 7, 2012; March 15, 2013; April 25, 2013; May 8, 2013; December 24, 2013; April 1, 2014; and April 9, 2014. RFAAX F–8, at 1–3, 10–17, 20–23, and 44–46. There is no reference to the ''Valium'' prescriptions anywhere in Respondent's patient files for S.D. RFAAX F–6. According to Dr. Chambers, ''Valium is a benzodiazepine and a Schedule IV controlled substance [–] it is generally prescribed for the treatment of anxiety disorders or muscle spasms but is also highly diverted.'' RFAAX G, at 13.

Dr. Chambers, based on his review of the patient file for S.D., observed that ''[t]he patient file does not include any records of examinations or visits related to the [benzodiazepine] prescriptions nor does it provide any basis to assess the reason for the issuance of a benzodiazepine prescription to Patient S.D.'' *Id.* at 14. According to Dr. Chambers, ''[w]hile Patient S.D.'s patient file includes a medical history, the medical history did not include any information about any history of anxiety or other mental health issues.'' *Id.* ''The only 'complaints' listed in Patient S.D.'s file—'weight gain' and 'hair loss'—would not justify a benzodiazepine prescription.'' *Id.* Dr. Chambers also noted that ''Respondent failed to document the Valium prescriptions that were issued to Patient S.D. between March 2012 and April 2014 and failed to maintain any records relating to those prescriptions or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.* Per Dr. Chambers, ''[w]hile the patient 'progress notes' reference various hormone prescriptions, the benzodiazepine prescriptions are not documented in the patient file.'' *Id.*

Based on these observations, Dr. Chambers found, and I agree, that ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' *Id.* Dr. Chambers further concluded, and I agree, that ''the eight [Valium] prescriptions issued by Respondent to Patient S.D. . . . were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

7. Patient S.H.

According to the subpoenaed pharmacy records, Respondent issued a prescription to S.H. for ''Tussinex,'' a controlled substance,[30] on September 29, 2011, and prescriptions for ''Adipex/Phentermine,'' also a controlled substance, on February 12, 2013; June 10, 2013; and July 19, 2014.[31] RFAAX F–8, at 48–51; RFAAX G, at 15. The earliest dated [32] patient records received from Respondent regarding S.H. was dated March 1, 2017. *See* RFAAX F–7. On March 1, 2017, S.H. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, the yes or no questions, ''SOCIAL HISTORY: Alcohol: YES/NO . . . [and] . . . Recreational Substance: YES/NO,'' were not completed; and the ''CURRENT MEDICATIONS/VITAMINS:'' section was left blank. *Id.* at 2. Respondent's records for S.H. also include ''Progress Notes,'' which likewise do not begin until March 1, 2017. *Id.* at 4.

Dr. Chambers pointed out that ''the prescriptions issued by Respondent [to S.H.] were dated between September 2011 and July 2014—years before the first entry in the medical records.'' *Id.* ''Respondent failed to document the prescriptions that were issued to Patient S.H. between September 2011 and July 2014 and failed to maintain any records relating to those prescription[s] or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.*

Dr. Chambers, based on his review of the patient file for S.H., opined, and I agree, that ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 15. Dr. Chambers further concluded, and I agree, that ''the four prescriptions issued by Respondent to Patient S.H. . . . were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 16.

To summarize my findings above, I agree with Dr. Chambers and find substantial evidence that Respondent issued a total of twenty-one prescriptions to seven different patients without maintaining adequate records in violation of §§ 333.7303a and 333.17745 of the Michigan Compiled Laws. I also agree with Dr. Chambers and find substantial evidence that Respondent issued these twenty-one prescriptions for controlled substances outside of the usual course of professional practice and beneath the standard of care in the State of Michigan. Further, I find that Respondent sold and dispensed controlled substances to B.S. approximately 45 times without any evidence of a valid doctor-patient relationship, and I find that Respondent failed to maintain dispensing or inventory logs.

III. Discussion

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

Under the Controlled Substances Act (CSA), ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon

[28] The progress notes reflect the issuance of progesterone, testosterone, HCG, Armour thyroid, and others. *Id.* at 4–9.

[29] Dr. Chambers stated that, ''Valium'' is a Schedule IV controlled substance. RFAAX G, at 13.

[30] Dr. Chambers stated that, at the time, ''Tussinex'' was a Schedule III controlled substance. RFAAX G, at 15.

[31] There are no records related to the prescriptions dated September 29, 2011, February 12, 2013, June 10, 2013, or July 19, 2014, in the patient file. RFAAX F–7 (Patient File for Patient S.H.).

[32] Respondent's records contain an undated record with S.H.'s general information, such as date of birth and contact information. RFAAX F–7, at 1.

a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). 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 Pharm., 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. *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 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 the Tenth Circuit has recognized, findings under a single factor can 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 Two, Four, and Five.[33] I find the Government has satisfied 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).

B. Factors Two and/or Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under Factor Two, I evaluate the registrant's ''experience in dispensing . . . with respect to controlled substances.'' 21 U.S.C. 823(f)(2). There is no evidence in the record as to the Respondent's positive dispensing experience; however, the Government has clearly established the Registrant's significant history of unlawful and dangerous dispensing practices through the text messages and patient files contained in the record.

Factor Four is demonstrated by evidence that a registrant has not complied with laws related to controlled substances, including violations of the CSA, DEA regulations, or other state or local laws regulating the dispensing of controlled substances. It is well established that a physician who engages in illegal drug distribution violates the Controlled Substances Act. *See U.S.* v. *Moore,* 423 U.S. 122, 135–36 (1975); 21 U.S.C. 841(a).

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Ralph J. Chambers,* 79 FR 4962 at 4970 (2014) (citing *Paul H. Volkman*, 73 FR 30,629, 30,642 (2008), pet. for rev. denied *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 223–24 (6th Cir. 2009)); see also *U.S.* v. *Moore,* 423 U.S. 122, 142–43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR 30,642.

1. Allegation That Respondent Unlawfully Dispensed/Sold to B.S.

Respondent's actions with regard to B.S. demonstrate egregious dispensing experience. The definition of ''dispense'' under the CSA is ''to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner. . . .'' *Id.* at § 802(10). Here, Respondent delivered controlled substances to B.S. when there was absolutely no evidence of a doctor-patient relationship, exam performed, or medical diagnosis.

Agency decisions have clearly demonstrated that in order for a physician to utilize his registration to dispense controlled substances, there must be a ''valid physician-patient relationship'' and that ''[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription.'' *Mario Avello, M.D.* 70 FR 11,695, 11,697

[33] As to Factor One, the Government alleged that Respondent holds a valid state medical license, and there is no evidence in the record of any recommendation from Respondent's ''State licensing board or professional disciplinary authority.'' *See* RFAA, at 16; 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration. . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15,230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011).

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 cases 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). Agency cases 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.*

(2005) (citing *Mark Wade, M.D.,* 69 FR 7018 (2004) and *Floyd A. Santner, M.D.,* 55 FR 37,581 (1990)). B.S. admitted that she had no legitimate medical purpose for receiving the controlled substances.[34] Specifically she stated that ''she had received controlled substances and prescription[s] for controlled substances from Respondent without a legitimate medical purpose between approximately late 2001 until August 2015.'' RFAAX E, at 4. B.S. also admitted that she was taking controlled substances ''illegally.'' RFAAX E, at 5.

I agree with the Government that these actions appear to constitute ''outright drug deals.'' RFAA, at 26 (citing *James Clopton,* M.D., 79 Fed Reg. 2475, 2478 (2014)). Here, Respondent dispensed controlled substances without a legitimate medical purpose in exchange for cash and without even the façade of a medical appointment or evaluation. Respondent and B.S. did not see each other in a doctor-patient capacity—they used code names and mailbox drops to hide their illicit activity. RFAAX E, at 4, and E–4, at 94. Respondent's actions with regard to B.S. amount to those of a drug dealer. I consider these actions under Factors 2 and 4 to demonstrate that Respondent's continued registration is inconsistent with the public interest and this egregious misconduct alone warrants revocation.

2. Recordkeeping Allegations

As I found above, Respondent failed to produce either a dispensing log or an inventory. The DEA regulations require that ''[a] registered individual practitioner is required to keep records . . . of controlled substances . . . which are dispensed, other than by prescribing or administering in the lawful course of professional practice.'' 21 CFR 1304.03(b). Further, ''[e]very registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance . . . received, sold, delivered, exported, or otherwise disposed of by him/her. . . .'' *Id.* at 1304.21(a). Similarly, Michigan law states: ''A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber. . . .'' Mich. Comp. Laws Ann. § 333.17745(3) (West 2020). Additionally, Michigan requires that a prescriber ''keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber: (a) Name of patient. (b) Name of substance and strength. (c) Quantity of substance. (d) Date dispensed or administered. (e) Name of individual who dispensed or administered.'' Mich. Admin. Code r. 338.3153(5) (2020).

The undisputed facts are that Respondent purchased hydrocodone bitartrate/acetaminophen from McKesson Corporation and dispensed it to B.S. RFAAX E, at 1–2, and *supra* Section II.D. Accordingly, I find that Respondent had a legal obligation under both federal and state law to keep a record of the controlled substances that he dispensed. *See Shawn M. Gallegos D.D.S.,* 76 FR 66,986, 66,991 (2011) (''DEA regulations state that a registered individual practitioner is required to keep records of controlled substances . . . which are dispensed.'') (internal citations omitted). However, when DI ''requested that Respondent provide [her] with dispensing records for the controlled substances he had purchased from McKesson Corporation[, he] informed [her] that no dispensing log had ever been kept.'' RFAAX E, at 3. Respondent's failure to produce a dispensing log violates 21 CFR 1304.03(b) and 1304.21(a), Mich. Comp. Laws Ann. § 333.17745, and Mich. Admin. Code r. § 338.3153.

Regarding an inventory, federal regulations require that registrants maintain ''a complete and accurate record of all controlled substances on hand. . . .'' 21 CFR 1304.11(a). Registrants must ''take a new inventory . . . at least every two years.'' 21 CFR 1304.11(c). The inventory ''must be kept by the registrant and be available, for at least 2 years from the date of such inventory . . . for inspection and copying by authorized employees of the Administration.'' 21 CFR 1304.04(a).[35] Michigan law also requires its licensees to ''make and maintain a complete and accurate inventory of all stocks of controlled substances,'' but it requires that the inventory be taken annually. Mich. Admin. Code r. §§ 338.3151–3152 (2020).

On July 13, 2016, DI requested ''that Respondent provide [her] with copies of any inventories of controlled substances.'' RFAAX E, at 3. ''[Respondent] did not provide them.'' *Id.* Respondent's inability to produce a biennial inventory constitutes a violation of the requirement to maintain such an inventory. *See Rene Casanova, M.D.,* 77 FR 58,150, 58,160 (2012). As such, Respondent's failure to produce an inventory violates 21 CFR 1304.11(c) and Mich. Admin. Code r. §§ 338.3151–3152.

In sum, I find that Respondent's failure to provide a dispensing log and an inventory is relevant to public interest Factors Two and Four. I find that the Government has established that Respondent was not in compliance with several state and federal laws—including 21 CFR 1304.03(b), 1304.11(c) and 1304.21(a), Mich. Comp. Laws Ann. § 333.17745, and Mich. Admin. Code r. §§ 338.3151–3153.

3. Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice and in Violation of Michigan Law

My full factual findings regarding the standard of care in Michigan (including the Michigan Laws reflecting the standard of care) are set forth above. *See supra* Section II.C. In short, it is the law in Michigan that a physician ''shall keep and maintain a record for each patient for whom he or she has provided medical services, including a full and complete record of tests and examinations performed, observations made, and treatments provided.'' Mich. Comp. Laws Ann. § 333.16213 (West 2020). Additionally, ''[b]efore prescribing or dispensing a controlled substance to a patient, a licensed provider shall ask the patient about other controlled substances the patient may be using . . . [and] record the patient's response in the patient's medical or clinical record.'' Mich. Comp. Laws Ann. § 333.7303a(3) (West 2020).

As set forth more fully in the factual findings section above, the Government established through a credible expert witness that Respondent violated §§ 333.16213 and 333.7303a of the Michigan Compiled Laws and issued prescriptions outside of the usual course of professional practice and beneath the standard of care for the State of Michigan as follows:

—He failed to maintain records regarding other controlled substances that patients were taking with regard to patients D.K., F.C., M.A., M.D., S.C., S.D., and S.H.

—He failed to take or document a complete medical history with regard to patients D.K., M.A., M.D., S.D., and S.H.

[34] Moreover, the text messages between Respondent and B.S. demonstrate that B.S. ''was not seeking the drugs for the purpose of treating a legitimate medical condition, but rather, for the purpose of abusing them.'' *James Clopton, M.D.,* 79 FR 2475, 2478 (2014).

[35] The OSC does not allege that Respondent violated 21 CFR 1304.04 as part of its recordkeeping allegations and therefore I am making no findings related to this section, but am instead including this reference in order to support my findings related to the alleged violation of 21 CFR 1304.11.

—He failed to document the patient's complaint with regard to patients D.K., F.C., M.A., M.D., S.C., S.D., and S.H.

—He issued prescriptions without first having any patient files or records of examinations performed with regard to patients D.K., F.C., M.A., M.D., S.C., and S.H.[36]

—He issued prescriptions without having any record of an examination performed regarding or any medical history regarding the need for the specific prescriptions at issue with regard to patient S.D.

See supra Section II.F. In total, Respondent issued twenty-one prescriptions outside of the standard of care including: One prescription to D.K, four prescriptions to F.C., one prescription to M.A., one prescription to M.D., two prescriptions to S.C., eight prescriptions to S.D., and four prescriptions to S.H. *Id.* Each of those twenty-one prescriptions also violated § 333.16213 and § 333.7303a of the Michigan Compiled Laws.

Based on my analysis of Factors Two and Four in considering these violations, I find that Respondent's continued registration would be inconsistent with the public interest.

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

Under Factor Five, the Administrator is authorized to consider ''[s]uch other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). Although Factor Five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,141 (2012) (citing *Tony T. Bui,* 75 FR 49,979, 49,988 (2010)). As the Agency has previously stated, '''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify' the revocation of an existing registration or the denial of an application for a registration.'' *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,725 n.43 (2017) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998)).

Here, Respondent continued to provide controlled substances to B.S. illegally despite indications of addiction and abuse. *See,* RFAAX E–4, 94–95, 100–01. Respondent was ''starting to worry'' about when she would get her pills; she begged Respondent to ''PLEASE call in a script,'' so that she did not have to ''check [into] a treatment center;'' she claimed she ''REALLY need[ed] [the pills];'' and she requested that Respondent ''put [the pills] in the mailbox so [her brother] does not see.'' *Id.* at 94–95, 100–01. These texts reflect a concerning ''need'' for the pills and a desire to conceal their existence from her family. The continued provision of pills to B.S. despite B.S. having demonstrated that she was abusing the controlled substances demonstrates Respondent's disregard for B.S.'s health and safety. *See e.g. Trenton F. Horst, D.O.,* 80 FR 41,079, 41,090 (2015) (''Respondent's behavior [was] also troubling under factor five . . . [because] Respondent continued prescribing hydrocodone . . . to [his girlfriend] despite knowing that [his girlfriend] regularly abused controlled substances . . .'').

''[A] DEA registrant is obligated at all times to act in the public interest.'' *Peter F. Kelly, D.P.M.,* 82 FR 28,676, 28,688 (2017). In April 2017, B.S. died, and ''[t]he Office of the Medical Examiner of Oakland County, Michigan, determined that the cause of death was medication overdose.'' RFAAX E, at 5. Although there is no evidence that Respondent was in any way associated with the medication that led to B.S.'s overdose and death, her death reinforces the import of the CSA's requirement that registrants act in the public interest. Further, in providing B.S. controlled substances to fuel her drug addiction, Respondent demonstrated a reckless disregard for public health and safety. The mere fact that Respondent did not provide the controlled substances that led to her overdose does not negate the very clear evidence that he knew or should have known that he was endangering her life by fueling her addiction.

As found above, the Government's case establishes by substantial evidence that Registrant issued controlled substance prescriptions without a legitimate medical purpose and outside the usual course of professional practice and beneath the standard care in the State of Michigan. I conclude that Registrant engaged in egregious misconduct, which supports the revocation of his registration. *See Wesley Pope,* 82 FR 14,944, 14,985 (2017). Overall, it is clear that the Government has established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest.

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Respondent has made no effort to establish that he can be trusted with a registration.

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

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument submitted to determine whether or not a respondent has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23,853; *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995).

''The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the

[36] For certain patients, Dr. Chambers opined that the failure to include any documentation in the patient files ''strongly indicates that Respondent failed to create or maintain *any* records contemporaneously with the issuance of the prescription[s].'' RFAAX G, at 12. Agency decisions highlight the Agency's interpretation that ''[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.' '' *Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,464 (2011).

credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,972 (2019); *see also Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here the Respondent responded to the Government's Order to Show Cause by waiving his right to a hearing—no written brief or other explanation of his behavior accompanied the waiver of his right to a hearing. RFAAX B; RFAA, at 1. In other words, Respondent did not avail himself of the opportunity to refute the Government's *prima facie* case, nor did he attempt to explain why, in spite of his conduct, he can be entrusted with a registration. There is no statement from Respondent in the record. Nor is there any indication that Respondent has accepted any responsibility for his actions,[37] much less the ''unequivocal acceptance of responsibility [that is required] when a respondent has committed knowing or intentional misconduct.'' *Mohammed Asgar, M.D.,* 83 FR 29,569, 29,572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728). Such silence weighs against the Respondent's continued registration. *Zvi H. Perper, M.D.,* 77 FR at 64,142 (citing *Medicine Shoppe,* 73 FR at 387); *see also Samuel S. Jackson,* 72 FR at 23,853.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. The underlying issues in this case (unlawful dispensing, recordkeeping violations, and prescribing beneath the standard of care, and failure to maintain complete patient records) fall squarely within the purview of the CSA and revocation as a sanction is calculated to deter similar acts from others. *See Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988) (describing revocation as a remedial measure ''based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.''). There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of sanction.

I agree with the former Assistant Administrator of the Diversion Control Division, that Respondent's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding. Its insufficiencies include Respondent's failure to accept responsibility, to institute adequate remedial measures, and to convince me to entrust him with a registration. 21 U.S.C. 824(c)(3).

I will therefore order that Respondent's registration be revoked and that any pending applications be denied as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FC2341876 issued to Salvatore Cavaliere, D.O. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Salvatore Cavaliere, D.O. to renew or modify this registration, as well as any other pending application of Salvatore Cavaliere, D.O. for registration in Michigan. This Order is effective August 28, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–16388 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–09–P

[37] Although it is not evidence of Respondent's acceptance of responsibility, I note that Respondent appears to have been cooperative with DI during the July 13, 2016 search of Respondent's registered address. RFAAX E, at 3.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–28]

Kaniz F. Khan-Jaffery, M.D.; Decision and Order

I. Procedural History

On April 12, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension Order (hereinafter collectively, OSC) to Kaniz F. Khan-Jaffery, M.D. (hereinafter, Respondent), of Absecon, New Jersey. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of her DEA Certificate of Registration No. BK9710939 pursuant to 21 U.S.C. 824(d) ''because . . . [her] continued registration constitute[d] an imminent danger to the public health and safety.'' *Id.* The OSC also proposed the revocation of Respondent's Registration pursuant to 21 U.S.C. 824(a)(4) and the denial of ''any pending applications for renewal or modification of such registration, because [her] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances to six individuals outside the usual course of the professional practice and beneath the standard of care for the State of New Jersey in violation of 21 CFR 1306.04(a) and N.J. Stat. §§ 24:21–15.2 and 45:9–22.19. OSC, at 2–5.

On April 12, 2018, based on his preliminary finding that Respondent issued multiple prescriptions to one individual without a legitimate medical purpose, and to five individuals, while ignoring inconsistent urine screens that indicated abuse or diversion of controlled substances, the former Acting Administrator concluded that Respondent's ''continued registration . . . [was] inconsistent with the public interest.'' OSC, at 5. Citing 21 U.S.C. § 824(d), he also made the preliminary finding that Respondent's continued registration during the pendency of proceedings ''would constitute an imminent danger to the public health or safety because of the substantial likelihood that [Respondent] would continue to issue prescriptions for controlled substances, which would result in the abuse or diversion of controlled substances.'' *Id.*

Pursuant to 21 U.S.C. 824(d) and 21 CFR 1301.36(e), the former Acting Administrator immediately suspended Respondent's Certificate of Registration and authorized the DEA Special Agents and Diversion Investigators serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances Respondent possessed pursuant to the immediately suspended registration. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Respondent's Certificate of Registration BK9710939. *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43).

By letter dated May 1, 2018, Respondent timely requested a hearing. ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the